UNITED STATES DEPARTMENT OF AGRICULTURE (USDA)
ANIMAL AND PLANT HEALTH INSPECTION SERVICE (APHIS)

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BIOTECHNOLOGY REGULATORY SERVICES (BRS)

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STAKEHOLDER MEETING

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WEDNESDAY
NOVEMBER 7, 2018

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The Meeting convened in the Oklahoma City Memorial Conference Center, 4700 River Road, Riverdale, Maryland, at 10:00 a.m., Dick George, BRS Communications Branch Chief, presiding.

PRESENT

DICK GEORGE, BRS Communications Branch Chief
SID ABEL, Assistant Deputy Administrator for BRS
BILL DOLEY, BRS Government Relations Specialist
MIKE FIRKO, APHIS Deputy Administrator for BRS
SALLY McCAMMON, BRS Scientific Investigator
IBRAHIM SHAQIR, APHIS Associate Deputy Administrator for BRS
PAUL SPENCER, Director, New Technologies and Production Methods Division, USDA FAS

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

(10:02 a.m.)

MR. GEORGE: Good morning, everybody. I'm Dick George, Communications Branch Chief here at the Biotechnology Regulatory Services. We're very glad that you're joining us today for our 2018 Stakeholders Meeting.

Those of you who attend our meetings every year may recall that last year we tried to liven things up a bit by adding music during the breaks. Last year we featured the music of John Philip Sousa: big, energetic march music. That worked okay, so we figured to do it again but maybe change it up with somebody else. But who? So, let me tell you a quick story.

I used to work at a Fortune 100 energy company. And like most places, we'd talk about other people we work with. Maybe you guys have done this yourselves. And this one guy I worked with, his name was Kevin, he had his own unique rating scale. He would judge people, and especially leadership, on whether they had any

Elvis. That was his criteria.

We'd say, Hey, Kevin, what do you think of so-and-so?

He'd shake his head dismissively and say, No Elvis. Or he'd give a thumbs up and say, Elvis.

We were amused by this apparently arbitrary rating, but it turns out it really meant something to Kevin, and we all got it after a while. High Elvises were the people who were totally engaged in their work and passionate about it, people who cared about getting it right, people who really knew what they were doing.

So, of course, Elvis Presley came to mind for this meeting because all of our speakers today rate very highly on that Elvis scale. So, we will play some music today to give the proceedings a little spark, especially to end the breaks. When you hear Elvis, it means we're ready to get back to work.

Some housekeeping details. Please

set your cell phones on vibrate or turn them off. We have coffee and water in the back. Down the hall, out this door to the right and then a first left is our little café if you'd like a different beverage or something to eat during the break.

In your package of handouts is a list of local lunch eateries. Many of them will deliver to this building, and pretty quickly, too.

As usual, we are webcasting our meeting and we don't want to forget our out-of-sight attendees. And by the way, those of you that are online, the handouts that we are giving out here today in the room are also now on our website.

I'll ask all of you here today to wait until we either get a microphone to you, or if it's closer for you to walk to one of our microphones, please do so before you make a comment or ask a question so that our webinar audience can hear. And please identify yourself and your organization, if you represent one,

before you speak, whether you're here in person or via the web.

We have a court reporter who will produce a complete transcript of this meeting. And that transcript will be posted to our website within a few weeks. That's why we need you to, please, always wait for a microphone before you speak, or walk to the nearest one, and identify yourself. And spell your name, especially if it's anything unusual, so our transcript will have it right.

Please hold your questions until each speaker has completed their presentation. We've allowed time for questions at the end of each segment.

Those of you online, on the telephone keypad press 1 and then 0. This will alert our moderator that you would like to speak, and we will un-mute you and invite you to ask a question. So, again, for online attendees to ask a question just press 1 and then 0 on your telephone keypad.

If you prefer, you can ask a question

or make a comment via the web. On your screen type your comment or question in the comment box and hit "enter." We'll have someone monitoring this, and they'll get your question or comment to us.

So let's get started. At this time, to take a look at the year just past and the year to come I'd like to introduce our APHIS Deputy Administrator for BRS and a guy, I might add, with a lot of Elvis, Mike Firko.

MR. FIRKO: Thank you. And thanks to everybody who joined us here today. We currently have 60 people who have joined us on the webinar. If you see this little blue sticker over there, Robin will be keep updating that. And based on my days of estimating insect populations in the field, we have about 60 people in here I would say.

(Laughter.)

MR. FIRKO: Sixty-three? Okay, that was pretty close.

Okay. Can we advance to the next

slide? Can you do it manually?

Good. You turned it off.

So, for the first nine slides or so I'm going to be talking about things that we accomplished during 2018. It was a very interesting year, very productive. We had good results in several areas.

I always show you this one every year: number of release authorizations. Down a little bit from last year.

Number of release sites, actually about the same.

And then the number of unique Phenotypic Designations, now different from the first two numbers this is for all activities, meaning it includes imports, interstate movements, and release authorizations.

Now, I should note that this number is substantially lower than last year. Because I had a question. Those of you who were here last year may remember it. I had a question last year about whether that number, 14,856 -- it was in

the 40 thousands last year -- did we account for redundancy across years, and across permits, and across states? And my answer was I'm not sure, but we'll look into that.

So, we looked into it and sure enough there were some things that were getting counted twice. So, 14,856 is the number of unique plant trait mechanism of action combinations that we revised during 2018 as we were considering authorizations for field releases, importation, and interstate movement.

So, in this year we completed two deregulation petitions. The first one was the Bayer dual herbicide. And of course all this information and all of the associated documents are available on our web pages.

You'll see here that we accomplished this in 332 days. Our published time frame is 395 days. So about 11 months instead of 13 months. So, we substantially beat our target for how long it would take us to complete this petition for deregulation.

The second one was from Nuseed America for an improved omega-3 canola. This was a Path 2, meaning we had an extra Federal Register notice with a public comment period. So, because it's a Path 2 the target is 463 days. We beat this one by quite a bit, about 100 days.

I'm cheating a little bit here because we've done another one since the end of fiscal year '18, so it counts for fiscal year '19, but I couldn't help but point out that we did this one in 362 days instead of 463. So we're, we're really cranking on these things. We're getting them done even more quickly than we thought possible.

Am I Regulated? That we get. And, of course, in the quote there is the typical translation of what this program, the Am I Regulated Program, is all about. Showing you statistics for the last three years we're doing, they're coming in at about a consistent frequency. We are answering them in about a consistent frequency. And again cheating a

little bit, we've already done two in October. Those will count for fiscal '19.

We currently have five inquiries under review. All of them have been received since July. So we're also answering these Am I Regulated? requests very quickly.

Now, this is a subset of the Am I Regulated? requests. These are requests involving Site Directed Nucleases. I showed you this slide last year, slightly modified from last year. And the numbers are, therefore, updated.

It shows the frequency of Meganucleases, Zinc Finger, TALEN, and CRISPR, how many of each of those we've gotten. You see that the only two Site Directed Nuclease Am I Regulated? pending are both CRISPR.

Now, every one of these responses has been not regulated. Our answer to them has been "not regulated," including our first SDN 2/3.

Now, why do I call that a 2/3? Well, there's a lot of reasons. One is that I think it's fair to say that there's no consensus on the

line between 2 and 3. We, based on most of the literature and the papers on this, we would probably call this a 3 because it is a complete allele replacement. Templates involved a thousand base pairs or more.

The requester thought of this as a SDN-2 because it was cisgenic. Not sure what that has to do with the criteria that I've heard, but it points to maybe it doesn't matter. There's SDN-1's without a template, and then there's SDN-2's and 3's with a template.

But one of the points I want to make here is in terms of our decision making, which is about plant pests and weeds, it doesn't matter. We don't have any legislation that tells us that we need to look at SDN. We don't have any legislation about biotech in particular. Our legislation is about plant pests and weeds. So that's what our decisions are about.

I also talked to you last year a little bit about the permit application we had received for fairly expansive -- every county in

Florida -- release of a genetically engineered Citrus Tristeza Virus of biologic control of Citrus Greening Disease. As most of you probably know, Citrus Greening is a really terrible disease of citrus in Florida. The poor folks in Florida have also been getting hammered by hurricanes off and on over the last few years, but this particular disease has been devastating.

This year we published a draft Environmental Impact Statement that was prepared in support of us issuing a permit for release in every county in Florida, up to the discretion of the permit holder, of this genetically engineered Citrus Tristeza Virus to control Citrus Greening Disease. We had a whopping 51 comments -- not a lot in other words.

Now, I'll talk about this more in a few minutes. But since we published the draft EIS and draft Pest Risk Assessment there was a paper published that we'll need to think about.

So, regarding our, the work that we do with our partners in the coordinated framework,

EPA and FDA, we did a lot of work on a Horizon Scanning System. This comes to a large degree from a National Academy of Sciences study. The title of that study is "Preparing for Future Products of Biotechnology." And they made a recommendation about creating a Horizon Scanning System.

Now, you're going to get many more details from Sally McCammon when she gives her talk in a little while, but we're very pleased with this work. The three agencies are working together very well on this. And we think folks will like what we're doing here.

Now, I added this as my last little bullet here because that's a heck of a URL. Sally will show it again. This will be available when the slides are made available. But you can go, you can go in and look at this system now and see what's on there. More details on this system to follow.

Another USDA-EPA-FDA collaboration has to do with the Biotechnology Unified Web

Portal. And as you might guess from the title, this is a single point of entry for regulatory information about the United States' regulatory program. This will have a dot gov URL. We have had a lot of discussions with EPA and FDA about hosting this as a dot gov URL. In other words, it's not a USDA URL, it's not a FDA URL, it's not a EPA URL.

And, of course, one of the major efforts here is to make this user friendly for any aspect of biotech regulation in the United States. Fortunately, since we're building from scratch we can use modern approaches to these tools. And as is of interest to this administration, we are thinking very careful about how this might be helpful for small developers, which is where we get most of the questions about what does it mean to be in compliance with the U.S. regulatory system, and how do I do that?

Again, this is also partly a result of the National Academy's recommendation. And this

talks a little bit about what that system will look like.

This launch is anticipated in the future. I suspect that there will also be a beta version available. We'll see how the development goes. It will have a variety of pages.

At some point things will get shunted to one of the three agencies because we in the USDA don't speak for FDA or EPA. They don't speak for us. But the idea is to make a system where you can get direct information about all of those programs. Some of the stuff that we're still working on is to what degree will particular agencies take responsibility to provide answers with the agencies working together in the background. Some of those details are still being worked out, but the idea is to make this as user friendly as possible to get folks the answers they're looking for.

So, we're going to have a whole afternoon session on APHIS eFile. I talked about this in previous years. This is the replacement

for our current APHIS ePermits system, electronic permitting system. I think I told you that we tried to be careful and called this APHIS eFile because the IRS already got the name eFile. So we had to be careful about that.

Some of the things that we're thinking very carefully about is what is the transition going to look like from ePermits to eFile? That's one of the key things that you'll hear about this afternoon if you're registered for that session this afternoon. There will be plenty of detail about exactly what that will look like.

You know, our goal in moving to a new system is many-fold. We have many goals. One is that our current ePermit system is built on an older platform. It was released in 2006. We started working on it about 2001. It's well over 15 years old in technology. There are newer tools out there. Dealing with mobile devices is much different these days. Users expect a much different type of user interface. We're very

excited that new tools will be available not only for us, because both of these systems to a large degree are a workflow manager for us.

We come in in the morning, we boot up the system, and there are work assignments, things that we do. We get the assignments out of the system. Behind the scenes documents are being shunted from biotechnologist branch chiefs back to biotechnologists. So there's a lot of movement behind the scenes.

I've always thought of ePermit as a workflow manager. But, of course, for external stakeholders it is a way to come in and apply for a permit electronically and to get your permit electronically.

So we understand that transitioning from ePermit to a new system is going to be traumatic for all of us. We have change management programs that we're doing internally. And you will hear this afternoon about some of the change management we're doing from an external point. In fact, our session this

afternoon is part of our change management.

Of course, as you know, we're also thinking real hard about changing our regulations. So, for about three years now we've been asking ourselves what does our system need to do under a new set of regulations? Because, frankly, it's being built right now for the regulations that we have right now. There will be some changes.

As I've been saying the last couple years, we anticipate not using notifications in the future. Notifications are the biggest type of input that we get. Now, that's a throughput issue, not necessarily something completely different. But we are, we're also building a permitting system now as well as a notification system. So if we're using only permits in the future, we'll have that built already.

The number of changes that we need to make to the system once the new regulations are in place are actually fairly minimal. So, that's very good news. We started work on what we call

a concept of operations two-and-a-half years ago, and we've been tracking that as we go. You'll hear much more about APHIS eFile this afternoon.

So, 340. The timing on this is a little interesting. I'm trying to remember. I think this 340 proposed rule that was published in January of 2017, I think that was withdrawn right before the last stakeholder meeting. Is that right? Fiscal '18, so in fiscal '18 that was one of our accomplishments.

And, of course, the reason that this rule was withdrawn is we received a lot of very disparate comments. And we felt it was necessary to start over, get more input from external stakeholders, get more input from states and do more outreach with foreign governments, do more outreach with EPA and FDA. And, of course, we've been very busy at that. And you'll be hearing more about that.

But withdrawing that proposed rule set the stage for a new level of engagement which we could not do as long as we were in open

rulemaking. And we've done quite a bit of outreach on that since then.

This year we published a notice of intent to conduct a programmatic Environmental Impact Statement. So that's the little "p," programmatic, and that's because it relates to the biotech program. Wow, another whopping 35 comments on that. I guess people aren't particularly interested in biotech anymore. I don't know.

And we have been preparing a new proposed rule, a new programmatic Environmental Impact Statement, and a Regulatory Impact Analysis, sometimes known as the Economic Analysis. And those are the things that we'll be going public with.

So, looking forward to 2019: 340, 340, 340.

This is our number one strategic initiative. I think last year I said that our regulations were 30 years old. Now they're 31 years old. The fundamental basis of those

regulations has not changed in 31 years. It's long overdue. It's very difficult to do anything with biotech regulations. I'm very confident that we're going to be able to do something now though.

So, our plan for 2019 is to publish a new proposed rule. It would be great if we could accomplish that in the first calendar quarter of 2019. That's our intent. We'll be publishing the draft Programmatic Impact Statement at about the same time. I think in 2017 that was done within a week of each other. That's partly because EPA is involved in publishing the Environmental Impact Statement, and the proposed rule - USDA has the lead on that, so getting them published on the same day is a little difficult.

The Draft Regulatory Impact Analysis will also be published at about the same time.

And at the end of my talk I'll have more to say about 340.

So, we currently have five petitions for non-regulated status. Our good old standby

ArborGen Freeze Tolerant Eucalyptus from 2011. We sent a request to Fish and Wildlife Service about three years ago for consultation. We have not yet gotten an answer about whether or not they will entertain consultation.

We have the Verdeca Increased Yield Soybean, the draft Plant Pest Risk Assessment and Environmental Assessment are in preparation. Those should be published for comment soon.

We have a canola product from BASF. Same thing, the draft EPRA and EA are in preparation. You should be seeing those in the Federal Register for comment pretty soon.

There we go. And we have two petitions that we have received quite recently. And those, the petitions themselves will be published soon. We are working with the petitioners now on the completeness of those petitions. And we typically do not announce those petitions until, or identify those petitions until they've been published in the Federal Register for comment. But we're at very

early stages. Just received. And you should see those petitions in the Federal Register soon.

So, back to the genetically engineered Citrus Tristeza Virus. It is our intent early in calendar 2019 to issue that statewide permit for release of genetically engineered Citrus Tristeza Virus. And, of course, when I say release what I mean is grafting budwood onto existing trees or roots. This is not like a spray or anything like that, it's a grafting process.

I mentioned in a previous slide that there was a new paper published about, about these issues. It was a transmission of Citrus Tristeza Virus by the insect vectors. And it's pretty new. We just became aware of it several weeks ago.

Because of some language that we had in our draft EIS and the draft Pest Risk Assessment we're looking at these new data to decide what, if anything, we need to do in response to these new data. And we'll have a

better idea about what impact that will have on going forward. But like I said, we don't anticipate this really delaying things.

I spoke with the permit applicant this morning, and we're completely in line with their, the timing of their business model. And that's important to me because my commitment to them and to the citrus industry was that we will not delay you. When you're ready with this important tool to combat citrus greening, we will be ready with the permit for you. And we're still in line to be able to do that.

So, you'll hear more about 340 outreach, but this is a sampling of the sorts of engagements that we've done in the past. Mostly in the past -- June, July, August, September, October -- six months about, we have traveled, I traveled personally to I think three universities. And there were multiple universities at each of those.

Doug McKalip, Ibrahim Shaqir, Sid Abel, a variety of people have visited, have gone

out to universities and met with them. And we reached face-to-face 17 universities in that route, in that way. And, of course, we chose these universities because of their involvement in plant development and biotechnology in the crop arena.

We met with a variety of non-governmental organizations and thought leaders, -- there's one in the audience here, I think -- small and large biotechnology companies, industry groups, commodity groups, grain trade value chain, tribes.

We do have some additional tribal engagements that are scheduled for about a week, week-and-a-half, state Departments of Agriculture, of course, our federal partners, other USDA agencies. And we have talked about our conceptual framework with at least 50 countries in a variety of different venues.

I will say that with very few exceptions our conceptual framework has been received very gladly.

So, this is my last slide. You have in your handout package a statement from Secretary Perdue about plant breeding innovation, and a companion document that has as its first name "Details." Let me see if I can see where this is. I guess it's about the fourth or fifth page in. Yeah.

So, the first of these two documents is the press release. And the second one is "Details on USDA Plant Breeding Innovations." Probably most of you are familiar with this already. You can take it with you and read it at your leisure. Basically what this document says is that we're familiar with plant breeding innovations. We've been regulating in this space for quite a while. And over the years, 30 years of experience regulating products of biotechnology, we have learned a lot about where risk comes from.

And there are four categories of modifications that we don't intend -- we don't now and we don't intend in the future to regulate.

And they are deletions, single-based pair substitutions, cisgenic changes, or what we call complete Null Segregants.

Now, this is where I segue into the next document, because what this statement also says in the details is that we do not currently regulate these things unless a plant pest was used in making this genetically engineered plant. That caveat would go away under our conceptual framework.

So, what I mean by that is we currently have three plant pest triggers in our current regulations: if a plant pest was used as a vector; if a plant pest donated genes; or if the organism that was genetically engineered is a plant pest itself.

We plan on losing 1.95 of those. So let me explain what I mean by that. Completely dropping the vector. There's never been any evidence in almost four decades that using agrobacterium tumefaciens to vector genetic material into a plant causes that plant to become

a bacterium or makes it into a plant pest of some kind. So we would like to drop that. And that's what we'll be proposing.

One part that we are keeping in full is if you genetically engineered a plant pest. That's the basis of our authority. That is our authority, plant pest authority. So, how we regulate genetically engineered plant pests, we don't really see that changing very much.

Now, the .95, that's the part about if a plant pest donated genes let's say to a plant, so the likelihood of that making a difference in terms of plant pest risk is exceedingly small. As a 4-decade risk assessor I don't believe in zero risk. But the likelihood of using plant pest DNA in a genetically engineered plant, the likelihood of that creating a plant pest risk is very remote, but it cannot be completely discounted, so that's the .05.

Oh, I do need to click. Now, one more click.

So, now let's move to the flow chart

which is I think the next document. Looks like this. Now, this is what all of us have been doing in all of those engagements that I showed you a couple of slides ago. We typically do these in two or three hours.

I have I think two minutes, Dick, so I'm going to go through this really quickly. But we'll be here over lunch. We'll be here this afternoon over the eFile thing. You can ask any of us questions about this. So, let me very quickly go through this.

Each of these boxes has in the upper lefthand corner a little number, it's a little tiny number, small font -- sorry about that, I might have to get my reading glasses out. So one of the reasons I started with the secretary's statement, at Box 1, the orange box in the middle top of this flowchart is about that.

So, if your genetically engineered plant -- and I should take a moment to say this chart is about plants, plants only, this is not about plant pests, plants only -- so, if your

genetically engineered plant fits into one of those categories described in the secretary's statement on plant breeding innovation, "yes" from Box 1 takes you to Box 4, the green on the left. Then the answer is that's not regulated.

Deletions, single-based pair substitutions, those happen all of the time. Every time there's a meiotic event, those things happen.

Cisgenic, if we're talking about sexually compatible species, those things happen all the time. You know, we would like to back away from regulating things that could happen naturally in nature or through traditional plant breeding.

The complete null segregant piece is if you use plant pests but then you remove all of the plant pest material, we don't see us having a nexus to regulate that.

If the answer is you have a genetically engineered plant and it is not one of those four categories, then formally ask the

question, ”Is the plant genetically engineered?” And the regulations will have a definition of that, similar to what -- to the definition we had in the 2017 proposed rule but not exactly the same.

If the answer is no, it's not genetically engineered, you're not regulated.

Down to Box 3. If it is genetically engineered, then the question is, “Is this something that we have looked at before?” If the answer is yes, we don't want to go through the same thing again. It's not regulated.

And, of course, this list -- we've been calling it the Box 3 list -- will be available on our web pages, and it will list all of the plant trait mechanism of action combinations that we've already rendered a decision on.

Now, notice the horizontal light blue line through the middle of the document. Above that line says "developer actions," below the line says "agency actions." Above that line

APHIS doesn't necessarily need to be involved.

Now, if a developer meets Box 1 or Box 3 and they would like a letter from us saying, no, you really are not regulated, you really aren't, we'll write you that letter. That's the box for it.

But if you don't meet any of those criteria, then you go down and you may be subject to regulation, we have to make that determination.

Now, Box 7 and Box 6 are a little bit different because Box 5 is new in our thinking compared with the 2017 proposed rule. We were hopeful that we could make decisions about whether or not something was regulated before we actually started regulating things, by making a jurisdictional analysis. Do we have any authority to be regulating this? That proposed rule got blasted. People wanted permits.

And we've been hearing over the last year from many, mostly large companies, that no, we want permits. We're always going to go to Box

7.

We're like, Well, okay. You want to be regulated; we can do that.

What we're hearing from mostly small companies and universities, they're going right to Box 6. They want an answer ahead of time: Is the thing that I made subject to regulations or not? We will be very happy to accommodate those requests. Similar to an Am I Regulated? Not the same as the Am I Regulated passage, but a similar idea.

Before you have been subject to any regulation, before you've had a permit for field trials, you can call and ask us: Is it subject to the regulations or not? We'll be happy to give that answer. We think we can do those very quickly.

And the things that we'll be looking at in that analysis are going to be the same things we look at now in our Plant Pest Risk Assessments. Is it a plant pest? Does it create plant pest risks? Are there indirect plant pest

risks? Is it a weed? Does it exacerbate weediness? Are there sexually compatible weedy relatives?

So, those are all the questions that we'll be asking. The authority that we anticipated employing in 340 going forward is the plant pest authority. If and when -- and I hope this doesn't happen -- we encounter a genetically engineered plant that we think raises serious weed concerns, there's regulations about noxious weeds that can be brought to bear for those.

Now, notice there's a loop from Box 7 back to Box 6. If someone believes that there are new data that would lead us to a different conclusion, or if they're done having a permit and would like to not have to get a permit anymore, they can go from Box 7 into a jurisdictional analysis. Maybe there's been one done before, maybe there hasn't.

Now, as we complete these Box 6 analyses, those answers will feed into Box 3. But every time we make a decision about a crop

trait mechanism of action combination that will get added to the Box 3 list, it will be on our webpage about things you don't need to ask us about anymore.

And I know you've all heard me say this before, but we are so done doing glyphosate resisting corn and soy, but we keep getting petitions for those, so we just have to go through the same thing. We want to stop doing those things. We've made those decisions already.

So, once you clear Box 6, if the answer is no, you're not regulated, that will be made public. The developer can get an affirmation letter and you're cleared with the USDA biotech regulations.

Now, one or two little notes. Notice that Box 3 and my emphasis on crop trait mechanism of action -- and I'll say a little bit about that -- that's moving away from the event by event regulation, to regulation by what is the thing you made? And is the thing that you made a plant pest? Does it represent plant pest risks? Or

is it a weed?

So it's a different approach based on risk.

How far over time am I?

MR. GEORGE: About 10 minutes.

MR. FIRKO: About 10 minutes, okay.

We're going to have questions later?

MR. GEORGE: Yes.

MR. FIRKO: Yes. Thank you.

MR. GEORGE: Well, thank you, Mike. Mike will be available for the breaks and also at lunch if people want to follow up with some other questions.

So, next I want to introduce a person here not only on the domestic front but also internationally, APHIS Associate Deputy Administrator Ibrahim Shaqir, who heads up our BRS International Group, here to tell us about it. Ibrahim.

MR. SHAQIR: Thank you very much, Dick, for the introduction.

Mike, great presentation.

And now I need to figure this out. Okay.

All right. So, I welcome everyone to our stakeholder meeting. I want to welcome you all. And I want to also acknowledge our international partners here and visitors from China and Czech Republic and EU. So, I'm sure there are other international representation countries, so we welcome you all.

So, I gave a general presentation last year about our international engagement and outreach. And I thought just to give you a quick reminder of what we do. And then I will be followed by a great colleague and friend who will be expanding on the international activities and implications concerning trade and updates on that. Paul Spencer is here, so a great presentation. So it's going to be a quick overview of what we do and why we do it.

So, what we do is really complement our international -- our biotechnology regulatory approach to doing things. And we, we cannot

operate in a vacuum. So, we have certain mechanisms to conduct our international outreach and also within government.

So, why do we do it? To protect the plant health, support international trade, and training and outreach. Protecting plant health through ensuring that plant health is safe, what comes into the country and also what goes out, to basically ensure that the products, basic products are safe and there are no international implications.

Supporting international trade, we do that through several mechanisms: with coordinating with colleagues, with FAS, CONAG service, cooperation with other agencies, USTR, Department of States, and also international partners.

The training and outreach, there's many several ways that we do that. But I will expand on that further.

So, these are some of the 2018 activities. We engage with the foreign

governments where we either visited several countries or have them come and visit us here in the U.S.

We've had several, well, several bilateral meetings, but there are some that are standing meetings, that these are annual meetings, and bilateral working groups as well.

We have ongoing global collaboration, again through either global platforms or international engagement through international, where we attend international meetings and talk about our regulatory systems.

And with all of that we do support international trade and commerce.

So, we've had several visitors from really various countries, from over nine countries this year with some 87 -- 86 visitors. And they basically have different backgrounds. There were presentations from different countries; from different sort of sectors within government; government officials; scientists; importers of seed, grain. And also have had

journalists that come and visit us from several countries who will basically talk about, you know, and understand genetically engineered organisms or regulatory systems and visit with us and visit with other important entities that deal with genetically engineered organisms.

There are several also kind of capacity building in partnership with universities. There is on with Michigan State University, University of Missouri-Columbia. And we've had now for the past two years National Defense University. And we've had also engagement with China Agricultural University.

The Michigan State and Missouri are with their regulators, scientists from various countries, from Asia, Africa, Europe, and South America, Central America that come in and basically have a full course on biotechnology and regulation.

So we receive many questions about -- from these visitors. I've had this question, a question about do Americans eat food derived from

genetically engineered crops? And they believe that much of what's really produced we export. Okay? So, and I think this is an important -- my EU friend is laughing at me, but that's okay.

So, of course, the question, of course Americans do eat genetically engineered product.

How do APHIS, EPA, and FDA coordinate? And I think this is an important question. And it's important for many of these regulators to understand how we operate and how we maintain our regulatory lanes, and coordinate so to ensure any biotech crop products are safe. And so that's an important question. And that's why we include at any of our meetings where we have visitors, our colleagues from FDA and EPA.

What resources are needed for to implement a system like ours? And so that's, you know, for many of these -- some countries they don't have a really formalized system in place for regulation. And so they come in and hear about what we do. And I think that's important that we share.

And what is your regulatory approach for new plant breeding innovation technique? That's really for the past years now we have been asked this question. And we have been sharing with them our experience, and particularly on the Am I Regulated? process and how we make the determination on how to regulate or not to regulate genetically engineered crops where genome editing techniques were used.

And the last one about co-existence with ag production, we basically talk about collaborate work with dealing with that.

So, I mentioned the bilateral meetings. We have a standing meeting with China. Well, this is the trilateral meeting with Canada and Mexico. We meet annually. We talk about -- we identify a theme to basically dig deep into and share information.

The last time we met we talked about our basically regulatory updates, but also we talked about the chestnut blight resistant trees that is genetically engineered. And we do have

also a kind of quarterly discussions as well as we organize scientific webinars. The last one we've had was about two weeks ago, and we talked about synthetic biology.

The meeting with, bilateral meeting with China is a standing annual meeting in partnership with our sister agency, Foreign Ag Service. Paul Spencer was there. And each year we basically share our, we share our updates. And then we identify a theme that's of mutual interest. And this also, our Chinese colleagues asked to learn about how we are dealing with citrus greening, really an important disease also for China. And they want to learn about the type of things we're doing in dealing with this important challenge.

The other one, this is my one of the slides before last. This is what we do in support of harmonizing, harmonizing the thinking around genetically engineered products. And we've had some issues of great importance in the U.S. but also for our international partners,

trading partners.

So, Sally McCammon, who you will be hearing from her later on, she chairs the Group on Environment. And that group came up with several documents, biology documents on weeds, even salmon documents as well. And there is an apple document. And she's doing a great job in that regard.

So, Sally chairs that group. The Food and Feed Working Group is shared by FDA.

So, at the last June 2018 meeting also we've had stock of an important issue of great interest internationally on genome editing. And OECD is very much interested in really finding a way to harmonize the thinking and the regulatory approach to genome-edited crops, not only crops but also animals.

And, so, the three topic areas that we talked on the animal and plant applications of genome editing: risk and safety considerations; and regulatory aspects.

Excellent discussion. Very fruitful.

But obviously showed the divide, and which I'm sure Paul will touch on some of that in his talk. So the other follow-up with that will be taking place. And I think there would be a report coming out soon on that.

So this is my quick update. And thank you. And I will be happy to answer questions later.

MR. GEORGE: Okay, thank you. Thank you, Ibrahim.

So, as you can see, there's a lot going on internationally at BRS, but we're certainly not the only ones. USDA's Foreign Agricultural Service, FAS, keeps its finger on the pulse of biotechnology regulation on a global level. And with some recent developments that's a pretty big job.

Here to tell us about it is the Director of the FAS New Technologies and Production Methods Division, Paul Spencer.

MR. SPENCER: Well, good morning. I'm here to talk a little bit about the

department's international policy engagement on precision breeding. But before I do that let me give you a little bit of background on our agency to give you context organizationally from how we're engaging.

So, FAS, Foreign Agricultural Service, is the international arm of the Department of Agriculture. And we represent the full range of interests of U.S. agriculture overseas, from farmers, ranchers, and also our food processing industry. We have 93 offices with staff, and we're covering over 170 countries globally. Usually we're co-located with a U.S. embassy or a U.S. consulate.

And our overseas staff help us do a lot of different tasks:

They help market U.S. agricultural products through trade shows and other marketing activities;

They provide commodity reporting. We contribute to the department's global picture of production supply and demand for major

commodities;

And then also we provide policy information and policy advocacy for -- in support of U.S. agriculture.

And as part of this work it's important to mention that we maintain a global information network that provides public reporting on all sorts of issues. This is called the Global Agricultural Information Network, or GAIN. And within this system we require an annual report from most of our overseas offices on agricultural biotechnology policies, production, and marketing.

So, this is kind of a long-winded way of saying that we have a unique source of information globally from our offices about agricultural policy. And it's from these public reports and from our interaction with other governments that a lot of my presentation today is drawn.

So, you might wonder why a trade agency would be so interested in the introduction

of a new set of technologies like genome editing and precision breeding. Well, there's some direct trade-related reasons:

Because exports are such an important part of U.S. agricultural income, if our production technology is not approved in a major foreign market it could lead to trade disruption. You can actually have vessels turned around. It could lead to the product being withheld from the market by the developer. Or it could be rejected by farmers or other elements of the value chain, which is grains traders.

But I think an even broader reason is that we want U.S. farmers to remain competitive globally. And this means having choice. Our farmers really do need to have choice when it comes to production technologies.

And if you look at genome editing technologies broadly, they really are of strategic importance. They can be applied to plants, they can be applied to fungus, they can be applied to animals, microbes, even insects.

And the long-term challenge is to make sure that the foreign markets remain open and foreign regulatory systems remain open to the technologies our farmers choose to use.

Our approach, and the best way we believe to handle potential disconnect between U.S. innovation and foreign market acceptance is to engage foreign governments early and often. And we do this in the context of an interagency process, and we work very closely with Food and Drug Administration, the Environmental Protection Agency, the Office of U.S. Trade Representative, our State Department. And we always engage with science and international rules-based principles in mind, especially with the World Trade Organization.

So, we're seeking, broadly, we're seeking regulatory compatibility, meaning that if countries can have similar approaches, implemented at similar times, then this will facilitate both innovation and choice.

So, the government's fiscal year began

on October 1st. And that provides us a good breaking point to kind of look backward and look forward. And if you look at, if you look at FY 2018, it's been a really busy year on international engagement with precision breeding, on genome editing. In early fiscal year 2018 we drew on these 93 overseas offices and created a complete assessment of the regulatory approaches that governments around the world are taking to genome editing. Many of them don't have an approach, but we do keep a spreadsheet that shows where each government is falling currently.

And subsequently we worked within the department to draft an international engagement strategy around genome editing. And we also defined the main policy risk. The main policy risk, you know, last year, as it is now I believe, is the potential for genome edited crops to be indiscriminately regulated as GMOs, as genetically modified organisms. And if this is adopted by our major trading partners, this will

unnecessarily subject a whole new class of production technology to restrictive and potentially trade-distorting regulations.

And there would be a lot of results of this if this happened. One result would be the likely exclusion of products developed by small companies and public research institutions. The regulatory bar for GMOs is just too high for them.

And if they are, if these technologies are regulated broadly as GMOs, only a handful of multinational companies would have the technical expertise, the funding, and the global regulatory affairs footprint to complete multi-country approval. Minor crops, and crops that are often -- that could be improved subsistence crops in developing countries would also be excluded if there is too much of a regulatory burden, simply because the seed sales for these crops don't justify the high regulatory costs associated with GMOs.

So, clear domestic policies on the regulation of genome edited plants are an

integral part of USDA's international engagement plan. And we also believe that having a clear domestic policy enhances the overall U.S. leadership on this issue.

And as was mentioned, on March 28th, and it's in your packet there, Secretary Perdue put out his statement on plant breeding innovation. And Mike's already gone through the details of that, but it really has provided us a solid basis from which to work as we engage with other governments.

And essential to our strategy, as I mentioned earlier, has been cooperating with other governments. And immediately following the secretary's March statement we followed with a USDA-funded genome editing workshop in Colombia that included regulators from 18 countries, and including USDA crops regulator, and Mike's boss, Undersecretary Greg Ibach. He gave the keynote address at that event.

And then, as I mentioned, that had 18 different countries in it, and provided a real

kickoff point for our international engagement on this issue. Subsequently, my boss, Undersecretary Ted McKinney, who deals with international affairs for the department, has raised this issue on each one of his visits to 15 different countries in fiscal year 2018.

So, USDA is also coordinating with partner countries for activities in the Cartagena Protocol on Biosafety, of which there's a big set of meetings in a couple of weeks in Sharm El-Sheikh, Egypt. And, as Ibrahim mentioned, we also worked in the OECD.

And then also there is a lot of work that is being done every year in APEC that is funded by the Asia-Pacific Economic Cooperation group that's funded by USDA. And Dr. Chao also participated in those activities in fiscal year '18.

And then, as mentioned, Ibrahim also covered some of the bilateral engagements we have. We have with China the Biotech Working Group; the U.S.-Canada-Mexico Trilateral Biotech

Working Group; and also scheduled visits by Japanese regulators. So we've had a pretty good state of engagement in FY '18.

So, this map will show some of the global regulatory status that we're aware of for genome editing. And there's a lot more data behind this map. And we do keep an ongoing running spreadsheet of regulatory approaches that we're aware of. And we're happy to share that with anyone in the room.

But let me just talk a little bit. The good news is that a number of countries have adopted policies that appear to innovate, to support innovation in trade in genome-edited products. Argentina was the first country to publish a policy on breeding technique. And under Argentine approach, consultations are required, and the products will be regulated depending on whether or not foreign DNA is introduced. And decisions are made usually within 60 days.

Now, interestingly, a decision not to

regulate by the Argentine Government is not made public. So that has implications for grain trade and competitiveness from my perspective.

Well, let me go on. Brazil and Chile have a functionally similar system to Argentina. And I think if you're going to generalize about South America, I think you can say that they are setting up an innovation and science-based system that will help their competitiveness.

Canada, as you see on the screen there, they regulate based on product, using an existing novel foods regulation. They regulate based on whether or not the end product is identified as novel, not on the process that was used to create it.

For Australia, Australia uses its Office of the Genome Technology Regulator. It has proposed to regulate genome-edited products where template DNA is involved, but not regulate products with small random changes such as deletions.

And also I'd mentioned two, that

China, Japan, and Korea don't really have specific rules in place yet. We believe China -- and you can ask our Chinese representatives here -- but China is operating under a draft proposed policy. And that hasn't really come out publicly yet.

Japan is developing, and we believe that they will publish something before the beginning of their fiscal year in April of 2019.

I think, though, the big news for this year is what is the European Union policy and the direction that they're taking. In July, the European Union Court of Justice decision said that newer mutagenesis techniques should be regulated as GMOs.

And so I want to talk about this a little bit more in detail. So, we view the EU decision as a major setback for the potential benefits that can be received from agricultural genome editing technologies broadly.

On July 25th, the European Court of Justice found that organisms produced from newer

mutagenesis techniques using CRISPR, TALEN, et cetera, are subject to their Directive on Genetically Modified Organisms. So, what this means is that the same risk assessments, the same monitoring, the same labeling, the same traceability laws currently applied to genetically engineered products will apply to gene-edited products imported into the EU.

Now, there's more to it than that. But we're primarily concerned with the trade elements of this.

Now, the implications of this is that the European Union's global policy influence could pose a threat to U.S. agriculture's ability to adopt and benefit from these genome editing tools. The ECJ decision emboldens the anti-technology groups. And that's already prevalent in EU member states such as France.

And in the broadest sense it's negatively impacting global agricultural innovation and food security. It potentially takes a whole set of tools off the table.

So, more narrowly, as new restrictions and regulatory regulations are developed and implemented, the ruling expands the potential for trade conflict between the EU and the United States as well.

So, in response, on July 2th USDA Secretary Perdue issued a statement on the European Court of Justice case. And I'll just say I'll quote him here.

He says, "The global regulatory treatment of genome-edited agricultural products has strategic innovation and trade implications for U.S. agriculture. For this reason, USDA has clear science- and risk-based policies that enable needed innovation, while continuing to ensure these products are safe. In light of the ECJ ruling, USDA will re-double its efforts to work with partners globally towards science- and risk-based regulatory approaches."

So, looking ahead to fiscal year '19 which we're just starting right now, our overall objectives will remain similar. But we have to

take into account the European policy changes that are coming as a result of the ECJ ruling. Specifically, the EU Commission will be looking how to implement the ECJ ruling.

But our international policy engagement will still seek to maintain and expand U.S. agricultural exports; shape the global policy environment in a way that preserves American agriculture's freedom to innovate; continue to build an active, multi-year global coalition of countries in support of science-based and risk-proportional regulations; and also to, frankly, limit the policy influence that the ECJ judgment has.

And we'll also be partnering with the private sector to build a communication capacity. One of the things that we'll be exploring more in this fiscal year is how to use U.S. farmers more effectively as international communicators. We actually have farmers who are making money growing genome-edited crops. And we think that that's something that we can share with the world

as part of our messaging.

And let me talk for a moment about a recent success that we had in the international policy arena, in fact last week. So, as I mentioned, the United States has a long history of cooperating with an informal coalition to advance trade policy positions related to the use of new technologies in agriculture. And since May, following the secretary's statement we've been part of a loose coalition of countries working on an international statement on agricultural applications of Precision biotechnology.

And that, that actually, that statement is included in your packet.

So, Argentina, with our strong support, led in drafting of this statement and introduced it to the World Trade Organization's Sanitary and Phytosanitary Committee meeting last Thursday in Geneva. And these principles, the principles in this statement rearticulate the commitment that all WTO members have already

agreed to, to develop science-based and non-distorted trade policies with regard to agriculture.

Now, the statement is non-binding, and it reiterates some high level principles regarding the science-based treatment of precision biotechnology. We like this statement because it's very positive. You know, it's a way to get countries to support enabling science-based regulations, but also shows that there's a broad international support for agricultural innovation, despite what the ECJ ruling says.

And so far we have 13 countries, so far 13 countries have indicated their support for this statement, including Argentina, Australia, Brazil, Canada, the Dominican Republic, Honduras, Paraguay, of course the United States, Uruguay, and a few others. The countries have the ability to show their support for the statement up until around the 15th in the WTO committee. And we expect more countries to do so.

So, let me just conclude by

reiterating a couple of points. We still see the biggest policy threat to genome editing technologies in agriculture as the broad conflating of genome-edited technologies with GMOs in the regulatory space.

There are also, just want to remind everyone, we think there's strong trade linkages between technology adoption and, you know, between trade and technology adoption and, for this reason, we need a lot more regulatory compatibility internationally. And we're working hard towards that.

I also have a little bit of optimism. I think we're, you know, a number of countries are off to a good start. EU will remain a challenge, but I'm still optimistic that we can be able to draw on these technologies in support of agriculture.

And, finally, USDA is actively advocating internationally on behalf of U.S. agriculture for these, for these products.

Thank you.

MR. GEORGE: So, we're scheduled to go for a break. But I think we should pause for a moment and ask if there's questions for any of our speakers so far today, Mike or Ibrahim or Paul, including online. If you're online and you'd like to make a comment or ask a question, press 1 and then 0 on your keypad and we'll open your mike.

OPERATOR: This conference is now in question answer mode. To alert the speaker that you have a question, press 1 then 0.

MR. GEORGE: Any questions?

So, we'll also have an opportunity right before lunch to take a few questions also. But if you have questions, also these folks will be available, obviously, during the break and lunchtime also if you have a question.

So, it looks like we have a question online, so.

MS. WANEX: One of the most common questions we've gotten so far is whether or not the slides are available for download. We're

actually going to give everybody who's speaking an opportunity to run through their slides during this meeting, so they'll be available online afterwards.

Other than that, we have a question for Mike.

Does APHIS still have a group evaluating genetically engineered insects?

Is there a group evaluating genetically engineered insect pathogens? For example, new insect-associated viruses are being identified frequently thanks to sequencing technology.

MR. FIRKO: So, in our biotechnology risk analysis programs we have two branches. One of those two branches is the pest branch. And in that group we have plant pathologists, entomologists, and a variety of other scientific expertise.

And to the extent that we encounter those as part of our biotechnology program, absolutely. We do whatever analyses are done for

risk assessment or risk management or decision making.

So, yes, we have a group dedicated to those efforts.

MS. WANEX: We had a question during Ibrahim's presentation.

The word "coexistence" seems to have different meanings in different contexts. Does the speaker interpret a conflict between pro-biotech versus organic/natural? Or is this a foreign relations context or a combination?

MR. SHAQIR: I think the intent was to basically when we look at these coexisting functions from not the regulatory aspect, and that's basically what our approach to that.

MS. WANEX: This question was typed in during when we opened it up for questions for all three speakers. So I'm not 100 percent sure which one should answer. I'm just going to leave it up to you guys.

Many kinds of genome editing had significant off-target effects. The U.S. and

other countries should require full genome sequences to look for off-target effects.

It's not so much a question but it was written while we asked for questions, so I was wondering if anybody wanted to answer that?

MR. FIRKO: So, under our current regulations, if we were to receive a petition for non-regulated status we would look at those. We always look at those.

Under our future regulations if the product is something that could be produced through traditional breeding techniques they would not need to come in. And the risk would be the same as if that product had been bred traditionally.

If it is not something we've made a decision on and it came into us for a Box 6 analysis, absolutely we would be looking at those things.

MR. TERZI: My name is Lorenzo Terzi. I'm the Minister Counselor for Food Safety and Health for the European Union.

I would like to thank today for this opportunity to be here. We tried to take the opportunity to be active partners as possible on the evolution. And I have a comment and a question.

So, the comment is that of course we are aware about the implications of our court ruling. But, you know, regardless of our taking a position, we have to abide the ruling of the court. And we have one similarity now, as the court is the supreme entity institution interpreting the new law. And we have to respect the ruling.

We are aware about the challenges. We are, again, of this administration it's unlikely that the internal debate within the commission will lead to anything before 2019, the year of the elections of the European Parliament. And then once the new commission, the new parliament will be in place, the debate will be reopened.

So, unfortunately, we have to wait till time of couple of years to have an evolution

within the EU on this file.

The question is, regarding the trades which are already cultivated and harvested, we had a meeting last week, USTR and commission, in the frame of the Executive Working Group. And USTR informed us that there are already a couple of events. We were already aware that this was the case.

So I have a question. What are the real commercial trades which are on the market at present? We've been told about the soybean, about the rapeseed. But if you could be more precise of what is really of commercial value currently on the U.S. field ready to be traded and eventually exported?

MR. SPENCER: Well, thank you for the question. This is a question we've gotten from a number of our trading partners.

You know, we are keeping an eye on the marketability of our products overseas. And, you know, we talked to the companies that we're aware of who are developing the technologies. And by

and large they're produced -- they're value-added products, so they have an incentive to keep them in a closed loop production. And so we're not really aware of any products that are in open production that would be mixed with the general commodities.

You'd have to talk to the individual country -- companies that are producing those to get much more detail on it.

MR. GEORGE: Thank you.

One more question, Miranda?

MS. WANEX: I'm trying to understand this question.

It's the dilution of DNA sequence size through genome editing question one. If you could clarify that question online, I'm sure that may help us.

MR. GEORGE: We'll give you an opportunity to do that. And if you get a little clarity of that, we'll take a break and we will come back and we can try to -- Oops, go on.

MS. WANEX: We still have one more

question. I'm sorry.

APHIS agreed with the USDA Inspector General in 2011 that you would develop regulations for GE effect on animals but you still have not done this. Why not?

MR. GEORGE: And the microphone is being passed to Mike Gregoire.

MR. GREGOIRE: It's not for lack of trying, let me say that. We've made two runs with that. It is updating the rule, and the third time's a charm. So, we are still mindful of the IG recommendations, and it's our intent to fulfill the commitment we made to update the regulation.

MR. GEORGE: Thank you, Mike.

So, with that I'm going to sort of, we'll pause for 10 minutes. Let's come -- tell you what, let's come back at 11:30, which is about 8 minutes from now. And then we'll go from there.

Thanks, everybody.

(Whereupon, the above-entitled matter

went off the record at 11:23 a.m. and resumed at 11:32 a.m.)

MR. GEORGE: Okay folks, we're going to get going. Our next speaker, and I see her approaching the podium now. Our next speaker is BRS Scientific Advisor, Sally McCammon, who will -- we'll take our seats please -- who will talk about our activities regarding the important area of biotech research and our engagement with the scientific community. Thanks, Sally.

(Off-microphone comments.)

MS. MCCAMMON: Good morning and thank you for visiting us out in Riverdale. I think there's a mansion that's an old plantation that's associated with this, but we've only been there once I think.

Anyway -- with Riverdale, Maryland. Anyway my name is Sally McCammon, I'm a science advisor in the Office of the Deputy Administrator, along with Neil Hoffman. Who is also a science advisor. And that just gives you an idea of the emphasis that we place on science.

I'm going to try to give you a bit of an overview of the kinds, our processes for getting the scientific research that we need. Identifying it, as well as the variety of engagement that undertake.

Oops, hum, well, that's Paul.

(Off-microphone comments.)

MS. MCCAMMON: Okay, basically I'm going to go over a little bit of the context. The latest policies that we've been handed. How we identify our research priorities, and the variety of different engagements that we have.

Okay, the context is as always, it's the law. It codifies our protection goals and what we're charged with doing, which is basically protect against pest and diseases. We've tested pesticides in general, we don't do pesticides, EPA does them.

But that's done by Congress and the Executive Branch provides regulations to implement the law. The science for us is critical. It provides the data and information

for us to do what we need to do, evaluate and manage those risks. And this also feeds into policies, the use of risk assessment and decisions and management.

All right, last year most recently, and this was done after the modernization of the Coordinated Framework Initiative, President Trump asked Secretary Perdue to put together a Task Force on Agriculture and Rural Prosperity. He pulled together 22 agencies, offices et cetera, across the government. And by October of last year, he had come out with the report of the Task Force on Agriculture and Rural Prosperity. There were over 100 recommendations, and five major Calls to Action.

And one of those Calls to Action was Harnessing Technological Innovation. And one of the major components of that was to Streamline Science-based Regulatory Policy for Biotech. And this involves coordination across the federal government, coordination in interagency actions, particularly to focus on making the regulatory

system clear and available for the small and mid-sized innovators, and protect consumers.

And the third component was to Expedite Commercialization of Biotech Products. So to make sure we're science-based, but to keep moving.

So, annually APHIS and BRS internally gets together to review and go over our research, and update our research priorities. I think, I was trying to guess how many scientists, PhDs that we have on our staff including our Deputy Administrator, Mike Firko. And I think it's probably 40 or so. So there's a lot of interest in the science.

And under -- these are just general categories of our most recent interests, a variety of aspects that have to do with weediness, genetic attributes et cetera, gene drives, comparison of sources of genomic variation, frequency and types of variation between genetically engineered plants and other kinds of plants, RNAi interference, a comparison

of potential unintended affects between traditional plant varieties and genetically engineered varieties.

Our primary vehicles for working on these priorities are USDA's National Institutes of Food and Agriculture, and the Agricultural Research Service. The NIFA implements the Biotechnology Risk Assessment Research Grants Program, that they will implement, they manage it, excuse me.

And yearly they come out with a request for applications, usually in December. And that request for applications is crafted and updated by an interagency process including APHIS, BRS, EPA, FDA, ARS, and NIFA.

Besides the request for applications, we work with -- we have reviewers that participate on the panel that reviews the applications. And we have an internal government workshop yearly with some of the principle investigators that have developed the information that we -- that have developed the research that

we use. Shane Ball is the primary person we work with over in NIFA.

There are five major areas that have to be covered in this request for application, and these are all elaborated by the research agencies. And the elaborations change from year to year in the RFA.

The management practices to minimize environmental risk of GE organisms, methods to monitor and understand the dispersal of organisms, gene transfer to domesticated and wild relatives, environmental impacts of GE relative to non-GE organisms in the context of production systems. And then there is, lucky for us, there's other research topics.

Okay, how is this authorized and funded? In the 2002 Farm Bill the grant program was initiated to provide necessary funding for environmental and risk assessment research concerning the introduction of genetically engineered animals, plants, and microorganisms into the environment.

It also later was updated to authorize appropriations that come from the biotech outlays for research in USDA. And that is two percent of those outlays, which is one of the reasons that ARS is very interested in this program too. Because most of those research outlays go to the Agricultural Research Service.

So, last year for the 2018 RFA, 35 proposals were submitted to BRARG and with awards of 5.4 million, and made for nine research proposals, and one conference.

We do also work with the Agricultural Research Service directly. Particularly for their -- they have five year strategic plans for each of their national programs. And National Program 301 covers Plant Genetic Resources, Genomics and Genetic Improvement.

And we are part of the stakeholder group that comes in when each of those five year plans are organized and put together. There's, under the Crop Biotechnology Risk Assessment component of this plan, there's a component that

deals with unintended effects of biotech improvements on crop plants, agricultural production, and the environment.

APHIS and ARS have recently upped the ante on their coordination and collaboration together. APHIS has internally put together a Science Committee at the administrator level in 2016.

And they've been working to make sure that we're coordinated at all different levels from staff up to top management, to leadership with the same counterparts in ARS in order to enhance our cross agency communication in a variety of ways, to identify innovative solutions to prepare or prevent major problems particular to pests and diseases. And to be prepared to for emergencies and for responding to dynamic critical research needs.

So, and this is across APHIS. It's not just BRS, but we're also a part of this. And I think Ibrahim is the BRS representative to this APHIS committee.

Another major -- to shift gears a little bit, we also have relied a lot on the National Academy of Sciences Engineering and Mathematics reports.

One of the critical ones that came out recently is preparing for future products of biotechnology. And this was the third component of the Modernization of the Coordination Framework effort that was undertaken by the White House Office of Science and Technology Policy between 2015 and 2017.

And the Academies were commissioned to do this report so that we could -- the regulatory agencies hopefully could continue to prepare for what's coming. And not just keep hanging onto past approaches and past conceptual frameworks.

Another, but there are a variety of reports the Academies do, whether or not we specifically support them financially. One on gene drives came out in 2016. But since the beginning, since 1987 when our regulation was finalized, we've been working with the Academies.

And I'm not sure if you can see that on here.

Introduction of, well anyway, I can't read that --

(Off-microphone comment.)

MS. MCCAMMON: Why I need new glasses. And my name is not Priscilla, Priscilla Presley, sorry. Darn it.

Okay, well I just -- anyway but the Academies came out with key issues of dealing with genetically engineering organisms in the environment. And that was a critical paper that provided the assumptions that have been almost used globally around the world.

In that they stated that when you're looking at the interaction of a genetically engineered plant in the environment, you look at the interaction of the crop, the trade, and the environment. That those are the critical components that you look at.

That -- the our DNA -- traits introduced using recombinant DNA do not provide unique risks. Or do not introduce unique risks

that need to be evaluated. And a couple of other critical assumptions that we still use today.

Currently, we are working with the Academies on a new report, the Potential for Biotechnology to Address Forest Health. I think Mike brought up earlier that we're looking towards having a Chestnut blight petitioned sometime in the future.

And that forest health and how we deal with these particular issues is going to be critical. These are not necessarily -- the thinking with forest health is not going to be same as we're going to have with the traditional crop plants in agricultural settings.

So, this study was funded between a variety of agencies in USDA, as well as EPA. We hope that this will become publically available next month. And it should be presented at the American Association for the Advancement of Sciences meeting here in the District of Columbia in Washington.

One of the outgrowths -- oh, not too

bad, five minutes -- one of the outgrowths of the future products of biotechnology's report that came out from the Academies was they recommended that we continue Horizon Scanning exercise. And Sid Abel has been the major point person on that for our agency to get -- we set up a cooperative agreement with the Environmental Law Institute to carry on this exercise.

They are an NGO. They're not a government agency. But the intent is to design and develop a Horizon Scanning system for the future biotechnology products, consistent with the NASEM report.

And I think Mike mentioned this report. And right now it's under testing. But you can see the prototype on the link that's both in Mike's talk as well as right here. So, we intended to at least have an idea of what's coming down the pipe.

Another organization that we've worked continuously, particularly Susan Koehler of our staff, is the Weed Science Society of

America. We've helped fund two major reports that came out in 2012 that have to do with herbicide resistance management and understanding the impact of herbicide resistant crops on the environment.

Now one of the major reasons we've gotten into this is many times we as regulators are called upon to solve problems that really regulatory approaches are not the best way to solve the problems. So we've tried to engage with the appropriate scientific communities to help us engage with all the stakeholders involved in solving some of these problems.

Currently we're working on another grant, and working with the Weed Science Society of America to come up with strategies for dealing with herbicide resistance issues with all the stakeholders. And Ms. Susan Koehler is part of the Herbicide Resistance Education Committee which is managing this particular initiative.

I'll give a couple of more examples of our engagement. I think Ibrahim brought up the

OECD, the Organization for Economic Cooperation and Development and the two technical groups that work on biotechnology risk assessment and regulation.

And the variety of documents, biology, trade, and composition documents that are initiated and developed by the actual countries and their scientific communities. So you can have a global scientific community working on any one of these documents that we try to identify and provide the basic information that regulators need for doing their assessments.

We've done emerging issues, particularly one in the last several years was low level presence of unauthorized plant material in imports. Particularly seeds and grains that, well obviously seeds are intended for the environment but grains can fall off the truck or whatever.

We've also had a variety of workshops and conferences on new plant breeding techniques, genome editing that Ibrahim mentioned and next

generation sequencing.

Also this year NIFA funded, has been funding these Specialty Crop Regulatory Assistance workshops. I think we had one in 2011, one in 2016, and most recently this year. It's intended to really bring the innovators, both from companies and academics together with the regulatory agencies for two days of uninterrupted access to each other.

So, and they let us know what they're thinking about in a way which helps us to identify what we need to do to help them. And they can see us as humans, not just as a monolithic agency logo.

And to put together relationships that can help them be cost effective and plan and design their research in the most effective and efficient way.

One of the outcomes of a previous workshop was that we, APHIS put together guidance for new users into the petition process, which gives recommendations of how you can interact

with all three agencies in a way that's beneficial to you.

This is my last slide, just we have a variety of other informal ways that we bring in science and interact. We have a journal club which our staff gives presentations on new papers.

We have four American Association for the Advancement of Science fellows that we currently have. We have Smriti, Tracy, Holly, and Kayla. And they're sitting in the back of the room kind of taking it all in.

And they have, they come on board with the newest training, the newest understanding of the science, the hands-on-science and we're very grateful to have those folks.

We have onsite presentations as scientists come in, and they call up and say, oh I'm in town. We say, oh good, you want to come over and give a talk?

Mike also mentioned outreach on 340 in which we visited a variety of academic

institutions as kind of a hub. To bring in stakeholders from surrounding institutions to discuss some of the scientific issues that the scientific community is dealing with. As well as to give us an understanding of what kinds of questions or concerns we need to be thinking about.

And Ibrahim also brought up that we have webinars with Canada and Mexico to kind of -- if we're putting on a presentation why not share it with your counterparts and other regulatory components of other countries?

So, there you go. This is the Tree of Knowledge circa 1490. Thank you.

MR. GEORGE: Thank you, Sally. Before you go, any questions for Sally? So the way we're going to do this is, we have two more speakers and we're going to take questions at the end of each of each of their segments, the questions for them. And then before we pause for lunch if there are other questions for any of our speakers, we'll take a few minutes to take those

questions.

So are there any questions for Sally? We have one online.

MS. WANEX: We have one on line. I was kind of thinking this is maybe better for Sid, but it was asked during Sally, so I'll give it a shot. For enhanced preparedness and prevention responses to potential incidents, will the USDA, DOI, FEMA, ESF11 also be updated with new findings and proposals as part of the USDA APHIS framework revisions initiative?

MR. GEORGE: I don't have an answer to that.

MS. MCCAMMON: If I understand the question correctly, the USDA is thinking about revising their 340 regulations. Are we coordinating and apprising other agencies across the U.S government about those regulations? Is that -- and we are.

We have discussed with a variety of agencies. Maybe not all of the federal government agencies, but our regulation is only

under our authorities in our agency. We don't have a regulation that is developed to respond to other authorities.

MS. WANEX: Thank you.

MS. MCCAMMON: Did you want to try?

MR. GEORGE: No that's it.

MS. MCCAMMON: Okay.

MS. WANEX: And to the individual on line who is asking about their question that was given right before the break. Any questions for the former panel, is we're going to make sure that we read before we go to lunch. Right now, we wanted to focus on questions for Sally. Unless you want me to read that question to Sally.

MR. GEORGE: I think we'll move on, okay thanks.

MS. WANEX: She wants you to answer it.

MR. GEORGE: Oh, okay.

MS. MCCAMMON: I'm good at making up --

MS. WANEX: Okay, double stranded

RNA, RNAi technologies have been generally classified as not GMO. Now it appears there is a movement to classify all dsRNA whether tested or functional in any way as a pesticide that must be handled with pesticide applicator certification. Does this make any sense?

MS. MCCAMMON: There are two components of the RNAis that I know -- this is more related to EPA regulations -- there's topically implied RNA, RNAis and there are, or RNAs. And then there are those that are incorporated into the genome. And in both cases, I think those are EPA questions as they relate to pesticides.

MR. GEORGE: Thank you, Sally.

So about six years ago we created our, "Am I Regulated?" process. Last year government relations specialist, Bill Doley was here to tell us about plans to make that process better. And he's back this year to tell us about the changes that have already been implemented. Bill.

MR. DOLEY: Thank you, Dick. Good

morning everyone -- what have we got for slides here? Oh, here we go.

As Dick mentioned, I reported on this last year. We did a business process improvement project in 2017 to make some improvements to our, "Am I Regulated?", process. And last year I told you about what our plans were. And this year, it's what we've implemented and what we've completed. And if some of this looks familiar it's because some of it is. Because I'm using a few of the same slides before I get to the new stuff.

And this one here, benefits of AIR process, somebody reworded it nicely so it's better than before. But really the bottom line is here, we don't want to spend resources regulating things that aren't regulated articles. It's not a good use of our resources and I would go out on a limb and say you'd probably agree. You don't want your things regulated if they don't need to be.

So the process has to do with the

definition of a regulated article. And because the definitions will be complicated, it's not always that easy to self-determine if you're a regulated article or not. So you can write us a letter. And we have instructions on our website about what we want to see in the letter, so we can respond and analyze your question appropriately.

Since we started this in 2011, so it's been seven years, we've answered 70 of these inquiries. And I'm going to guess based on Mike's presentation that last year this slide said 56, because we did 14 over the last year, something like that. And a lot of these relate to new plant breeding techniques. And of most interest really is the genome editing. So we've had a lot on where people have created products using site-directed nucleases.

You can't see that too well, but if you go to the website you can look at all of the inquiries and responses. So after we complete them, we post them on the website. So all 70 are

up there. And you can't really see too well, but right here it says description. And that's a big field there, and what I'm going to mention in the end is we have some ideas to improve that presentation.

So the analysis is basically a legal analysis of whether, what you describe meets the definition of regulated article. So there's two main components. Is it altered or produced through genetic engineering? And is the donor, vector or recipient a plant pest?

And of the 70 that we've looked at, three have been regulated articles. Bad news for those people, they were hoping otherwise. The 31 at the top, where it says no plant pest components, most of those are genetically engineered plants that were made with biolistics. But there was no plant pest component in the donor. And the vector was biolistic, so it's not there either. So most of those are actually genetically engineered plants.

And when you get to the second

category, the site-directed nucleases. This is where in most cases, you're making a genetically engineered plant. And then after you stop it, you have something that only contains a deletion. And then it's not regulated because there's no plant pest components incorporated. And you could argue about whether those are genetically engineered or not.

So now we're into the business process improvement project. We had three main goals. We wanted to make our responses more predictable in time frame. And to have less variance around those times. And to make the responses consistent from a technical and policy standpoint.

And I was just thinking today that number three could actually work against number one. And that's one of the things we've been doing is trying not to implement things that slow it down, to get number three accomplished.

So we have three things I'm going to tell you about that we improved. First, we redid

our Standard Operating Procedure to take into account places in the process where we, where things that slowed us down, to get past those things and move them along faster.

Also there was a bunch of checklists and other documents associated with the SOP to help the process be consistent. The Triage Review Committee was something we implemented to work on that third bullet about technical and policy consistency.

So we have a group of, oh, five people who look at these increases as soon as they come in and try to flag significant issues so we can be on top of them right at the beginning instead of having them bite us at the end of the process.

And the third thing we implemented -- that was two, let me go back here. Oh, those we implemented right after the stakeholder meeting last year. So those have been in place for a year.

And then this third one here is something we just got out last month, or two

months ago. But we updated our guidance for developers.

And this had two main purposes because we've had a lot of delays with the confidential business information aspects of the increase not being formatted properly. Or we didn't get all the copies. We have to have the CBI, and the CBI deleted on the justification.

Sometimes that holds us up for up to a month in the beginning. So we've tried to make that more clear and actually we redid our CBI instructions too. So those are hopefully easier to follow.

And then we also want to reduce delays due to requests for additional information. So we try to make real clear what the information we need in that guidance so that we can complete the analysis without having to come back and ask for more.

So we have a little bit of data. When we did the BPI, we had BPI data. So it was data that we looked at going into the project. So we

had 24, "Am I Regulated?" that took about eight months each to complete. And now we have what we call the control phase in the BPI process, the generic process, the last step is called control. Where you, basically you're supposed to be looking at whether your improvements are working.

And so we haven't actually completed all our improvements. So this control phase should get better after we implement more things. But you can see there we've basically cut the time in half from eight months down to three and a half in the ones that we've completed since.

And the last improvement we have in mind is to improve the website display. That one column called, description, we intend to divide it into all these columns, species, transformation method, genetic alteration, phenotype. And that would allow you to sort or allow people to get more information about these. And to zero in on the ones they want to look at.

And right now, we don't always provide all that in the -- you can't search for all those

things. You'd have to go in one at a time to figure out what some of those things are. And hopefully that will be up soon and you'll like it better. And that's all for me.

MR. GEORGE: All right, thank you, Bill. That's a very brisk pace. We're almost back on time even, just a little behind. Any questions for Bill?

(No audible response.)

MR. GEORGE: No? Questions on line, no. Okay, we'll move on. USDA has been working with FDA and EPA on the Agricultural Biotechnology Education and Outreach Initiative, a lot of syllables there. Our own Assistant Deputy Administrator, Sid Abel, has been a member of the Steering Committee and is here to fill us in. Sid.

MR. ABEL: Thank you, Dick. Good morning everyone. All right, let's get started.

So this time last year we, our colleagues at FDA opened up their session with supplying information to everyone that we had

begun this initiative to provide information to consumers on biotechnology and the products thereof, in a way that would be understandable to them, scientifically based, unbiased type information.

That was an offshoot of a 2017 Congressional appropriation of about $3 and 1/2 million, or $3 million. And then again in 2018 they were granted another $1.5 million. The total of $4 and 1/2 million to build this initiative.

They are working with us and USDA and FDA to provide this information to the public. The tentative timeline is to produce a final product in the way, in the terms of some type of material. I'll get to that a little bit more later on, by the end of this fiscal year, in the fall of 2019.

So in addition, FDA has built some web pages for people who are interested in this project, to go there and see the progress of the work that's being done by the three agencies.

So in establishing this initiative, FDA created a Steering Committee that's put into place to kind of give guidance to the project, make decisions on the project, review materials, and those kinds of activities.

And underneath the Steering Committee, there's four workgroups. And these workgroups are the ones that are actually doing the work to build the products that will be part of this initiative.

One of the workgroups that we have in there would be a workgroup like, the External Input Workgroup. There's also a Consumer Research group as well. There's the Education Outreach group itself, which is actually building the material for us. And then there's a Stakeholder Update group that provides information to the stakeholders on these updates, answer inquiries, and things like that.

In addition to those things, we have about 60 people in total, maybe a little bit more than that, because I added more people from USDA

to this group that are actually working on this initiative. So, we've got a pretty large cadre of people that are working on this.

The project is built around building some form to the research, around the area of consumer attitudes toward biotechnology. What they respond to? What they know about biotechnology? Where they get their information from on biotechnology? And we're using this information to guide us in how we're going to prepare material that would be useful to them.

So we've done this through a number of ways. We've done this through a series of literature reviews, which are being conducted by a contractor. We've held some, what we call audience listening analyses, I'll get to that in just a second.

We've done some social listening groups as well. We've done some focus groups, which I'll give you some more details on in just a few minutes. And all this is geared toward obtaining the latest information on consumer

messaging.

So the public listening sessions, back in November of last year, we started off along with opening up the docket for comments from the public. Two listening sessions, one in North Carolina, the other one in California to get information from the public on the kind of information that would be useful to them in learning more about the products of biotechnology and how biotechnology affects them.

Whoops, I lost a slide here, guys. Okay, I'm going to jump. We'll come back to that slide I was just on because that's the closing slide. Got them out of order.

So, I want to kind of just stop here just for a couple of minutes. The docket, we got about 600 comments, and we've analyzed those comments. We had the listening sessions. We gathered that information, and you know, we've analyzed that information. And using all that information, we decided to hold a couple of focus groups.

First one was back earlier this year, February-March, and the one we just completed was in August and September. The first listening group we kind of gauged the consumer's perceptions, motivations, beliefs, feelings, attitudes towards biotechnology.

And then using that information in another focus group, we built materials and then shared that material with these consumers to test their response to the materials and themes that we built.

And we've centered those two themes around knowledge and empowerment. And then we added some taglines to that as well. So it says, Feed Your Mind, it's rather hard to see on the slide that's up there. But there's a little tagline on the bottom that says, Feed Your Mind. And then there's another one about, you know, Know Your Food.

The tagline for, Feed Your Mind, was one that resonated very well with the public. And it was information that, you know, that they

thought if they needed they can go to, to get, by the fact that we have these presentations.

These focus groups were made up of a wide variety of people. We had various age groups, educational levels, demographics in terms of race, in terms of ethnic background. We stratified these groups in a way that we can get information that would be useful in building these various materials. And then as you can see, we put together some things, some slides to get the response from those.

Some of the things we heard from the public during the course of these focus groups is that they didn't know the basic facts about -- and I'm going use the word GMO from this point on because they, that word resonates with them better than GE, bio-engineered, and other terms are used to represent genetically engineered products.

But they just didn't know the basic facts about genetically modified organisms. But they wanted to know. So we knew we had an

opportunity there. Didn't know the facts, but they wanted to know those facts.

They had general negative feelings about GMOs, but they couldn't say why. They just had generally negative feelings about that. They felt that GMOs contributed to health problems, obesity, allergies, cancer, other ailments. But again, they didn't have the facts that would link those things together. More often times, confused GMOs with things like hormones, pesticides, antibiotics, obesity other things like that.

And then they were ultimately very skeptical about information from the FDA, other government agencies, and very skeptical about the overuse of the word safety. Every time they had conversations, or they read materials from government agencies, it always had a heavy focus on safety.

So with this information in hand, and the outputs from these two focus groups, we decided, we came to some conclusions about some

opportunities we had in terms of building this material.

And the first and foremost is that food is very personal. And so we felt, you know, we decided we needed to use the human angle that was value based to that consumer, to put together these materials.

Consumers make many decisions on health, wellness, and especially nutrition. And they want their answers about this information to be very brief. We got that out of these focus sessions. And they wanted to connect what was important to them.

So we decided that maybe the approach of using storytelling may be helpful. And the storytelling, not from the perspective so much of a federal regulator, but from say, an academic who they trusted very well. Or from a farmer, or from a nutritionist, or from a physician. Those kinds of people providing storytelling to the consumer resonated well with them.

And if we were going to use the word

safety, we wanted the word safety to be used in the broader context, not in and of itself. We also decided it was very important for us to address head-on the issues of pesticides, hormones, additives, and other things, rather than letting that stay in the background unaddressed by the federal government.

And so in sum, we wanted the message -- it needed to be upbeat, it needed to be positive, it needed to resonate with those consumers.

And so these materials that you see up on the screen here were just the things we shared with the consumers. We got their feedback. We're going to go back using all this information. We'll modify these pictures. Have it more connection with a person and the food.

And then again, later on in this year, probably sometime this fiscal year, we're going to do another set of focus groups to get those final responses to the material we get out.

So let me go back to this frame so

that you know what the next steps are. So we're going to use this, so called "formative research and guidance" from the Steering Committee to develop these final educational materials.

The materials will take the form of videos. They make take the form of fact sheets, story boards, or storytelling, and some various types of infographics. We're going to use every, at least to the extent we can, every possible media to be able to share this information with the consumer.

We also understand that consumers want basic quick answers to things. So we're looking at maybe a 101 level type information to the consumer. If they want to know more about a particular product technology issue, or a product, they can then go to what we would call a 201 level and get more information out of it.

And the last thing I want to just mention real quickly is that, you know, there's the Bioengineered Food Disclosure Law that's in the process. The whole initiative will be

updated relative to the outcome of that final rule once it's been published.

And so we've got a lot more work to do, and again the tentative initial launch will be sometime in the fall of 2019, once all these materials are finalized.

And let me go back. And so I mentioned the webpage -- there we go. So the webpage is up for USDA. You can go to USDA's webpage, there's Google in there for the, for this initiative. And it should bring up their page and you'll be able to read what we're going in terms of the initiative. So that's the update of this.

I think by the next year there will be a lot more information provided to you at the Stakeholder Meeting. The perspective is hopefully by then we'll get everything done. We'll see. With that I'll take any questions, Dick for this group. And then we'll turn it over to questions for all of the speakers.

MS. WANEX: We have a question on

line. Which social engineering venues are targeted?

MR. ABEL: Okay. That, we haven't made a final decision on those venues. And I think by venues you mean things like, YouTube's type venues. If that's the case, what you mean by venues there's a good chance that we would use those kind of techniques. But there will certainly be web-based.

MS. WANEX: They asked, Reddit.

MR. ABEL: Reddit?

MS. WANEX: Reddit.

MR. ABEL: It's certainly an opportunity to use that. I'm a little bit familiar with it, not that much familiar with but it's certainly something we'll take into consideration.

(Off-microphone comments.)

MR. GEORGE: Okay, so I will invite questions for any of our speakers. Before we go for lunch, I think there were some, might have been some questions we didn't get to. If anybody

has questions for any of our speakers? So far, we'd be willing to take them now.

I will mention that for those of you in the room, our speakers will be around during lunchtime if you wanted to ask your question personally, get a one-on-one answer, but -- no?

MS. WANEX: We've had two questions that have been waiting since we breaked. I wanted to go ahead and make sure that we got to them.

The first question is, is there any limit on deleted DNA sequence size for genome editing?

MR. FIRKO: No.

MS. WANEX: Nope, and the next question is addressed specifically to Dr. Firko. It says, I would like to read the new study on Citrus Tristeza Virus Transmission. Can you provide a citation? Thank you.

MR. FIRKO: If you provide us with a mailing address, email address whatever, we'll make sure you get that.

MS. WANEX: Type that into the box. I can make sure that we get you a copy of that document.

We've had a couple more questions come in. It looks like some folks are still typing them out, so if you want to switch to the in the room questions for a few minutes, we can come back and make sure that everything here gets addressed.

MR. GEORGE: Other questions in the room?

MS. WANEX: You're welcome to raise your hand, or come up to the microphone.

MR. GEORGE: I think we have one in the back.

MR. GIDDINGS: My name is Val Giddings. I'm with the Information Technology and Innovation Foundation. I have a question for Sid about the outreach education, and outreach plans that are being developed.

It seemed that most of what you were thinking about as to materials to be shared in

these outreach efforts, you know, it was written documents that could be posted and shared on the web, things like that?

Have you contemplated more active engagement such as, Ask Me Anythings, on Reddit? Or you know, engaging in pushing some material out by social media, like Twitter and Facebook?

I think those are the places where the disinformation coefficient is highest. And so arguably those are the places in which the opportunities for getting return on the investment that Congress has made in this outreach, would be highest.

So I'm curious as to, you know, what thoughts you might have along those lines?

MR. ABEL: Excellent question and good timing actually. We are in the process of looking into what we will call amplifiers of our information. Those people that we would use to push this information out, for us.

So, go to -- we have mentioned here like using perhaps information that we can share

with STEM schools, or STEM teachers to push information to students at the youngest age possible.

And one of the things we've been looking into, these storytellers that we would get to, or recruit to provide information on biotechnology and the products thereof. We're using them as well to push information out.

So yes, that's one of the things that's in consideration like now, is what will be the material that we'll actually create? Whether they're in hard copy or on the web? And then of course YouTube and things like that we'd also be considering, yes.

MR. GEORGE: Thank you. Take it?

MS. WANEX: Anyone else in the room?

MR. GEORGE: Anyone else in the room? No, so we're going to online.

MS. WANEX: Currently are grants only available to non-profit and government agencies?

MR. GEORGE: Sally, I think that one is for you.

MS. MCCAMMON: That's a good question.

MR. GEORGE: You need a mic.

MS. MCCAMMON: Sorry, I don't know the exact answer to that. It's a good question. I think you can look up on the NIFA website just with the Biotechnology Risk Assessment Grant Program. And it'll give you last RFA, which will have all the context and background on that, as to who can apply and who can't.

My sense is, you know, non-profits. I don't know about for-profit entities, but the information is available. I basically just focused on the actual substance of what's in them, the RFA. But there's a lot of other language that can give you the who can apply and when you need to apply.

MR. GEORGE: Thanks Sally.

MS. WANEX: Next we have a comment for Sid, and related to Margaret's question. Those methods that you mentioned, the videos, the interactives, have all been effective in my

opinion in DoD website updates for better viewer interaction.

It's -- I think this is more of a comment. The methods that you mentioned, the videos, the interactives, have all been effective in my opinion in BOD website updates for better viewer interaction.

MR. GEORGE: Thank you.

(Off-microphone comments.)

MR. ABEL: Sounds more like a statement than it does -- sounds more like a statement. And we would agree with that. Yes, those are effective ways of communicating.

MS. WANEX: The FDA includes pesticide residues in the family diet survey every year. Can the FDA change the study to include pesticide residues from eating GMO products?

MR. ABEL: I'm not sure that I can answer that question completely. But I can say that the foods that are included in the FDA or USDA's food survey that they conduct are

irrespective of whether or not they're genetically engineered, or sourced from genetically engineered materials.

It's very possible that many of the foods that they're actually doing surveys on and collecting these residue data, do include products that are sourced from genetically engineered products.

MS. WANEX: That's it for the questions we've gotten on line.

MR. GEORGE: Other questions in the room?

(No audible response.)

MR. GEORGE: Okay, so we're going to break for lunch. I'm going to make a quick plug for the afternoon session on eFile. It's something you've been hearing about for a while and it's going to be within 2019. So we'll give you a little sneak peek how that's going to work. So we hope you stick around for that.

And when we convened, there's information in your handouts about local eateries

and some of which will deliver. So please take advantage of that. And Elvis will call you back at 1:30. Thank so much.

(Whereupon, the above-entitled matter went off the record at 12:23 p.m. and resumed at 1:31 p.m.)

MR. GEORGE: So as you all know for the past couple of years we've been working on a replacement for ePermits, our electronic permitting system. That system is APHIS eFile.

Here to tell you about it is our APHIS eFile team, and they will be running this afternoon's session, starting with the Chief of our APHIS MRP Digital Support Offices, Laura Lewandowski. Laura.

MS. LEWANDOWSKI: Good afternoon. Thank you very much. I appreciate the introduction. My name is Laura Lewandowski. And I work in MRP IT, which is part of APHIS. And I work for the Digital Services support office. And our office is responsible for the implementation of APHIS eFile.

So today our main focus of this session is to provide a demo for you. But before we do that, we're going to take a few minutes just to talk a little bit, to give you a little bit of context, a little bit of history, maybe answer some questions about why we're making this change in the first place.

So for this session, we're going to talk a little bit, like I said, about why we're making the change. So we're going to tell you about what's going on inside of APHIS and then beyond APHIS through the Department USDA so that you can understand what some of the drivers are in making this change.

We're going to go through the demo and run through and show you what an actual application is going to look like. My first caution is that the application and the solution is not completely finished. We are in the middle of the implementation.

So we're going to show you the functionality that has been built now. But know

that in three months' time or so there's going to be additional functionality. So this is the first peek.

And we're going to continue our communication on how this implementation is going and continue to talk to you about what the improvements are that you're going to be able to see.

And then we're going to have Q&A after the demo. And then to close out talking about preparing and forwarding an APHIS eFile.

So to talk about modernizing IT in our mission area, I will start by saying that it's been a real vision for Secretary Perdue to modernize IT systems to have your USDA in line with what you expect to see in industry. But also, you know, and probably even more importantly, so that people who are stakeholders of USDA can expect a similar look and feel, not feel like they are off, you know, going from one silo to another silo. So making sure that we're doing this in a well-planned and consolidated

effort.

To talk to you a little bit more about that, I want to introduce Mark Davidson. Mark Davidson is the Deputy Administrator for MRPBS, which is Marketing and Regulatory Programs Business Services.

MRPBS is in charge of our mission area, not just APHIS, but marketing and regulatory programs, which includes APHIS, which includes AMS and the former GIPSA.

And Mark, before becoming MRPBS Deputy Administrator, has a history of being a champion for eFile. Mark came to us from Veterinary Services. So he's a Doctor of Veterinary Medicine, and he was a steering committee member on the VS side of the eFile implementation.

So we're very fortunate to have Mark as Deputy Administrator overseeing this project and all of the experience that he brings from his earlier days as an eFile champion.

And so without further ado, I want to introduce Mark Davidson.

MR. DAVIDSON: Thanks, Laura, and good afternoon, everyone. We appreciate you staying and joining us for the demo today.

I want to talk a little bit about, you know, why we're modernizing APHIS permitting. And if we can go to the next slide. Oh, I've got the clicker. Oops. There we go so.

So one of the things as we're moving forward, you know, we've been on the ePermits platform for about 15 years. And it served all of us very well and has been a good mechanism for us to handle all of our permitting issues in APHIS.

However, as we start to move forward, we need to look at all of our legacy system. And ePermits is built on an outdated technology, ColdFusion. And as we move into these older systems that very heavily rely on custom coding, we experience increased maintenance costs.

And we have some of the lack of the flexibility of where we want to go as we modernize our business solutions and scale up across all of

the APHIS and AMS platforms in using different things.

Right now there's a really good opportunity as we're working to embrace digital transformation in the federal government. And Doug will talk with you all in a little bit, but USDA is a leader on that forefront in partnering with the White House and the General Service Administration.

I think another important thing is that permitting is the first part of what we're building on this platform. And we're looking to a lot of our different functions, including certifications, registrations, licenses to build off of this platform and be able to support just one platform within APHIS.

So what are we hoping to accomplish through our steps here? And we're looking towards implementation in the spring of 2019 with the APHIS eFile BRS release.

Now BRS won't be the first component out. We're already doing live dog permitting

with our animal care units. We also have started with registration renewals with animal care.

So we're doing some work right now utilizing the eFile system. But BRS will be our next and one of our bigger, more complex pathways that we're addressing as we go forward.

And there's three really important areas. First, we want to have an improved customer experience. That's for you all and also for all of our staff that is using eFile. We want to take advantage of some of the newer more flexible intuitive user interfaces, things you would experience as you're doing your banking and other types of internet transactions that I'm sure all of you do every day in your life.

We're hoping to use this to improve our business workflows and reduce our submission times, give us some more collaboration tools within the system and have an increased system reliability.

And some of the ways we're going to get there is through a more sustainable IT path.

We're using the Salesforce platform, and it's a platform being used not only within APHIS but also strongly within the Department, USDA.

We're trying wherever we can to use the more off-the-shelf functionality out of the software. And this gets it where it's easier to maintain your code updates and all of that. We rely on the vendors to help us update and move forward with this.

As we bring together all of the information with APHIS, we've got a data management plan with it. And this modern infrastructure helps us from our deployment time frames, our cybersecurity and the enterprise approach within the marketing and regulatory programs.

And it all ties into how we work and we support the OneUSDA initiatives around technology. And as I mentioned USDA is embracing Salesforce in a number of platforms. And we'll use this for the system enterprise for our overall CARPOL project. I mentioned

certification, registration, those types of things.

So as we do this, we'll build it into other legacy systems as we replace and modernize those. And so as our customers are stakeholders, there will be a more common field across all of our platforms as you move forward.

And so I want to thank you again for joining us. And I want to thank the team for all of their work to get us to this point. I think you'll see some very exciting things today. And there's quite a bit of work to get us to the spring of '19 yet but thank you.

And I want to introduce Doug Nash. Doug is our Assistant Chief Information Officer for all of marketing and regulatory programs.

Doug just joined us from the Agriculture and Marketing Service. We just underwent a consolidation of all of our information technology into MRPBS.

And Doug brings a wealth of experience from not only the Department, but also Forest

Service and AMS to here in APHIS. And Doug is going to talk about our broader modernization efforts.

MR. NASH: Thank you, Mark. Good afternoon. It's great to be here talking with you. And I appreciate the opportunity to share what's going on with the modernization of ePermitting, eFile and BRS services.

The work that APHIS is doing to modernize the ePermitting system is not being done in a vacuum as Mark mentioned. Our new Secretary, Secretary Perdue, has really put a big focus on making USDA one of the best managed federal departments. And he recognizes that to do that is to modernize information technology.

You are probably pretty familiar with USDA in the sense it's a fairly decentralized agency in terms of missions and also the IT and how that was managed and developed was very similar.

And so what the Secretary with his IT modernization initiative has done is he's really

taken a step back and asked us all to look at how do our stakeholders, like you, how does the public look at the systems that we provide in the USDA so that when you go to each agency it doesn't look like a completely different agency, a different experience, a different technology and all of that.

He talks a lot about using the Amazon metaphor, the Amazon experience, where you get a consistent high quality 21st Century digital experience. And so that's what we are part in APHIS and ultimately with the BRS ePermitting modernization is to build a modern technology platform that takes advantage of all of the good work and the capabilities you had with ePermitting but also brings in a lot of new 21st Century features that you didn't have.

And so just to provide you some broader context, as we are doing this modernization across the Department, we're approaching IT modernization through five different focus areas.

And the first is around IT infrastructure optimization. So this is where we're taking all of our old applications, what we call on-premise data centers, and we're moving them to the commercial cloud.

Why that would be of interest and importance to you is it will make APHIS and how we provide services more agile, more efficient in how we can build, deliver and support IT services plus it ultimately will help drive costs down for IT services.

We are using cloud. Cloud allows us take advantage of commodity IT and also just allows us to do things more efficiently and quickly.

Another big focus of the Secretary's IT modernization is around the customer experience. So rather than USDA employees alone trying to anticipate what you're looking for in services, digital services you get from USDA from APHIS, USDA is actually doing pretty broad comprehensive stakeholder engagement sessions to

find out what you like, what you don't like, using industry best practices and then building that into our digital modernization.

And then we're also building better capabilities for data analytics so that you'll be able to access data more easily. It won't be a stovepipe and difficult to access, but you can use it in much more creative ways and useful ways. And then finally improving our contact centers and how we provide support and reach out to customers.

We're on a fairly aggressive time frame to implement these IT modernization initiatives. We started last year. Many of these are going to be significantly -- well, they are all started and many of them are going to be finished by the end of 2019. So it's pretty quick.

And certainly we look forward to releasing the BRS ePermitting capabilities in the spring. So that's coming fairly quickly in large part because of some of the technologies that

we're using and also all of the engagement from our subject matter experts and our stakeholders.

So we look forward now to giving you the actual demo so we can get away from just kind of this high level discussion. You can actually see precisely what improvements have been made, how that looks. And then we really look forward to your comments and feedback.

So I'd like to introduce Monica Galli, BRS Senior Regulatory Specialist and then Ashok Anant, who is our eFile product owner.

MS. GALLI: Good afternoon. I'm Monica Galli, Senior Regulatory Specialist for BRS Compliance Evaluation, Enforcement Branch. And over the last two years, I've served as the project manager for the BRS portion of APHIS eFile. And my APHIS colleague is Ashok Anant.

MR. ANANT: Hi. Good evening, everyone. Good afternoon, everyone. My name is Ashok Anant. I am the eFile product owner responsible for ensuring the new system meets the business and functional requirements for the BRS

permitting.

I want to introduce Mahvash Taqi, Business Analyst. Mahvash and their team has been working with us for the past several months trying to elaborate these requirements and get them implemented into the system.

Today Mahvash will navigate the system while me and Monica talk about some of the features in the new system. I can only do one thing well at a time.

So I am excited to give you all --

MS. GALLI: Oh, just bear with us for a minute. It's going to take a second for the remote users to see the switch between the presentation and APHIS eFile.

MR. ANANT: Are you guys ready? Thank you. Today I'm excited to give you all a preview of our new eFile system. The new permitting system as you've heard is cloud based and is built on the Salesforce platform, widely adapted across the federal sector.

The cloud-based application has many

advantages for us, scalability, better performance and more availability.

The delivery of this cloud-based system puts APHIS in the forefront of the IT modernization effort across the federal government. Before I get into the demonstration, I want to reiterate that what you are about to see is work in progress and many of the features are still being developed and refined.

MS. GALLI: So as Mahvash logs in to get us started, come fly away with me to eFile land where Ashok and I will be playing the part as an experienced applicant today. We're going to be applying for an import permit for genetically engineered corn being imported from Peru to Riverdale, Maryland.

We're going to be using web entry to apply today, but XML upload is also an option. So buckle up and please hold your questions until the end of the demo. Ashok, take it away.

MR. ANANT: Thanks, Monica. Similar to the current ePermits system, access to the new

system requires Level II e-authentication. What you are seeing currently on the screen is a landing page once a user logs into the system with Level II access.

Before I create a new application here, I wanted to go over some of the key screen elements on this page. What you are looking at is the applications tab. The applications tab shows the application page where it lists all your current or active applications. As you can see, there are many applications this user has submitted.

If you have a large number of applications like this, you will be able to configure the system to allow whatever number of applications that you would like to view.

With each of these applications, if you see across the column, there is a status field. The status field shows if your application is still open, submitted or withdrawn. Columns are also sortable if you could see up, if you want to look at application

type, with new applications, you can sort those columns.

There is also the search feature on the right side. If you know your application number and you directly want to get into it and work on it, you can type in the number and get directly into your application.

On the top of the screen, you see four tabs: dashboard, contacts, applications and authorization. The dashboard has not been fully developed, but this will be the landing page once it's developed.

Once developed the dashboard will provide you a quick snapshot of status of applications, authorizations and permits in a visual format.

Please note we haven't fully developed so you're not able to see anything. But it should be a more graphical view once it's developed. You'll be able to see the number of open applications, the number of authorizations that have been issued, et cetera.

The contacts tab. The contacts tab is where the user can update his profile information. Sometimes you want to change your phone number or put a different email address, you will go here and update your personal information.

And finally, I wanted to talk about the authorizations tab. The authorizations tab is where you can find the disposition or status of your submitted application, whether a permit or notification for an application has been issued or acknowledged.

If you notice, every application has an equally valid authorization number. And BRS will eventually issue a permit or notification. The layout of this page, if you observe it, is very similar to the one you saw earlier, the applications page.

You have the number of entries where if there are a large number of authorizations, you can control how many you want to see on a page. In this page, you also have a few other

columns on the top, decision type, decision status, permit number, exit draft.

If you want to sort those columns, you can click on that and you can see a permit number, that's an issued permit for that authorization.

So with that said, now I'm going to take you through the process of creating an actual application. In eFile before you proceed to create an application, the user is prompted to answer a series of questions similar to Turbo Tax. These questions are similar to what you do in ePermits today.

Based on the user's responses, the system automatically determines if the user is required to apply for a standard permit or a notification or if a permit is required at all in some cases. In this instant, as we click through, based on the user's responses, the standard permit is required.

Now, let us proceed with creating the actual application and putting in the contents. If you look at the top column, there are several

columns. This is called a chevron view. If you look at the top, you see the application data, related articles, constructs, location, SOP, attachments and line item review.

We have made filling out the applications very easy for the user by breaking it down into different logical sections.

If you look at the top, we also provide instructional text throughout the applications and to make it easier for you to get some instructions on how to fill out the application.

We first start by asking CBI information. This will ensure we collect any additional data required in the application as appropriate. Also in some areas of the application, as you just noticed in CBI, the application will only allow certain types of characters.

Based on the notification of permit that was required in this, the related active duty section appears below, and it will have the

necessary fields to be filled out based on whether a permit or notification is required.

With that said, there are a few more sections, and I will turn it over to Monica to present them to you. MS. GALLI: Thank you. Now we'll navigate to the regulated article's page. Instead of manual text and tree fields, I use a lookup feature to search through a list of regulated articles.

Today I'm adding maize commonly known as corn to my import permit. I use the search box to search either by the scientific name or common name and then select the appropriate regulated article. You see that it automatically populated the regulated article text field with the scientific name.

If I didn't see the regulated article I was looking for, I would simply email BRS so that the regulated article could be added to the system.

So once I click save, I was taken back to the regulated article table where I can

confirm that I've added the correct regulated article.

Now I can proceed to the constructs stage. The constructs page has a new feature that I love and I think everyone else will like, too. APHIS eFile has previously submitted constructs.

This feature allows me to search and re-add constructs that I previously submitted on other corn applications. This feature is so great because it cuts down on the amount of manual text entry I have to do.

Each previously submitted construct is associated to a given regulated article. So I have corn previously submitted constructs and avocado previously submitted constructs associated with my eFile account because in eFile land I'm also conducting trials on non-browning avocados.

Another bonus is that I don't have to worry about data security. Only my account can see my previously submitted constructs. Like

regulated articles, constructs also appear in a table format as I add them to the application.

I'm going to search -- I'm going to use the search function to locate a construct that I submitted in my last application. I'll click the magnifying glass to review the phenotypic and genotypic details so that I can make sure that I'm adding the proper previously submitted construct. It looks good.

So we'll select the checkbox and click add selected. I'm taken back to the construct landing page where I can see that my previously submitted construct was added.

Now we'll go ahead and add a new construct to this application. I'll add the construct name and associate it with a regulated article.

Next, I'll select the mode of transformation from a drop down list. I make sure to click the claim as CBI box since this a drop down list and brackets are not accepted in this field.

Once I click save, I am given the chance to add the phenotypes and genotypes. So I'll click add phenotypes, select the phenotype category and input a phenotypic description and click save. For this construct we'll go ahead and add an extra phenotype.

Next I use the add genotype button to add my genotype details, including the genotype category, construct component name, construct component, the description of the component and the details similar to the experience now with ePermits.

Now that I have completed my construct, I will navigate back to the construct landing page to verify I have added all of the constructs needed for this application. So they're all displayed on this table in the construct landing page. So far so good.

Next I'll move on to the next section of the application, locations. In this section, I'll enter both an origin location and a destination location since this is an import

permit.

In this case, the material is being imported from the U.S. Embassy in Peru. To select a foreign country, I use a lookup table to select Peru as the country of origin. Once I hit save, the option to add location contacts appears.

Today we're going to skip adding the contacts for the origin and move into adding -- navigate back to the location landing page to add our destination location.

Since the destination location is APHIS here in Riverdale, Maryland, I will also use additional lookups to provide the state and country information. I will also indicate whether the location has been inspected by APHIS in the past.

Now I will describe the material that will arrive at this location, including the quantity, unit of measure and material type. And then I want to claim my information as confidential business information so I click the

checkbox for CBI.

Now I'll add a location contact for this location. The contact is my boss, Secretary Sonny Perdue. Better make sure that I use brackets and checkboxes to claim all of Secretary Perdue's contact information as CBI. I definitely want to make sure that his information is protected.

Once I save, I can confirm that all the information for this location is correct. Everything looks good.

The next section is SOPs and attachments are pretty straightforward. So we're not going to cover those today. Instead, we're going to jump ahead to line item review.

I see that each section of the application is visible, making it easy to review the information that I've entered into my application so far before submitting.

Now we're going to jump to the application review page after certifying that all of the information submitted is correct and true

and follows BRS' regulation.

The application review page again requires you to certify that all your information follows APHIS regulation. And then you're able to submit your application.

In the future, eFile will have validations in place to prevent me from submitting an incomplete application. But with the magic of eFile land, we were able to successfully submit this application today.

That's all we're ready to show you today. But hopefully everything you've seen so far gives you a sense of what's coming with eFile. Now Ashok will talk about other exciting eFile features that will be available at Go-Live and then we will take your questions.

MR. ANANT: Thank you, Monica. If you could switch back to the presentation? Thank you. All right. Thank you, Monica. In addition to what you saw in this review, there was going to be additional functionality you can expect when you first log into eFile after it is

released.

As I mentioned earlier, applications dashboards will be available and fully functional. Application cloning will be available. And we mentioned renewals, self-reporting and XML uploads. These are all going to be part of the first release, but you didn't get to see that today. We are still -- development is in progress.

MS. GALLI: Well, the next slide is questions. So if anyone has any questions, we can go ahead and get that started.

MR. ANANT: Thank you.

MR. WEEKS: I'm Michael Weeks, BASF. I'm excited to see the retention of previously submitted constructs for ease of use in the future. If accounts are transferred between applicants then organizations, is there a possibility that they also transfer using previously submitted constructs within the system?

MS. GALLI: I'll have to look into

that. But there is a concept we didn't talk about today that has been introduced to all the stakeholders before called organizational applicant where you'll be able to actually manage multiple applications who all work for the same company. And those will actually be able to share previously submitted constructs across the applications. So I think that might get to the business need.

MR. WEEKS: Yes. That's excellent. Similar question, will locations and contacts also have retention in the system similar to constructs?

MS. GALLI: Locations will not. Contacts will and the article, supplier and developer may function that way to retain that information.

MR. BOTTOMS: Jeff Bottoms with Syngenta. A couple of questions. I just want to confirm that your application cloning is copying that application?

MS. GALLI: Correct.

MR. BOTTOMS: Good, awesome. Thank you. The other question that I have.

MS. GALLI: Copying and also allowing editing, yes.

MR. BOTTOMS: Perfect. Thank you. The other part, I noticed there were a couple different ways to designate CBI. Could you address why there's the inconsistency and why certain fields have the checkboxes versus certain fields you actually manually enter the brackets?

MS. GALLI: Yes. So today in ePermits you use brackets to signify confidential business information. In eFile, certain fields are formatted to either be a phone number or an email address or you select them by a drop down list, so in those type of fields you cannot physically use checkboxes -- or, I'm sorry, brackets. So we've introduced the checkboxes for those fields to be able to claim CBI. Any other free data entry field you will still signify CBI using brackets.

So when you review your PDF, you will

see the checkboxes format that data in brackets also.

MR. BOTTOM: Great. Thank you. One last question for me, you noted that if you don't have an article in your drop down list, to contact the USDA to add it. Do you have any estimation on the timelines to get that added?

MS. GALLI: No, not at this point we don't. But we're coming up with a process now. And on the last page of your handout is kind of an overview for this afternoon. And there's an email address on that. So if you have any other additional questions or anything, you can start using that email address right away to get in contact with us about eFile.

MR. MUNDELL: Scott Mundell, Corteva Agriscience. So first I want to applaud the modernization and --

MS. GALLI: Thank you.

MR. MUNDELL: -- moving on and making things better for all of us. One question specifically about using cloud that I have

relative to protection of federally protected information under CBI. Can you describe a little bit how you're working in regard to security in this area?

MS. GALLI: Wait a minute. Okay.

MR. NASH: It's a great question. And security is always the first thing that comes up when we start talking about commercial cloud and those kinds of commodity services.

And we have to use -- within the federal government we have to use cloud services that are certified by GSA basically. FedRAMP is our techy term for it. But that's kind of the first level is we have to use federally certified cloud systems.

And then on top of that, we do analysis of the kinds of data that gets stored in the cloud in this particular system and how it's used. And then we also have to do a specific what we call re-certification for the application.

So we kind of do it in multiple layers

to make sure that all the data is protected. So we take it very, very seriously.

MS. WANEX: We have a number of questions online. Does anyone else in the room have any questions before we go to that?

MR. MUNDELL: Scott Mundell with Corteva again. Thank you for returning the mic. So you noted that there would be a role -- that there would be an organizational oversight. I suspect a number of us in large organizations have a group and they might like to all see each other's stuff.

So can more than one individual be set up at that organizational level? So say you had four employees all working in the same space, they would have cross-visibility on what's been put into the system?

MS. GALLI: Let me make sure I understand your question right. Within the same organization or even across organizations?

MR. MUNDELL: Within the same organization.

MS. GALLI: Within the same organization, yes, that's correct.

MR. MUNDELL: Fantastic. And when might the schema templates for the system be available? Or if you're going to get that later, please feel free to put me on ice.

MS. GALLI: We don't have an exact date of when the schema templates will be available. We're working to minimize the changes that will be needed on the new schema.

MR. MUNDELL: Okay.

MS. GALLI: I suspect we'll have a template available at least a month before Go-Live and then later on I'm talking about the transition period and I think that may answer your question.

MR. MUNDELL: Okay. Thank you very much.

MS. WANEX: Okay. The first question online that we had is where is the downloadable file with the handouts? It's in the box to the right-hand side of the screen in the webinar.

The next one is there any provision to see previous permit numbers for renewal permits?

MS. GALLI: So if you are going to renew a permit, renewals have to happen in the system the original permit was issued in. So if you are going to come in with a renewal into eFile, it would be processed as a new permit the first time it came into the system.

MS. WANEX: I think the question might have been more about if the first permit was in eFile would you be able to see the trail from where you started to where you ended up with renewals?

MS. GALLI: Yes. So when you renew a permit in eFile, the experience will be very similar to renewing a permit in ePermits.

MS. WANEX: The next question, notifications issued during the transition to eFile will be converted to permits automatically or will they need to be reapplied?

MS. GALLI: So nothing will be converted. If you apply for a permit or a

notification in ePermits, it will live out its life in ePermits. So, yes, if you need a renewal or a permit or notification the next year, any payment through eFile, it would be a new permit number, a new system.

MS. WANEX: Since there is no provision for a user to add a regulated item, they have to email BRS, how long do you expect the response time to be to add the item once you email BRS?

MS. GALLI: We're still working on what that process would be, but the delay should not be too long.

MS. WANEX: Will there be an unknown choice for inspection history questions?

MS. GALLI: Yes, that is something we're working on adding. The question of has the destination been inspected by APHIS before will probably be updated. It will definitely be updated before Go-Live and may not even be required.

MS. WANEX: Will preparers have

access to all of the constructs associated with the permit of these accounts?

MS. GALLI: We're still working through how the preparers will access the system and interact with it and what data they will have -- will be available to them after it's actually submitted. So I don't have a full answer for you at this time.

MS. WANEX: Will we still be issued USDA ID numbers?

MS. GALLI: I'm not really sure what the USDA ID number is.

MS. WANEX: The format that everybody is used to the numbers being in.

MS. GALLI: Oh, of our permit notification numbers now. No. Unfortunately our permit and notification number format will change.

Right now it is the year Julian day or the calendar and then it's 101 for the first notification that comes in that day or 102, 103. Unfortunately, we are going to lose that format

and we're going to a standard format that will be used all across APHIS.

MS. WANEX: If one simply wants to extend the permit period, how do you do the amendment?

MS. GALLI: An amendment never extends the expiration date of a permit. The only way to extend the expiration date of a permit or notification is to apply for a new notification or permit.

MS. WANEX: Will eFile have a message box feature for communication with biotechnologists and condition acceptance?

MS. GALLI: Yes, it will have a message box. And that's an exciting feature that we will display to you through webinars and other training materials as a way to communicate back and forth with the biotechnologists and have communications retained in the system.

MS. WANEX: Will eFile have a way to add a location as an origin destination and release location at one time or will they have to

be entered three different times?

MS. GALLI: Unfortunately, no. But we do have a new type of location, which is an origin/destination. So you will only have to enter it twice instead of three times. So not everything you want, but at least it's an improvement.

MS. WANEX: Will reporting, planting/field tests be done in eFile or in another system?

MS. GALLI: All self-reporting will be done in a system that the permit or notification originated in. And we'll talk more about that in the coming slide.

MS. WANEX: Somebody was clarifying their question from earlier, I believe, it was about the renewal. He said if you have Permit 1 which is renewed to Permit 2 and then renewed to Permit 3, will there be a trail in Permit 3 that has the other permits listed?

MS. GALLI: Yes. In eFile there would be a trail if all those permits were issued

through eFile.

MS. WANEX: Will our existing user ID and security levels transfer from ePermits to eFile?

MS. GALLI: So I'm assuming you are talking about the eOffice authentication ID? Yes, it will transfer.

MS. WANEX: If a new file is very similar to an existing permit, can you reuse the existing file to avoid entering all information all over again?

MS. GALLI: The schema file? I'm assuming?

MS. WANEX: I believe this might be a question related to cloning.

MS. GALLI: So you can go into an application, and it will copy it. You will have to still upload new SOPs and attachments.

MS. WANEX: For MRP IT, PPQ has also heard that ePermits was going away. Do you know if PPQ will be moving towards eFile? Will a similar presentation and demo be offered to PPQ

stakeholders?

MR. ANANT: Yes. It will happen in the future. We don't have any definite dates, but we have multiple releases planned. And we will get to PPQ and we have some more to add to that.

MS. LEWANDOWSKI: I also wanted to add that ePermits will not go away as long as we still have a need for it. So any decommissioning of ePermits while it may be in a planning stage, it's not going to go away until we know that eFile is up and running and handling permits that ePermits is currently being utilized for.

MS. WANEX: After transition to eFile, will applicants still be able to access applications that were done in ePermits? I think you might have just answered that.

MS. GALLI: Yes. As Laura said, ePermits isn't going away. You'll still be able to access. You might not be able to apply for new permits, but you will be able to access those records.

MS. WANEX: Has the USDA considered creating a similar portal for submitting export applications for health certificates, for example, the VS 16-4 form?

MS. GALLI: Yes. Eventually eFile will be built out to handle all of APHIS' permitting and licensing requirements. So a similar system is in the plans for that type of work.

MS. WANEX: Will applicants be able to initiate a message to the biotechnologists in the message box? Currently the applicant can only reply to messages initiated by the biotechnologist.

MS. GALLI: Chris, do you know for sure?

MR. HOLBY: I would say --

MS. GALLI: I'll have to look into that question. I'm not exactly sure of that functionality if that exists without the biotech first initiating the conversation.

MR. HOLBY: Yes, I would say the same.

MS. GALLI: Yes.

MS. WANEX: Will inspection letters be in eFile similar to how they are available in ePermits?

MS. GALLI: Yes.

MS. WANEX: We have some more questions being typed. Are there any additional questions in the room?

MR. MUNDELL: So what steps -- you showed a process there and currently there's an initiation process in ePermits. And then you get to the point where you reach the XML upload stage.

MS. GALLI: Yes.

MR. MUNDELL: Will that be essentially in the same spot in the process or will it move to earlier or later? Do you have any information on that?

MS. GALLI: Yes, so when we went to the question, we clicked a tab kind of up in the corner and there was, like, four different choices, and she chose one that took us to the question. There will be an XML upload right

there. So you'll just select and start the process for XML uploads that way.

MS. WIETZKI: Christine Wietzki with Betaseed. I was just curious. After filling out the application, will we still have the ability to generate a PDF to view that application?

MS. WANEX: Yes, you will. And if you're filling out a CBI application, you can generate both the CBI version and CBI deleted version of the PDF.

MS. WANEX: Online, please make sure you type your question in the chat box. I see somebody pressed 01. I'm going to take their question. Hi, there. You can speak at any time if you have a question.

MS. GALLI: So if you're interested in giving input of what you'd like to see in the system, we will be conducting user acceptance testing the week after Thanksgiving.

So go ahead and email the email on your handout. And then I'll be soliciting from

some of you who have helped test in the past also to see if you're still interested in participating and available.

MS. WANEX: To the individual that had a question, you should be able to talk. Please stay in the chat box because we're not hearing you. I definitely hear somebody talking. Well, we're not hearing anything in the room so I'm just going to read the next question. At any time you should still be able to talk.

Will the applicants be able to see the status of submitted applications in eFile?

MS. GALLI: Yes, you will be able to see the status of all of your applications in eFile.

MS. WANEX: If the applicant already knows that the material is regulated, is there a way to bypass the "am I regulated" questions?

MS. GALLI: Unfortunately no. There is no way to bypass the "am I regulated" questions unless you were to clone a previous application that you used in -- or you have already gone

through the questions to get to the correct outcome.

MS. WANEX: We have some more typing. Thank you, everyone, so much for your questions. It's been a really helpful discussion for us.

MS. GALLI: Yes. We definitely want to hear your feedback.

MR. BOTTOMS: Jeff Bottoms, Syngenta. Has there been any explanation of given more descriptive statuses for the applications once they're submitted? Currently, the permit is just ending but you don't know --

MS. GALLI: Where it is in the process?

MR. BOTTOMS: Exactly.

MS. GALLI: That is a possibility. We haven't really explored that very much, but yes. Okay. Thank you. We will definitely write that down.

MS. WANEX: We have another question. I think one we already answered. Will current access be migrated from ePermits to eFile

automatically?

MS. GALLI: Yes. You will use your eAuthentication logins for both systems. And it will be the same login.

MS. WANEX: And if CBI boxes aren't checked, who has visibility to the CBI?

MS. GALLI: Well, you would as the applicant and then BRS would. But the main reason that you claim information as CBI is in case that information becomes FOIA'd because the public can ask for it. So anybody that could potentially FOIA that information would be able to see information that you did not CBI protect.

MS. WANEX: Will there be a way to add supplemental documents to a submitted application without it having to be kicked back?

MS. GALLI: Supplemental documents -- but once it's submitted, I don't believe so. There will be a reports and notices section though so we could probably have the documents there after it's issued.

MS. WANEX: Do we need to write a new

XML upload program to mesh with the eFile system?

MS. GALLI: Yes. You will probably have to make small changes, but we're trying to minimize the amount of changes.

MS. WANEX: Last chance for anybody in the room if you have any extra questions. I see a hand.

MR. MUNDELL: Scott Mundell for Corteva Agrisciences. More of a comment. The sooner you can get us the schemas for all of this, the faster we can transition and we can be out of ePermits.

MS. GALLI: Yes.

MS. WANEX: I think you might find some useful information on that topic. One more question, will this system be ready to go for field crops by next March?

MS. GALLI: The Go-Live date is planned for spring of 2019. We're not ready to release the exact date or announce the exact date. So March falls in the spring. There's a possibility, but I'm not exactly sure.

MS. WANEX: Thank you, everyone, for the questions. We'll have another opportunity to ask more questions. You're always welcome to type them into the box.

MS. GALLI: Okay. So we'll move on to preparing for APHIS eFile. So let's talk about the transition from ePermits to eFile. The dates and timeframes that I mentioned are estimates only and are subject to change. eFile will go live, meaning it will be available to apply for permits and notifications in the spring 2019.

The transition between ePermits and eFile will occur in three stages. Each stage is expected to last approximately three months. Now let's explore how different business needs will transition.

First, we'll talk about reporting requirements. And what we mean by reporting requirements are the required self-reports such as planting reports, field test reports, volunteer monitoring reports and any other types

of reports that you're required to submit for permits and notification.

For issued permits and acknowledged notifications, permittees will submit their required reports in the system that issued the permit or notification. So anything issued out of ePermits, you will submit your self-reports in ePermits. Anything issued out of eFile, you will submit your self-report in eFile. And self-reports can be submitted both via web entry or XML upload.

Now new permit applications, so this is the diagram that you have in your handout on the last page. To minimize the total transition time between the system, BRS has already stopped accepting applications for multiple year permits.

So today you can apply for a one year permit or a one year notification in ePermits using web entry or XML upload.

At Go-Live you will be able to apply for one year permits, multiple year permits and one year notifications using XML upload or web

entry.

During stage one, both web entry and XML upload will still be available in ePermits. During stage two, only XML upload will be accepted in ePermits. Web entry applications will have to be submitted in eFile.

I encourage everyone to use eFile as soon as possible. But we have the stages for those of us that are reluctant to change or to get our XML schemas in order.

Beginning in Stage three, BRS will no longer accept applications in ePermits and all applications will need to be filed in eFile. And you'll be able to file those either using web entry or XML upload.

So the next business need would be for renewal permits. And only permits can be renewed. Notifications cannot. And you can only renew a permit via web entry. And that will change with eFile.

BRS will no longer accept permit and renewal applications in ePermits at the end of

stage one. And to reiterate, any renewal request submitted through ePermits will only be granted for one year. To get a multiyear permit, all applications must be submitted in eFile.

And the final business case is for amendment request applications. In both systems, we only issue amendments for permits. Notifications are not eligible to be amended.

BRS will accept amendment requests for permits in the system that issued the original permit. So if your original permit is from ePermits, you would need to request in ePermits. And if your original permit was issued in eFile, you would make your amendment request through eFile.

And as a reminder, no change can be made to the expiration date of the permit. Once you renew it, the expiration date stays the same as the original permit. I'm sorry, once you amend the permit not renew it.

Now I'll turn the mic over to Ashok to talk about what we can expect to see in the long-

term from APHIS eFile.

MR. ANANT: Thank you, Monica. Like with any product, we will continue to enhance the product and provide more features. You know, I have my iPhone, which is 6S. I started with 3S.

So we hope to do more releases. You know, we haven't decided the time frame of these releases. But some of the features, like, you know, more robust organizational applicant feature. Of course, we will continue to get usability feedbacks from you and others and roll these out as we do future releases.

And I think there was a question about plant production and quarantine permitting. So we are also planning towards getting the PPQ permitting into eFile. We don't have a date yet for that. Similar to that, Veterinary Services permitting will also roll into eFile in the future in 2019 or 2020 maybe.

So in addition to permitting, we are also looking into a one stop shop where certifications, accreditations, registrations

and other licensing can all be part of this eFile system. In fact, in animal care, annual reporting is already live. They have already gone to the next letter of ours, and they are in eFile.

So expect continual releases after the first BRS release, and we will tell you what where those new releases are going.

So in terms of getting up to speed with APHIS eFile, as you look at the system, we don't expect it to be very difficult to learn this interface. But we are going to definitely make sure you have the necessary support resources.

We will have webinars, which will be recorded and available any time you want to go to it. We will have FAQs. And we will have user guides to support this process of learning the new system. And one more opportunity for questions.

MR. WEEKS: Michael Weeks, BASF. The organizational applicant is something we've been

chasing after for years. And now that I'm thinking about it, I'm just curious, what the measures will be when someone becomes eAuthenticated and claims an organization to verify they do belong to that organization from the perspective that once they're in they would have access to everything else that was submitted within that organization. Does that make sense?

MS. GALLI: What we're imagining is that the organization will be able to designate their own system administrator, which will be able to control who in the organization shares information with each other. Chris, do you have anything else to add on how that functionality might exactly play out?

MR. HOLBY: I think that's right. I mean, I imagine it being a pretty direct to BRS conversation on who is that person and then that person then is kind of the gatekeeper. Yes.

MR. ANANT: Any questions online?

MR. MUNDELL: Scott Mundell, Corteva Agrisciences. So the current ePermits system

does have some system limitations on the size of the XML file that we can upload. And that creates extra workload for you, as an organization and for us. Do you anticipate file size upload limitations with this system?

MR. HOLBY: I understand there's a current page limit XML, and there's no page limit on the new uploads. We expect the system to support up to 500 constructs. So that's how we're measuring the size of the application.

MS. WANEX: The next couple of questions online. Will scanned blue and white import label history be in the file?

MS. LEWANDOWSKI: So any import that is issued in eFile you would use eFile to get your blue and white import labels from. The history from blue and white labels issued for import permits through ePermits, you would continue to get that label history out of the ePermits system.

MS. WANEX: How can we make sure we know when this system is live, when training

occurs, et cetera?

MS. GALLI: Don't worry. We will publicize and let you all know when the system is live and ready to use. We will let you know loud and clear.

MS. LEWANDOWSKI: Yes. That's absolutely right, Monica, and I just wanted to emphasize that this is really one of the very first of, I hope, several exchanges.

We are working on an entire change management plan to assist not only the applicants in their use of the system, but also to communicate with stakeholders, communicate throughout internally as well.

So this is -- you know, you're here at the very beginning, seeing the sneak peek. You're seeing the application even without all the functionality. And I know that there are questions about schemas. And so as we are developing more and more, we will be providing more and more detail.

And another point I wanted to make

kind of related to that is that we are using an agile methodology. So we are building the system and releasing and then building again rather than the old waterfall methodology where you build the whole thing before you show any of it.

So as we go, we will be communicating what's new and as we get closer to dates we will communicate those as well.

MR. MUNDELL: Scott Mundell, Corteva Agrisciences. One of my team back home actually texted me this one. So one thing to keep aware of in terms of your user authenticity, that being in the fall here, November/December, that's also the time that our teams inside our organizations are busy writing the applications that you all receive and review typically in December, January and February.

So if you could stretch that user acceptance testing out a little bit into January or February as well that also might help us communicate with you more effectively. Thank you.

MS. LEWANDOWSKI: Yes. That's a really good point. And thank you for that feedback. We're taking that.

And one thing I want to emphasize is that the user acceptance testing for November is actually for what we're referring to as pass one, which is a portion of the implementation. We'll have another user acceptance testing round as we get closer to the actual release. So we'll have several opportunities.

MS. GALLI: Any last questions in the room? Seeing none, thank you, everyone. Thank you for joining us. And we look forward to informing you more about eFile as it develops.

(Whereupon, the above-entitled matter went off the record at 2:44 p.m.)