U.S. DEPARTMENT OF AGRICULTURE

ANIMAL AND PLANT HEALTH INSPECTION SERVICE

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BIOTECHNOLOGY REGULATORY SERVICES

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STAKEHOLDER MEETING

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WEDNESDAY
DECEMBER 9, 2020

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The stakeholder meeting convened via Teleconference, at 1:00 p.m. EST, Doug McKalip, BRS Senior Policy Advisor, presiding.

PRESENT
DOUG McKALIP, BRS Senior Policy Advisor
IBRAHIM SHAQIR, BRS Associate Deputy Administrator
BERNADETTE JUAREZ, BRS Deputy Administrator
ALAN PEARSON, BRS Associate Deputy Administrator
DOUG GRANT, Director, BRS Regulatory Operations Program

C-O-N-T-E-N-T-S

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

(1:06 p.m.)

OPERATOR: Ladies and gentlemen, welcome and thank you for joining Biotechnology Regulatory Services Stakeholder meeting.

Before we begin, please ensure you open the WebEx chat panel by using the associated icon located at the bottom of your screen.

If you require technical assistance, please send a chat to the event producer. Please note that all lines are muted until the Q and A portion of the call. We will give you instructions on how to ask a question at that time.

As a reminder, this conference is being recorded.

With that, I will turn the call over to Doug McKalip, Senior Advisor with BRS. Doug, please go ahead.

MR. McKALIP: Thank you so much. And welcome to the BRS Annual Stakeholder meeting for

2020. And for those of you in Mountain Time Zone and West, good morning to you all as well.

We are so happy that everybody could join. We had a large number of science and a lot of folks on the WebEx this afternoon. And I think really the highest number of registrants that I have seen in recent years.

The BRS Annual Stakeholder meeting is somewhat of a holiday season tradition in that we typically wrap up the end of the calendar year with this meeting, and we usually would do it together in the APHIS Headquarters in Riverdale, Maryland.

It's a chance to greet and shake hands and catch up with each and every one of you.

We recognize that 2020 is a different year. And while we regret that we can't visit in person, we aim to make this meeting this afternoon every bit as comprehensive as usual with all the same policy contents and actions to share with you.

For BRS, though, 2020 has meant a year of less commuting activity, but it certainly has been a year of more program activity. And there is a lot to share, and a lot to discuss with all of you here this afternoon.

In terms of the game plan for today, we'll kickoff in a moment or two with Ibrahim Shaqir to talk about some of the new faces and new staffing that we have on board at BRS partly the increase of staffing that we have done to get ready for implementation of our new regulations.

Following Ibrahim, we'll have really the centerpiece presentation today with our Deputy Administrator, Bernadette Juarez, providing the overview of 2020 and a look ahead to 2021 for BRS.

Following Bernadette, Alan Pearson will talk about some key regulatory issues. Many of you submitted questions ahead of this meeting, and Alan will walk through many program specifics relating to the regulation and address many of

the topics that folks submitted in advance.

And then, lastly, Doug Grant will provide a regulatory operation overview for BRS.

For any of you who might have had any technical issues, the APHIS website for BRS does contain all of the materials for this meeting. That includes the slide deck presentation and the agenda and associated materials.

So if you are able to take a look at our website, it is featured front and center there. And I believe we're going to post that web address as well to the chat box to provide another avenue for you to get to the key materials for this session.

Our intention is not to take any breaks today. We're going to try to go straight through the presentations. And we may need a moment as we switch presenters to have each presenter take control of the slide deck.

We'll do our best to monitor the chat box. So if you have questions and put them in

the chat, we'll try to answer those in turn following each of the presentations.

And we'll try to handle any questions that come in writing first.

That we recognize not everyone will have the capability to submit those so after we've gone through written questions, we'll ask the AT&T operator to help identify any verbal questions. And then, we'll open the phone lines for those verbal questions as well.

In the meantime, if you're not asking a question, please make sure that you remain on mute.

And if we don't respond to a written question right away, if I don't read it right away, sit tight. It could be that your question will be answered as we go through the slide deck. And we'll make sure that we cover it certainly by the end of the presentation today.

So we want to, again, thank you, for being here. This is a great chance to share.

And to make sure that all of our BRS stakeholders are up to date with the latest activities that we have underway.

So with that, I'm going to turn it over to Ibrahim Shaqir who is our Associate Deputy Administrator for Emerging and International Programs.

Mr. Shaqir participates in the formulation and in the administration of broad policies and objectives of APHIS biotech programs. He works with international organizations to develop many standards for biotechnology.

From 2009 to '16, Ibrahim was the Director of the Office of International Research Programs with ARS.

From 2001 to 2008, he was an International Affairs Specialist for Middle East and North Africa as well.

Prior to coming to USDA, Ibrahim worked for the University of Maryland and was

also a consultant with the USDA FAS.

So, Ibrahim, I'm going to turn it over to you for your presentation.

MR. SHAQIR: Doug, thank you so much for the kind introduction.

And thank you everyone for joining us this afternoon.

It's always a great honor to be with you and our stakeholders. And this is an event that we truly look forward to as Doug mentioned.

So now, I'm on the agenda to talk to you about our addition, our new addition, to our team in BRS. And we are very excited about having them and including them on our team.

So we have had an active year in hiring new staff in BRS. BRS had about 11 percent staff increase in 2020.

We were proactively thinking about staffing in preparation for developing and implementing the new SECURE rule.

And in anticipating, you know, what

to, like, you know, in terms of expectations on what we need to do and what's required to meet to meet our obligations.

So I will, again, I'm delighted to share these names with you. But in advance of that, I would like to just give you our structure, a reminder of how BRS is structured.

And then, introduce the new staff with the program area.

And I will go with that. Moving the slides here, and so, first let me talk with, as I mentioned, how we are structured.

We have two main programs in BRS, Biotechnology Risk Analysis Programs, also referred to them as BRAP.

And moving BRAP, there are three branches, Plants Branch and Plant Pests, Protectants Branch and Plant Evaluation Branch.

The second major program is the Regulatory Operations Programs, ROP, and there are three different branches. And they're also

in the three different locations as well.

Eastern Compliance Assurance Branch, ECAB, and Compliance Evaluation and Enforcement Branch, and Western Compliance Assurance Branch.

And that's really the names that we made programs in BRS but also the four support service groups and science advisors in the Office of the Deputy Administrator.

And these, you know, important, these are important function. They keep BRS moving, and they are the heart of BRS as well in terms of our function.

So there's the Communications Branch, the Intergovernmental Operations, and you have Policy, Program and International Collaborations, PPIC, and Resource Management Services.

And this is the first part of BRAP. Many of you probably know and have engaged with BRAP but by bioregulatory analysis programs that includes scientists who review detailed

information submitted by applicants who want to move plant and fields and conduct field testing of organisms developed using genetic engineering. And they also ask us the potential plant pest risk and potential environmental impact to inform APHIS decision making.

Within BRAP, really much of the hiring were in support were basically in BRAP. The first one that the, you know, the name, we have the important addition for one of our new branches which include Dr. Suma Chakravarthy. She's our new Plant Evaluation Branch Chief.

She has years of research experience in molecular biology and manages work related to implementation of the SECURE rule.

We are actually super happy to have Suma because Suma was one of our AAAS fellows. And we're very happy that she came and joined us.

Another addition we have Tyler Reid. And we're always happy to include our pathway or entrance in our program.

Tyler Reid is a junior undergraduate major in agriculture. He is working with BRAP scientists on documentation reviews.

We, also, are happy to let you know that we also hired two senior biology scientists, Dr. Michael Stulberg and Dr. Martha Malapi-Wight. And both, they came to us from a sister program, from PPQ. And we're so delighted to have them.

We have also hired eight biological scientists and that, scientists also on this slide, Srinivasa Chaluvadi -- and excuse my pronunciation -- Rebecca Fletcher, Herbert Eichenseer, Natalie Howe, Ordom Huot, Colin Murphree, and Sarah Prewitt and Katharine Swoboda-Bhattarai.

So we truly are excited to have them. They are trained, our new colleagues are trained experts in genetics and entomology, plant pathology, root ecology, botany, molecular biology, agronomy, biochemistry and risk assessment just to name a few.

We are very excited to have such a broad range of scientific and regulatory expertise to support the nation and assist our stakeholders.

Next, I'll move onto ROP. And ROP, our Regulatory Operations Program, has regulatory and compliance analysts who ensure compliance with APHIS Regulations through inspections, evaluating the noncompliance incidents and overseeing the required supporting.

So this is really important too. We are delighted to introduce to you Dr. Doug Grant. Doug was our, he's from, where we were able to recruit him from within BRS. He was our Staff and Branch Chief in Fort Collins and now serves as ROP Director.

It is the program's activities in ensuring compliance with APHIS biotechnology regulations.

So we're so super happy. And Doug Grant will be presenting to you later on.

We also, I'm happy to introduce Heather Brown. Also, Heather was with us within the BRS ROP. And she is at a new capacity now, a new role. Heather assist stakeholders with compliance questions, evaluates compliance of regulatory activities and referrals from the BRS inspection program. And so, we welcome Heather.

The other new hires, we have also from our sister program, from PPQ, she joins us, Elizabeth Burns. She joins us from PPQ in Illinois and will work for BRS from Illinois, as well, providing oversight of regulatory seed trials and specialty feeds in the upper Midwest and facilities -- I'm sorry -- in the upper Midwest conducting inspections and evaluating compliance reports.

Now also a new hire for our Communications Branch and Communication Branch Closed Media. It's a really important role and coordinates in BRS communication strategies and our outreach efforts. She manages the BRS

website, conferences, supports strategic and operational planning and manages BRS response to Freedom of Information Act per our request and provides guidance on multiple administrative procedures as effected by biotechnology regulations.

I'm delighted to introduce to you Dr. Hannah Hamilton. She comes to us, she comes to BRS with several years of experience in public affairs and science communications from the Department of Interior.

She leads the branch effort to effectively communicate the work of BRS to our stakeholders and other interested audiences in the U.S. and around the globe.

We are delighted to have Dr. Hamilton. But also, I want to thank her and her team for actually for the meeting and making all those particular arrangements for this event.

So thank you, Hannah, for everything and your team as well.

Next is PPIC group. And PPIC group conducts legal and policy analysis and also guides policy development, manages compliance assistance programs and assists program units to implement quality management and principles and practices. And also, very important role in international coordination and outreach as well.

We are delighted to have also our newcomer, Kayla Knilans. And she is also a AAAS fellow, and we are delighted to have her and be able to recruit her to stay and retain her BRS.

And so, Kayla coordinates BRS activities under the trilateral technical working group with Canada and Mexico and other nations as well.

She also develops strategies for engagement for domestic and international governmental organizations on technical and regulatory information.

So welcome, Kayla.

And next in this group, I'm delighted

to also introduce Mr. Russel Duncan. He is on the long term detailed to BRS from one of our sister programs for international services, IS.

So he provides technical assistance for international activities, policy and engagement, customer care coordination with AFS, International Services, and supports prior technology capacity building efforts.

We are delighted to have Russell on our team, and he has been fantastic helping us with many international aspects of the SECURE rule and communication outreach.

And finally, I just want to add that we also added new team members to the Resource Management Services Branch. That is responsible for all administrative function as it pertains to human, physical capital, and resource management, financial management and data management.

And we are delighted to have on our team Djene Sylla who is the program assistant and provide administrative assistance for Human

Resource function, fleet, and facility management.

So we welcome Djene.

And finally, Mr. Jason Chatman is the management analyst and work with the other management team on eFile and other IT functions as well.

So we welcome Jason and he has been hitting the ground running, working and helping us with eFile-related issues, and he's a great addition to our team.

So just to, in summary, we want to let you know that we are excited. We made staffing changes for very important reasons, for implementation for our new rule, the SECURE rule. We have very trained staff who managed and coordinated for reviews and evaluations. They have smoother transition into new role and ways of doing business.

So even, you know, if we have adopted to the new work environment during the pandemic,

in a way that we have, we hope it has been seamless for you, our stakeholders.

With that, I want to thank you so very much for your dedication. That concludes my presentation to you, and I would be happy to entertain any questions.

And for now, I'll turn it back to Doug.

MR. McKALIP: Thank you so much, Ibrahim, really impressive to see all the additional capacity and the number of new names and new faces that were not part of this meeting one year ago.

So thank you for that overview.

In the chat box, we did have a question. Would it be possible to have the presentation? And the answer is yes.

The full slide deck from today's meeting is available on our website. If you just go to the BRS website and click at the banner on the top for the stakeholder meeting, it will take

you to a listing of all the resource materials associated with today's meeting. We'll try to also put that link up in the chat box as well.

I don't see any further questions for Ibrahim in writing. Just had one to Ibrahim asking about capacity on the team to work on microbial regulatory issues which, I know, we do have some staff expertise already in house on that. Ibrahim is there anything that you would like to add specifically about staffing capacity on microbial regulatory issues?

MR. SHAQIR: I do believe we have the capacity to handle any issues that is microbial related kind of application or anything of that regard.

But I will ask Subray if he's on for any, if there are specific areas of microbial related technical issue that that questioner has?

MR. HEGDE: Okay. Can you hear me, Ibrahim?

MR. McKALIP: Yes. We can hear you,

Subray.

MR. SHAQIR: Yes.

MR. HEGDE: Okay. Yes we have five staff members who have experiences in the microbial dedicated to microbes, virus, fungi, and bacteria. And we are handling most of those questions already related to microbes within the community.

MR. McKALIP: Great. Thank you, Subray. I appreciate that input there.

Do we have any questions for submitted verbally by phone. I'll turn it over to our event operator to do that check.

OPERATOR: Sure, please press pound two on your telephone keypad to enter the question queue. You will hear a notification when your line is unmuted. At that time, please state your question. Once again, pressing pound two will indicate that you wish to ask a question.

At this time, we have no one in the queue.

MR. McKALIP: Okay. Well, Ibrahim, thank you so much for that overview on staffing. I really, really appreciate that information for our team.

So we're going to now shift to you the second item on our agenda which is the overview of BRS for 2020 and the look ahead to 2021 which will come from our Deputy Administrator, Bernadette Juarez.

Bernadette was appointed Deputy Administrator in August of 2019. It's really impossible to believe that it was that recently. It really seems like much more in terms of the amount of action which I'm sure Bernadette will be covering.

Prior to this appointment, Ms. Juarez served as deputy administrator for animal care since 2016, and she joined APHIS in 2009 first as Investigative and Enforcement Services Deputy Director for nearly five years and then as Director starting in 2013.

Before coming to APHIS, she began as a trial attorney with USDA's Office of General Counsel from 2002 to 2009. And she is originally from the very great and beautiful State of New Mexico.

So Bernadette, I'm going to hand it over to you for the next agenda item.

MS. JUAREZ: Thanks, Doug. I appreciate that introduction. It has been a busy 16 months, and I look forward to sharing with you what we've been working on over the past year since we last visited in December.

Doug mentioned earlier that on our landing page for the meeting we posted a number of materials. One of those first pieces of material that I'd like you to take a look at when you have time is BRS by the Numbers.

It's a one-page document that provides a nice overview of our key accomplishments during this year many of which you'll hear a little bit about today. But if you're looking for a nice

snapshot of what BRS delivered in terms of services in Fiscal Year '20, that's a great place to look.

A lot of our focus in '20 at Fiscal Year '20, was on finalizing the SECURE rule. It was issued in May 2020.

We have a variety of materials on our website that provides an overview of the SECURE rule both from a textual perspective and a presentation perspective.

We've also posted frequently asked questions on our website about the SECURE rule. I've included the link to those materials in my presentation. If you go to our website, you'll see them there.

You can view the presentation and click directly on that linking and get right to them if you're interested.

One of the first parts of the SECURE rule to take effect were the exemptions and the method by which developers can seek confirmation

that a plant meets the criteria or one of the new regulatory exemptions in the SECURE rule.

Those provisions took effect in August of 2020. We had a number of technical webinars before those provisions took effect to make sure that the stakeholder community had a good sense of how the exemptions work under SECURE and also the methods by which they could seek confirmation that their product meets the criteria for exemption.

We developed guidance materials and frequently asked questions and posted them on our website. The link that you see there will take you right to the material for your information as well.

Part of standing up the new exemptions in the SECURE rule for plants developed using genetic engineering meant to retiring one of our legacy processes known as the "Am I Regulated" process.

That was a nonregulatory method that

we maintained for developers to provide us and learn whether or not their product was subject to the regulations.

We've announced to our stakeholder community that we would stop accepting requests using that method in June 2020. And we have now concluded our responses to all of those "Am I Regulated" requests that were either pending in the queue or that we received as part of our closeout of that process.

Collectively we responded to over 80 inquiries this year.

You can find all of those incoming inquiries along with our responses by following that link on our website.

As part of the SECURE rule, the folks who did submit an inquiry and received a response and learned that their plant was not covered by the regulation,

that determination maintains and carries forward or is grandfathered in under the

SECURE rule. That determination applies to that specific developer and that particular plant or organism that they were writing about in that inquiry.

So if you'd like to take a look at any of those, you can certainly find them by following the link in the presentation.

Another important component of the SECURE rule exemption involve Plant-Trait-Mechanism of Action combinations that we previously evaluated and determined were not regulated under the prior regulations.

As part of the SECURE rule, we developed a Plant-Trait-Mechanism of Action table so that folks know those combinations that would remain exempt under the SECURE rule. And we posted it on our website.

We still owe a small update to that table to include insect resistant traits so that developers have a good sense of how those exemptions will work for the Plant-Trait-

Mechanism of Action associated with insect-resistant traits.

We hope to do that soon. And when we do, we'll be sure to let you know of our update to that Plant-Trait-Mechanism of Action table.

So that was sort of the first stage of implementation of the SECURE rule.

The next stage comes in April 2021. In April 2021, we will begin to stand up the regulatory status review process for certain types of plants.

We will also be implementing the new permitting requirements in the future rule as we look forward to sharing an overview of our conceptual thinking in terms of guidance for submitting requests for regulatory status reviews.

Dr. Alan Pearson will be spending about half of his presentation today walking through the general thinking for that guidance document.

We really look forward to receiving questions from you in terms of our thoughts. We want to make sure that by the time we get to the point of sharing, that document, in writing, that we have shored up any potential gray areas and make sure that it's useful for both internal and external users. So he'll be talking to you about that.

Another important part of this new rule that I should have mentioned before moving on to the Regulatory Management Review process has to do with our ability to add additional exemptions for plants with additional modifications that would meet the criteria for exemption because they were otherwise achievable through conventional breeding.

This is one of the key components of the exemption section of the SECURE rule that allows us to ensure that our exemptions remain current with technology and advancements in conventional breeding.

We have developed a high level overview of the guidance document that we'd like to share with you on how to submit proposals for expanding or listing additional plants with modifications that would also qualify for exemption.

Again, Dr. Alan Pearson will be visiting with us in just a few moments about our thinking on that topic. We certainly look forward to your feedback and questions during that session.

Lastly, I did mention that the permitting practice would take effect in April. We haven't yet turned our attention to developing guidance for that new process. We know it's important to you. It's important to us.

We want to make sure that when we have that guidance in place it will help facilitate not only the transitions that were made to the SECURE rule but also to our new information management system, eFile.

We'll provide you with an update on where we stand with regard to our transition to that new information management system that will soon become the sole method by which developers will submit applications for permits.

We also are excited to be able to fill the component into that new information management system that will allow developers to submit requests for confirmation that a plant meets the criteria for regulatory exemption as well.

In the future, we envision that system being further developed so that any regulatory status review request would also come through that platform so sanctions for additional work in that regard.

We've spent, also, in terms of implementation of the SECURE rule, quite a lot of time thinking about our international strategies and outreach to make sure that our trading partners around the world have a good sense of

USDA's Policy approach for handling plants developed using genetic engineering.

Following the issuance of the SECURE rule, we shared talking points and materials with 98 offices to our foreign Ag service and 28 additional offices with our international services.

We've had a variety of multilateral, bilateral and regional meetings for sharing encouraged science through this approach.

Our vision is to have greater harmonization and tell countries around the world to view this product so that we can help facilitate development, innovation, and also export those products that are approved using genetic engineering.

We've met with several countries. It's even listed there, Canada, Mexico, Brazil, Latin American countries, Taiwan, Korea, Dubai, Japan.

And we have upcoming interaction plans

again to circle back with Korea, meet with EEU. We have plans to visit with Spain and Portugal and the Latin American countries and them too.

So we certainly look forward to continuing to share information on the SECURE rule in 2021. Even though we haven't been able to do so in person, we really worked to improve our strategy for using virtual meetings to convey and share this information and have learned a lot through that process.

Finally, I wanted to share with you an update on the work that's been in our pipeline.

We haven't had the with respect to final determination of nonregulated status in 2021. We haven't reached the final solution for any, but we're getting very close on several.

In 2020 itself, we had one involving the Simplot Potato you see there.

We've completed or closed out the comments period for draft plant pest risk assessments or draft EAs or extensions through

products. But my Monsanto Lygus cotton, Westhoff petunia and the Pioneer enhanced yield corn.

Again, those are kind of in the middle stage, and we look forward to getting those to the finish line sometime soon.

We also have an open comment period for Pioneer there with their one product as well.

We've published several petitions for comment. We've got closed comment periods now on four petitions that you see there and one open comment period for Pioneer with an insect and herbicide resistant maize.

So there was, admittedly, a little juggling that we had to do to, both, push the SECURE rule out the door and continue to push petitions through the pipeline.

I think we see from the distribution of work here that we have several that are coming to fruition and others that are in the queue to push through the process.

So we look forward to doing a little

bit of catchup work early in the fiscal year and continue to move petitions along in the administrative process and review process in 2021.

Finally, one of the shadow projects that we've been working on in BRS with contemplating how USDA may evaluate animals developed using genetic engineering.

In late November, November 26th, USDA submitted an advanced notice of proposed rulemaking to the Office of Management and Budget that would describe the regulations for the movement of animals modified or produced using genetic engineering.

It brought this conceptual framework that would partner with another sister agency within USDA, the Food Safety Inspection Service, so that USDA could provide a one-stop shop for a certain animals known as amenable species developed using genetic engineering that are intended for agriculture purposes.

This advance notice of proposed rule making remains under OMB review. So we're not able to discuss much of the content of that proposal at this point. And this rulemaking -- we look forward to that material being publish so that you can take a look at what additional business line we may have in the future and seeking your feedback on the contemplated regulatory framework that we describe there.

So that's what we've been up to in BRS over the past 12 months, and for me, 16 months. Doug, you're right it does feel like a longer period than 16 months, but I'm happy that we had a strong hustle and were able to get some of the things out the door and cooking under hot heat.

MR. McKALIP: Great. Thank you, Bernadette. We did have a question submitted in writing which was coming from Ray Dobert asking what has been the general feedback from other regulators regarding the SECURE rule? What concerns have been voiced on the elements of the

rule?

MS. JUAREZ: Thanks. One of the steps that we took in the development of the SECURE rule was really working with our fellow regulators like EPA and FDA to gain as much alignment and consensus and try to pass forward as possible.

We've received positive feedback from our colleagues for that outreach and connection prior to issuing the final rule for those who have an interest in some of the work that EPA does, you know that they published a proposed rule to provide additional exemptions for certain types of PIP. And we looked to harmonize terminology between the two rules, our SECURE rule and their PIP rule.

So I think what you will see moving forward is our continued effort to promote alignment within the USG particularly in terms of the handling of products using genetic engineering and to making it easier or wherever

possible for developers and stakeholders to navigate those processes.

And so, we have overall positive feedback to the SECURE rule. Lots of interest in understanding the scientific underpinnings of how we established our regulatory exemptions in particular. We've had lots of discussions in that area.

And of course, our partners are interested in seeing our phased implementation of the rule as well.

MR. McKALIP: Great. Thanks, Bernadette. Yes. And I totally agree having gone on a lot of those international trips that the response has been very, very positive from folks.

Another question submitted in writing might even get to perhaps an oversight in our slide deck. It's asking about China's connection on our outreach for SECURE.

MS. JUAREZ: Oh, you know, I don't

recall that we have had a meeting with China yet on SECURE. And certainly, it's just not something that we're opposed to doing.

It's just a matter of moving along on in the process. Some of the countries that we've met with are countries that expressed interest early on in meeting with us. And that was prioritized and getting back with them as quickly as possible.

And so, as part of our international strategy for 2021, we're developing a framework for how we'll approach that. And I'll be sure to take a look at where China might fall in that list.

MR. McKALIP: Great. Operator, if there are any questions submitted verbally, please open up the lines for them.

THE OPERATOR: Once again, please press pound two on your telephone keypad to enter the question queue.

At this time, we have no one in the

queue.

MS. JUAREZ: Okay. Thanks, Doug. Then I will turn it back to you.

MR. McKALIP: Great. And thank you, Bernadette. I really appreciate that overview.

Okay. So we're going to move into our next agenda item which relates to some of the more specific regulatory issues associated with SECURE and so forth.

So we will now be joined by Alan Pearson, our Associate Deputy Administrator of BRS.

Alan was previously the BRAP Branch Chief, and he was originally hired on to BRS in 2009 as the biological scientist. He was a AAAS science fellow from 2003 to 2004.

He did his post doc at Mass General and Harvard Medical School and has a PhD from MIT and an undergraduate degree from Brandeis.

So, Alan, hopefully, you're in the queue. I'm going to turn it over to you for the

next portion of the slide deck.

MR. PEARSON: Okay. Thank you, Doug. And welcome everybody to our meeting. It's my pleasure to talk to you today about a couple of the guidance documents that we are preparing and will be making available for your review soon.

I'm going to talk about two guidance documents. And the first I'm going to talk about the Guidance for Preparing Proposals to Exempt Plants with Additional Modifications from the SECURE rule.

And second, I'll give an overview of the Guidance on Preparing Requests for Regulatory Status Review.

So starting with the first item, the Guidance for Preparing Proposals to Exempt Plants with Additional Modifications from the regulations.

As you know, we three express, no we have an expressed exemption in the rule for plants that could have been produced through the

conventional breeding.

And we've identified three specific types of modifications that a plant can have any one of. And qualify for exemption.

In addition, we've developed a process whereby the administrator can list additional modifications that a plant can have and qualify for the exemption.

And we can either initiate such a listing modification ourselves, or we can, respond to a request someone from outside of APHIS for that.

So this guidance is really meant to let you know what comes with information you would need to provide if you wanted to request that we list an additional modification plants can have and qualify for the exemption.

So I will brief you through some of the required information and talk to you a little bit about the process.

There are, briefly, the first I want,

you know, you need any contact information and really the key point is that clear description of what the additional genetic modification and modifications that the plant can contain and qualify for an exemption.

For example, perhaps a specified number of changes that are achievable in cultivated plants.

So perhaps you want to propose a specified number of changes achievable in a particular plant species or a type of modification rather than one of the ones that's already listed in Part 340.1(b)(1-3).

Along with that, you need to provide us with a statement of a factual grounds that demonstrate that plants contain the proposed modification can be achieved in conventional breeding and provide supported scientific literature or publicly available information that would support those factual grounds as well as any information you may know that would be

unfavorable to having that modification to the list, that modification plants can have and qualify for exemptions.

Our decision standard when we say could be achieved through conventional breeding, means that the genetic modification is practically achievable through the conventional breeding methods in the plant.

For example, evidence that multiple desired traits or genetic modifications could be introduced in a plant on a practical basis would meet that standard.

We're unlikely, on the other hand, to adopt an invention for plants that contains specifically nearly implausible modifications.

So that's just to make clear and that standard really comes from what we laid out in the preamble to the SECURE rule by what were meant by the terms to be achieved through conventional breeding.

Our process is that you would submit

proposals electronically via a mailbox listed here, an email address (b)(4) exemptionrequests@usda.gov.

If there is not sufficient, publicly available information supporting the proposal. Or if after we review it, we disagree that plants containing the modification or modifications could be achieved through conventional breeding method, then we'll return the proposal to you and provide our reasons for returning it to you in writing.

On the other hand, if we determine that plants containing the modification could be achieved through conventional breeding methods, then we'll publish the proposal and supporting information in the Federal Register for Public Comment.

And after reviewing that comment, we'll publish a subsequent notice in the FR announcing our final determination on the proposal that's been sent to us.

We'll complete our review and make our final determination. And in 12 months of receiving all the required information, we'll list it unless there's circumstances that could not have been reasonably anticipated.

And finally, we recommend that before you submit your, you know, if you are intending to submit a proposal and you've never submitted one before, that you talk with us first just to make sure that you fully understand what we're looking for.

And we understand what you are intending to be submitting so that we can make sure that the process runs smoothly.

Finally, the Guidance Document that we are going to be making available on our website will include a couple of examples of proposals.

And these are the examples based on the modifications that are already listed in the SECURE rule.

So that concludes the overview of the

guidance we'll be making available on proposing additional modifications that plants can have and be exempt from SECURE.

And the rest of my presentation and the bulk of the presentation, I'm going to give you an overview of the guidance that we're developing for requesting a regulatory status review.

We're in the process of completing that guidance now. And we want to provide the overview today and take any questions or feedback you may have.

And also, let you know that there will be opportunity to comment further on this when we publish the guidance.

So to begin with as you know if a plant does not meet one of the regulatory exemptions listed in the SECURE rule, then the developer can seek a regulatory status review for that plant to determine whether or not it's regulated.

And in the regulatory status review,

APHIS evaluates whether a plant pest risk posed by the plant is any greater than that posed by its comparator plant.

We based that on looking at the biological properties of the plant looking at its trait or a new characteristic that's been conferred on the plant and looking at the mechanism of action or how the modification caused the new trait to occur.

I just want to review a few important definitions that you should know when thinking about a regulatory status review request.

The first is the definition of comparator plant which is essentially the plant that's used as a comparison or a reference for the plant developed using genetic engineering to determine if that plant, the plant being evaluated poses an increased plant pest risk.

Typically, a comparator plant is a plant that hasn't been developed through genetic engineering and from which the plant being

evaluated is derived.

However, the comparative plant can also be a plant that was developed using genetic engineering if the comparator has been -- if APHIS has already determined that comparator plant is not regulated under part 340, and, or if it's determined to be the most appropriate base line for comparison on the plant subject to the RSR request.

The other three terms are all defined in the regulations themselves, the definitions of trait, definition of mechanism of action, and the definition of plant pest risk.

And as we explained in our in our Confirmation Guidance.

When you're thinking about a trait and the trait sometimes referred to as a phenotype, a phenotypic trait.

It's not a whole station. It's the result of the underlying genotype of the plant, and its interaction with the environment.

And so, we'll make those plants that are in the guidance.

Before turning to the information requirements, I wanted to go through some information on the process, the RSR process which is really a one- or two-step process depending on the plants that we've received a request for.

So evaluation in step one where we receive the initial request, and we start in step one that evaluation looks at the characteristics of the plant relative to the comparator who identify whether it is a plausible pathway to increased plant pest risk.

And that is where we ask is there a scientifically plausible hypothesis by which a trait and the mechanism of action in the plant can change any of four factors in the way that can lead to increased plant pest risks.

Either the distribution density or development of the plant or its sexually compatible relatives if there are any sexually

compatible relatives.

We look at the production, creation or enhancement of a plant pest or a reservoir for a plant pest.

We look at harm to non-target organisms beneficial to agricultural even if you consider immediate impacts of a plant and its sexually compatible relatives and whether those could contribute to increased plant pest risk.

In general, you will complete step one in 180 days from receipt of request that meets the information requirements.

There are -- unless there's, and again, some certain things that can't reasonably be anticipated.

There's 180 days to receive a completeness check. You'll know more in two weeks' time.

And then, once a request is deemed complete, our risk assessors review will have sufficient information from the requestor in

order to complete step one of the process.

Now if APHIS does not identify a plausible pathway to increased plant pest risk during its first step, then the plant would not be subject to the regulations. And we would post the plant, the trait and mechanism of action on our website.

I know that we had comments during the -- on our proposed rule about confidential business information. And we of course will honor any confidential business information that is claimed in the request assuming that we accept the submitted CBI claims, and so I posted those in our MOA -- clearly in that context.

If in step one we do identify a plausible pathway to increased plant pest risks, then we'll provide feedback to the requestor about the plausible pathway that we've identified and the type of additional information, if any, that we might need to complete a plant pest risk assessment in the second step of the process.

And at that time, they have a conversation with the developer to make sure, or the requestor, to make sure they understand our specific areas of concern so that they can evaluate the next step that they wish to take.

And there are various options that a requestor could choose from. They may elect to take no further action and simply be done.

They may elect to request a permit from us to allow movement and/or confined release.

They may submit a formal request that we complete a plant pest risk assessment as part of step two of the RSR process.

Or they could pause the RSR process and simply ask us to just hold it there until they're ready to proceed.

And I want to add that, you know, the requestor can also submit a request that APHIS complete a PPRA and also a obtain of permit at the same time so that they can be doing work with

that plant while we're continuing the RSR process.

They may choose to obtain a permit and pause the RSR process while they collect laboratory and field data to support a plant pest risk assessment.

There are various options that a requestor can take once we completed step one, if we do identify a plausible pathway to increased plant pest risk.

In step two, if we identify a plausible pathway to increased plant pest risk and the requestor wishes to proceed into step two, then we'll conduct a plant pest risk assessment to evaluate the identified pathway and the factors of concern in order to determine the likelihood and consequence of the plausible increased plant pest risk.

We will publish this PPRA in the Federal Register along with any applicable environmental analyses when we make a preliminary

finding that the plant is unlikely to increase a plant pest risk.

Now at that time, we will solicit any comments from the public which we'll then evaluate and determine if there's information that impacts our PPRA.

If we find that the plant's unlikely to pose an increased plant pest risk, then the plant would not be subject to regulations at that point.

And of course as the plants where we made such a finding after step one, the plant trait and then they would go onto our PT MOA table so that plants would have the same PT MOA would qualify for exemption from the SECURE rule.

If APHIS is unable to find that the plant is then likely to pose an increased plant pest risk, then the plant would remain regulated.

In this process, we anticipate generally completing within 15 months of receiving a complete initial request. This

includes a 30-day completeness review for any data that we've requested or the developer has submitted.

It excludes any pauses in the process, and I'll discuss pauses in a moment.

At any time during the RSR process, the developer or requestor has the opportunity to submit additional information or data to aid in our evaluation of the factors that we've identified.

And in addition, if we are unable to make a finding that a plant is unlikely to pose an increased plant pest risk, a requestor can later submit a request for re-review of the plant if they have additional scientifically valid evidence related to plant pest risk.

For the re-review, you will essentially be starting at step two again. We would have already identified the plausible pathways of harm in step one.

So we would not be starting the

process earlier from the beginning if a re-review is requested because we had already found we were -- that we weren't able to find it was unlikely to pose an increased plant pest risk.

In addition, though, anyone can request a re-review based upon scientifically valid evidence related to plant pest risk. They would need to have that evidence in front of us in order to act on any request for re-review.

I mentioned pausing the RSR process. APHIS will pause the process after step one until we receive a response from the requestor as to how they want to proceed.

So here I'm talking about, if in step one, you have identified a plausible pathway to increased plant pest risk, at that point we'll pause the process until the requestor tell us that they want us to proceed with step two of the RSR process and then conduct the PPRA.

We'll also pause the process while awaiting a response from a requestor to the

completeness review that we undertake at the beginning of step two in the process.

In our experience with petitions and considering the possibility that requestors may not have collected all of the data necessary to support a PPRA, at the time that they request us to conduct one, stopping the clock here for a while or pausing the process while waiting response to this completeness review, this would also be a good option.

It avoids putting undue time pressure on requestors to generate data or reanalyze existing data and, thereby, enables us to make sure we've got a complete data package. And then, the requestor is ready to proceed and then we'll continue with the RSR process.

We're only going to conduct one round of completeness review at step two. After that, we will proceed with conducting a PPRA with the data that has been submitted to us in response to end the completeness review.

The requestor should recognize that we could conclude that we are unable to reach a finding of unlikely to pose an increased plant pest risk based on the currently available data.

If they ask us to proceed and haven't clearly provided us with all of the data that we've indicated would be needed, when we send out the results of our completeness review.

Of course, if that happens, again a requestor could submit a request for re-review after that.

A requestor can request a pause in the RSR process at any time. So it's not just APHIS to pause the process, the requestor can request the pause in the process, for instance, as I mentioned with data from the lab or data that is given to inform a PPRA then the requestor can pause the process until they provide that data to APHIS.

Now, I am going to turn to the information that's required in an RSR request, we

laid this out at a high level in the proposed, in the final rule and the preamble to the final rule.

And I'll go into some more detail here. First, of course, we need your name, organization and so on the -- if you had made a CBI statement. That is whether you are claiming CBI, or there's no CBI claim.

And if there is a CBI claim with CBI justification, the scientific name of the comparator plant or the RSR, the genotype of the modified plant including a detailed description of the differences in genotype between the modified plant and the unmodified plant, and a detailed description of the new trait.

And I'll step through those last two bullet points in more detail now.

So in terms of genotypic information, if genetic material is inserted, you need to provide the DNA sequences of the inserted material, as well as an annotation of the inserted material that includes the following

items for each component of the construct or constructs you are using.

The nucleotide position of a construct of that component, the name of the component, for example, 35S promotor or catalase, or nos terminator or noncoding spacer.

Plus the donor organism or source from which a component has been obtained, and then a short description of the function of that component and like for examples here, if it's an enzyme involved amylose synthesis or it confers glufosinate resistance or it's a native promoter or it's nopaline synthase terminator.

The specified sequence information is needed by APHIS in order to confirm the intended trait or traits at the molecular and genetic level. And to better understand the mechanism of action, for purposes of assessing the potential for plant pest risks in any of the modification or modifications. And also if relevant to help us assess similarity of previously reviewed

plants.

The other item named donor organism source and a short description of the function are really similar to the kinds of information that developers are already providing in permit applications.

So developers of these kinds of plants who have obtained permits or authorizations or any notification from us in the past. We'll already be very familiar with the kind of information we are asking for here when we talk about name, donor organism, and short description of the function.

In addition, if genetic material is inserted, it's provided with any publicly available sequence identification number or protein accession number or enzyme commission number. Now, we know that that may not be publicly available, but if it is publicly available, it will be provided in the request.

Any promotors or regulatory elements

should be identified as in the case of promoters or subscription of abuse of or developmental or tissue specific, and if its developmental or tissue specific, describe the stage and/or tissues in which the promoter is intended to be active.

Also if there are sequence alterations in the genetic material that you're inserting relative to the sequence in the donor organism, then identify the nature and purpose of those sequence alterations such as graft or codon optimization or changing the binding site of an enzyme, and provide us with an alignment with the sequence of the unmodified in the donor organism.

If genetic material is not being inserted into the organism, then identify the genes or genomic regions that have been modified or the functions that have been modified and provide the sequence of the entire modified region including alignment with the unmodified.

Turning to the required information on

the description on the new trait, in that category, provide the purpose and the intended phenotype of the new trait including any expected differences from the phenotype of the comparator.

Provide any available information from the mechanism of action by which the intended trait is conferred. That is the biochemical process by which the genetic modification leads to the desired trait or phenotype.

And provide us with any expected changes in metabolism, physiology and/or development due to the trait or the genetic modification to the extent that you know them.

And you'll notice I'm saying expected changes. They're not -- this isn't to say requests were up at step one in the process were not required that you have undertaken a full phenotypic product ---, but rather that you provide us with information on what the intent, intended phenotype is and what other phenotypic

changes, the changes in the paddles and so on to be expected as a result of the modification, to the extent that is known.

So in descriptions, these are just a couple of examples of descriptions of the new trait. For instance, the trait would be herbicide resistance, the phenotype, resistance to glyphosate and the mechanism of action listed as an insensitive form, EPSPS with a decrease binding affinity of glyphosate.

Or to take another example, a trait might be an altered tuber amino acid profile. A phenotype is reduced asparagine or reduce asparagine levels. And the MOA is a potato tuber-specific double-stranded RNA-mediated degradation of asparagine synthetase-1 gene transcript decreasing protein level and resulting in reduced version conversion of glutamine to asparagine in tubers.

And to form insight into these MOA descriptions, you can also look at PT MOA tables

where we provide short description of the mechanism of action for all of the various plants that we have due regulated under the prior regulation and which are now eligible where those plant trait MOA combinations are eligible for exemption from SECURE.

We also list some optional information that you can provide if you wish. This is additional information that may be submitted.

But this information really should be limited when you're first submitting an RSR request in step one. It should be limited to that which informs the initial evaluation that is under taken in step one.

So for example, you could let us know whether the MOA is identical or similar to a previously reviewed MOA and provide us with the explanation of the similarity.

You could rely on additional information on how the genetic material or its product participates in or interacts with

metabolic, physiological or developmental processes in the plants or other organisms.

Or any other information that you think would help us to complete that first step in the process.

Now additional, if you submitted additional information that actually pertains to a plant pest risk assessment in step two, we will not review that information unless we've identified a plausible pathway to plant pest risk.

And, ideally, I would prefer that you not submit that kind of information to us until you ask us to undertake the PPRA.

In order to have an objective analysis for step one. It can reach a decision that not's subject to any challenges, but it can't be reviewed information in a manner that can constitute the plant pest risk assessment that we would be carrying out in step two.

Additionally, we really want to avoid

slowing down the completeness review in step one where we've indicated that we would undertake that review in ten days.

If we have voluminous extra information that we end up receiving we would then have to kind of go through that information to figure out which is relevant to step 1, which isn't and parse all that out and that would slow the process down.

After we've completed step one, if we find that a PPRA would be required, then at that point a requestor can submit additional supporting data or at any time after that as well.

They can support, they can submit additional supporting data up until the time when we make our final determination.

In that, in getting that additional information to support step two, the data submission should be limited to those that address the plausible pathways to increase plant pest risk identified in the initial review.

So if the information that you're submitting is not germane to the, you know, the plausible path of increased plant pest risk, admitting that information now only gives us more information that we need to then read through and look at but it slows the whole process down.

APHIS will use publicly available information and any additional information that you submit when we conduct our PPRA.

And with that, I will, this concludes this presentation and welcome any questions you have.

And I will also welcome Bernadette and Subray Hegde to weigh in on questions that you may have as we undertake this as it sits, Subray's division, BRAP that would be conducting the regulatory status review.

So with that, I give it back to you, Doug.

MR. McKALIP: Yes, thank you. I really appreciate that presentation. And if

folks want to press pound two to get in the queue for verbal questions.

In the meantime, Alan, we did have a couple questions that were submitted in writing. One, Audrey Leonard, asked, are re-review requests only available when a request has been denied due to PPR or is it possible to request a re-review of a plant that has been approved?

MR. PEARSON: If we have completed step two and gone through the FR process and found at the end of that that the plant is unlikely to pose an increased plant pest risk, then therefore, would no longer be regulated under SECURE, the re-review could be requested after that.

However, I want to emphasize that there would have to be scientifically valid evidence submitted in that request for re-review. And we are not stating here that a request for re-review would automatically trigger re-review. We would have to evaluate that request and decide

then.

MR. McKALIP: Okay. Thanks, Alan. And regarding the RSR review, could you please expand on the applicable environmental findings? What sorts of characteristics in addition to weediness, et cetera might prompt an environmental review assuming that this is a formal NEPA review?

MR. PEARSON: So we would not, I want to clarify that the RSR process does not itself constitute an environmental review under the NEPA.

If we undertake a review under NEPA, that would be determined, you know, we would have to look at that at that time to determine whether such a review is needed.

But it wouldn't be driven by our RSR request itself but rather by whether or not the decision is one that might trigger the NEPA re-review process. That is an area that we're still exploring.

I don't know, Bernadette, if you want to comment further on that.

MS. JUAREZ: I think that's exactly accurate of where things are. Thanks.

MR. McKALIP: Okay. Thanks, Alan. We've got a question submitted in writing, can you elaborate on the purpose of the plant trait MOA table which was located on the BRS website.

MR. PEARSON: Sure the purpose of the plant trait MOA table is really to inform the regulated community of which plant trait MOAs would qualify for exemption.

The exemption listed in section 340.1(c) of the SECURE rule, which is an exemption for a plant that has the same plant trait MOA as one that we had already determined either pursuant to our old petition process or pursuant to the new RSR process is unlikely to pose an increased plant pest risk and therefore is not regulated.

That's why once we complete an RSR

process either at step one if we make that finding at the end of step one or at step two if we make it after completing step two if you are to add that plant trait MOA the PT MOA table.

MR. McKALIP: Thanks, Alan. Another question submitted in writing, what happens if the APHIS review, a publicly available literature comes across any data not provided by the requestor that would indicate a potential risk?

MR. PEARSON: If we came across that data, we would evaluate that data and that would go into our risk assessment or risk analysis.

MR. McKALIP: Thanks, Alan. Operator, do we have any verbal questions in the queue currently?

OPERATOR: At this time, we have no one in the queue.

MR. McKALIP: Okay. Thank you, Alan. I don't see any further questions in writing, so I really appreciate that presentation and your responses to the folks' questions.

MR. PEARSON: Certainly, and I'll just repeat again that we do hope to make this guidance publicly available in the future. And there will be opportunity for any of our stakeholders to comment on the guidance prior to us finalizing it.

So we will certainly be opportunities to, in the future, you can ask us additional questions or comments, suggestions and so on. We welcome any suggestions so we can make the guidance, you know, as useful and clear for our stakeholder community as possible.

MR. McKALIP: Terrific. Thanks, Alan. Yes, that's a good reminder the stakeholder meeting is just one of any day that folks can approach us and request additional clarification and additional information. So we're always here to help folks. Thanks, Alan.

MR. PEARSON: Sure.

MR. McKALIP: Okay. That moves us to our next and final agenda item, which is Doug

Grant to provide a regulatory operations update.

Doug is one of the new names, at least new in his new position, but certainly a veteran of BRS, who was provided in the first slide deck of our meeting today.

Doug is the director of the BRS Regulatory Operations Program, and he formerly served as the Chief of the Western Compliance Assurance Branch, which is located in Fort Collins, Colorado. And he was in that position from 2011 until June of this year.

Doug holds a master's degree and Ph.D. in plant ecology from Colorado State University. He grew up in Ohio and then moved to Colorado to go to college.

Doug joined APHIS in 2005 after working for the USDA ARS at the Crop Research Laboratory from 1999 to 2005.

Prior to working for USDA, Doug held several positions in Colorado State University as well as the Colorado Department of Natural

Resources and the Colorado Natural Heritage Program.

So, Doug, I'll turn it over to you for your portion of the presentation.

DR. GRANT: Great. Good afternoon, everyone. Thanks, Doug, for the introduction, and thanks to everyone for joining us today.

We're changing gears here to talk a little bit about some of our compliance activities, and then, I will also be giving some eFile updates for folks.

First, I want to share some information about how BRS chooses which trials to inspect.

So we gathered the post planting report data, known as PPRs or sometimes we just call them planting reports, and we use that data to select which site will be inspected.

Most of our inspections are for field trials or releases into the environment. But some are also for destination facilities that

BRAP identifies and for those they may be inspected prior to final permit issuance.

For the field trials, we use the information that we get from the post planting reports. And those data are compiled into a database.

And then, we also map them using geographic information systems based on the GPS coordinates provided in the planting reports. And we take compliance history into account as well.

So we basically select the sites for inspection to make sure that we're inspecting them at an appropriate time. And our inspection selection is based on risk where lower risk trials with lower risk species are selected for inspection at a lower frequency.

We've made a big shift this year to doing virtual inspections during the COVID-19 pandemic.

And we actually piloted these virtual

inspections a couple of years ago in FY '18, and we refer to them often as monitoring and evaluation interviews, or MEIs.

So once we entered into the travel restrictions associated with the pandemic, we made the shift to doing all of our inspections with this virtual process beginning in March of 2020.

And just to tell you a little bit about how that process works, the inspector schedules the interview with the responsible person for the given authorization we are inspecting and requests records such as volunteer monitoring, or equipment cleaning records, a map or diagram of the site, the GPS coordinates and at least one current photo.

And then, the BRS inspector evaluates the submitted record, checks the compliance history of the regulated MV and then compares the map and the GPS coordinates that we've been given with the information on the authorization and the

information submitted on the planting reports.

So we've found that we've had really good success with the virtual inspections as a way to provide meaningful virtual oversight of regulated activities.

We incorporated using video conferencing technology when possible to help with our visualization of what's going on at a site. And we also have started using remote sensing technology to help assist us with looking at trial sites from afar.

Just to highlight a couple of the projects, we really focused on over the last year and in the last two years really, this portal project has been a really big one.

We have this APHIS GIS portal that is used by all different programs within the APHIS to analyze geospatial data. And, you know, that depends on getting accurate GPS coordinates, obviously, for where these trials are located.

And if cloud-based data secure portal

for use and it's a FedRAMP authorized system, then the portal really allows us to share information with BRAP, between BRAP and ROP for some of the analysis they do prior to issuing a permit.

And then, we look at the relevant data layers, and we actually can pair some of the GIS work with some of the remote sensing work that we've been doing.

So we use the remote sensing to find information, and this is primarily satellite imagery. And it can be used to look for the relevant dates of when the trial occurred.

So we can use this imagery to help verify isolation distance. It can be used to help verify planting and harvest dates for a trial site. And essentially to support or refute observations that are made during the virtual inspections.

So in terms of what we did this year, this fiscal year that we just wrapped up, we had

pretty high compliance rates, as we do most years. They were a little bit lower, 95 percent in FY '20 compared to 97 percent FY '19.

For the inspection outcomes, we have 80 percent of the inspections were noted as compliant in the closeout letters for those locations.

We had 5 percent that were deemed to be non-compliant with regulatory requirements. And those consist of notices of non-compliance.

We have another category as well which is, we sometimes share information about issues that were identified by the inspector, but the trial is still compliant.

So essentially, conveying concerns about issues that could lead to compliance issues down the road. And those are in a couple of different categories; notice of compliance with comments or with notices of findings.

And we also have in our compliance evaluation and enforcement branch, they handle a

lot of self-reports that come into our compliance inbox and to our compliance hotline.

Those self-reports deal with things such as losses of confinement related due to severe weather-related events.

We did notice the number of compliance challenges in FY '20, and I sort of have the most common types of challenges we encountered listed here. There were 12 instances where we had a release in an area or quantities not authorized. We had 19 instances of failure to comply with Supplemental Permit Conditions. We had 28 instances of late or missing Post-Planting Reports. We had 21 instances of late or missing Field Test Reports.

And I think, you know, we noticed a definite trend that a lot of these challenges were associated with the pandemic and people not having access to the location where their information or records might be stored.

Or they may have accidently shipped

the material to the wrong location or even planted it in the wrong location.

And when those happen, we worked to quickly bring those locations back into compliance.

So taking a look at where we had plantings across the U.S. in the past year, we had over 3,000 planting locations authorized.

In terms of what was actually planted in FY '20, we had 1,027 sites that were planted or active.

And then, when you look at the map, you can see some areas of higher concentration such as in Iowa and Illinois here in the Midwest, you know, down in the Southeast along the coastal areas.

And we have, you know, quite a constant amount of activity in our winter nursery locations in Hawaii and Puerto Rico.

In terms of inspections conducted, in FY '20, there were a total of 554. And that

equates to roughly half of the sites that are planted. These inspections consist of inspecting annual as well as perennial crop.

The majority of the inspections are conducted in season which means during the years that the trial is planted. But some are also conducted post-harvest and the year after the trial.

And we also have some plant-made pharmaceutical or industrial trials or PMPIs. And those get inspected multiple times during the year of the trial as well as the year following the trial.

Now I'm going to move into just sharing a little bit about the distribution of work for who is conducting the inspection.

I use this graph to highlight how going back to 2014 -- this just shows even years -- but we've really increased the percentage of inspections that are conducted by BRS personnel.

And so, we've got a decrease in the

number of inspections that are conducted by our sister program APHIS Plant Protection and Quarantine or PPQ.

And this year we also saw a decrease in the number of inspections done by our state partners who conduct inspections on behalf of APHIS in a number of locations.

And this was primarily related to the shift that we made to conducting all our inspections virtually. And we have trained up a number of PPQ inspectors to do the virtual inspections at this point.

So you'll, you know, you could be contacted by someone from BRS or someone from PPQ or from the state's department of agriculture depending on which state you live in to arrange time for an inspection.

Looking at the numbers broken down by quarter, you can see we had 69 inspections in Q1, 89 in Q2, 69 in Q3, and then 317 in Q4.

And that sort of log jam or big chunk

of work generally happens in that most of the trials in continental U.S. aren't planted until Q3 of the fiscal year. And then, we have a little bit of lag time before we get those planting reports and get the inspections scheduled.

So we definitely have an extremely high inspection workload in Q4, and that is typical for us.

All right moving on to eFile update and the ePermits transition.

So since go-live we've had 48 applicants working in the pilot for the APHIS eFile system. Eighty-two applications have been submitted for BRS authorization. So far, a number of those have come in quite recently.

Fifty-nine authorizations have been processed so far. And we've actually done inspections on some of these as the folks in the Regulatory Operations Programs learn the workflows in the APHIS eFile system.

And we've made some really good

progress with the eFile system. There's improved user registration and continued development. And that development is heading in the right direction.

In terms of the transition dates that folks want to make sure to be aware of to APHIS eFile, the transition from ePermits to eFile really begins in earnest with -- April 1 of 2020 was the last day to submit notification in APHIS eFile.

And I believe that these slides should say April 1 of 2021 for the last day to submit notifications in APHIS eFile.

The April 4th of 2021 is the last day to submit any permits or notification applications in ePermits. And these are obviously, related to the transition to the new SECURE rule.

And then, April 5th of 2021 will be when applicants must use eFile. We will only be accepting applications for permits at that time,

and APHIS applicants will also be able to use the eFile system to request confirmation of an exemption from regulation.

So in the transition that we have going to eFile, we have providing supported user guides, and we are also going to be offering training available to applicants.

So the user guides will be available to assist you in the transition as seamlessly as possible from ePermits to eFile. And the instructor-led training opportunities for applicants are sort of being planned around those final transition dates in early April of next year.

If you are interested in doing some of this training, there is a email that we'll provide on the last slide in terms of how to contact the help desk when you need assistance.

And you can also see our BRS website here and get signed up for that stakeholder registry. There's a link to that on the left-

hand side of our BRS website.

So if you get signed up for that registry, then you'll be able to stay informed about when these instructor-led and other training resources are available to you.

So in terms of the future availability of ePermits, it's going to sunset at some point in time.

But for applications that are submitted in ePermits, they will complete their entire lifecycle in ePermit. There is no way for us to move the information from an application or an authorization in ePermits to eFile.

So if it starts in the ePermit system, it will finish its lifecycle in the ePermit system.

So likewise, if you're submitting reports or notices that are necessary for a compliance of an authorization, those for authorizations issued through ePermits should also be submitted in ePermits.

And for the foreseeable future, there's really not going to be any restriction to ePermits read access.

And we don't really have a timeline set just yet for the date that ePermits will no longer be functioning because it depends on a lot of other APHIS programs but we will definitely be keeping stakeholders informed.

And just a reminder, like I said, there won't be any data migration from ePermits to APHIS eFile.

APHIS eFile early adoption. You know, we want to encourage applicants to make the transition early. Don't wait until April.

There some nice features that we have in eFile that have been turned off or not in place in ePermits, such as submitting multiyear ePermit applications.

You can get familiar with the system. You can use the previously submitted construct feature to easily add constructs from previous

eFile applications.

And you can also set up sharing accounts. And those will allow your teams to collaborate within your organization on applications.

But the first step is really to get registered with your e-authorization account via the APHIS eFile webpage. And that address is right here.

So once you get your registration, your e-authentication account registered, you'll be able to work on submitting your first application.

So I hope this information has been helpful for you today. We're here to assist you through this transition to the new APHIS eFile system.

And we have a really great team that's happy to help you.

If you have questions, comments, or concerns, or just need help with the transition

to the new system, please contact the team at this email address, efile.communications@usda.gov, and they'll be happy to help you.

I want to thank Miranda Wanex, Megan Dexter, and Heather Brown for help with the slides, and thank you all for your attention.

With that, I will be happy to take some questions.

MR. McKALIP: Great. Thanks, Doug. We did have a question submitted in writing asking has the new virtual inspection shift proven to be successful, and do you see this being a mainstay for your program?

DR. GRANT: Yes. Thank you, Doug, for the question. You know, we've found it to be quite successful.

We have a little bit more lead time involved in terms of preparing for a virtual inspection than we do for an in-person inspection.

And we've really felt like we've been able to provide good virtual oversight using our technology and the tools that we have, such as video conferencing.

So we will continue to use it to supplement our regular in-person inspection work as we go into the new year.

I don't think we anticipate doing a lot of in-person inspection work early in the new year. But, hopefully, by the time the growing season rolls around, you know, we'll have travel restrictions lifted. And the pandemic will be subsiding to the degree that we can get out and safely do in-person inspections.

I think that there's a lot of value to both, so we'll probably have a little bit more of a hybrid model as we move through the future.

MR. McKALIP: Terrific. Thanks for that response. I would remind participants that pound two is the way to get into the queue for asking a verbal question over the phone.

And I know we've got just a little over ten minutes left that we had allotted for this meeting.

And, Doug, one of our participants commented in the chat box that they have an inspection coming up today at 3:00 p.m., so we certainly want to keep everybody on schedule here so that they can get to their meeting.

DR. GRANT: Right.

MR. McKALIP: -- take care of their needs.

DR. GRANT: Yes.

Event producer, do we have any calls currently in queue verbally?

OPERATOR: We currently do not have anybody in the queue.

MR. McKALIP: Okay. We'll give it just a couple moments here if folks do have either written question or verbal one to give them a last chance to ask.

Okay, Doug, we did have a question

submitted in the chat box. The individual asked -- and if they missed this, they apologize -- but wanted to know if it's possible to see a list of plantings of new material, if not by name, by crop?

DR. GRANT: I'm not quite sure that I understand the question.

So they're asking for how many of the plantings that we had to be broken down by crop species?

MR. McKALIP: That's how I read the question. Is there some additional detail on what's being planted?

DR. GRANT: You know, I think we might be able to provide some information like that. I certainly don't have it at my fingertips. And we would need to, you know, make sure that we were protecting any confidential business information.

So I would suggest that that person send their question to the BRS inquiry -- I'm

forgetting the name of the email address, Doug, maybe you can share that -- and they can submit it and then we can take a look.

MR. McKALIP: You bet. Yes. We can look that up in the chat box. I think their question, Doug, was precipitated by the slide that had the 2020 unique planting's, the one thousand twenty-seven unique planting's.

So this participant was interested in more detail about the planting's.

Doug, you made a really super important point about CBI there. But yes, we can further, you know, follow-up with them about that question.

DR. GRANT: Yes. The BiotechQuery email address would probably be the best place for that question, Doug.

And I can tell you that if, you know, a lot of corn, you know, a lot of soy beans, a good amount of cotton, and a whole bunch of other species, you know, almost anything you can think

of under the sun.

So, yes, we can work on a list like that. And it varies a little bit from year to year, but corn is definitely king in terms of taking up the most time for our inspection activities.

MR. McKALIP: Okay. Doug, an additional question in writing about the training to industry for the new eFile process.

And I think folks are just sort of, if they're not familiar with what we've done already, just hearing a little bit more about what even may be planned further in terms of training stakeholders and how to utilize the eFile system.

DR. GRANT: So we'll be holding webinars, and we've held those in the past, too, with some of the initial pilot participants for the APHIS eFile system.

And those dates for those webinars will be posted on the BRS webpage.

I'm not sure exactly how many of those opportunities there will be, but I do know that they will be recorded, and the recordings will also be available via the BRS website.

MR. McKALIP: Good. Thanks, Doug. Just a reminder, you did cover this.

But if folks are not currently registered on the BRS stakeholder registry, that's a great way that will help, you know, rather than checking the website, to get information.

It is pushed from us to all of you. So if you're not registered, that's a great way to keep current on those kinds of opportunities as they are scheduled.

We got a question about will the recording of this presentation be posted or emailed?

So again, the entire slide deck is available on our website. We also have a transcription service that will take the entire

meeting and will make a transcript available of this session.

Event producer, do we have any calls, questions verbally in the queue currently?

OPERATOR: At this time, you have no one in the queue.

MR. McKALIP: We'll wait just a moment more, Doug, to see if anyone submits one in writing.

Okay, hearing none, Doug, thank you so much for that very comprehensive overview of the regeat operation.

DR. GRANT: Thank you.

MR. McKALIP: Okay. That was the agenda for today, and we really appreciate all the very thoughtful questions and really excellent comments that were provided throughout the session.

And as I think we covered a few times, the stakeholder meeting isn't the only chance to connect by any stretch.

So we've provided a lot of resources here to go along with this meeting and a lot of different ways for you to connect with us. And we would encourage you, at any time, to ask questions and keep clarity because that certainly is helpful to us as much as it is to you too.

Along those lines, we'll be looking for feedback on the format of this session.

You know, this is a very special year, and we're all trying to feel our way through it. And we hope that this has been a really good way to conduct the stakeholder meeting, but we certainly welcome your thoughts and ideas on how we can best share with you.

So with that, Bernadette, do you have any closing comments that you'd like to make before we wrap up and close the phone line?

MS. JUAREZ: I just really appreciate everybody who connected with us today.

And like you said, Doug, we hope you found this information and format helpful.

In some instances, it may have been very information dense, and we recognized that you may need some time to think about other questions you might have and come back to us.

And we look forward to connecting with you if you have further questions on some of the topics that we talked about today and in the future.

MR. McKALIP: Great. Thanks so much, Bernadette. Yes. Thank you. With that, Event Operator will close out the lines.

And for all the stakeholders on the call, we sure look forward to connecting with you real soon in the future.

And thanks for all you do.

(Whereupon, the above-entitled matter went off the record at 2:57 p.m.)