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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THURSDAY
DECEMBER 5, 2019

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The stakeholder meeting convened in the Conference Room, 4700 River Road, Riverdale, Maryland, at 1:00 p.m., Doug McKalip, Acting Communications Branch Chief, presiding.

PRESENT
DOUG McKALIP, Acting Communications Branch Chief, BRS
MAXINE BALL, Management Analyst, BRS Communications Branch
FAN-LI CHOU, Ph.D., Biotechnology Coordinator, USDA Office of the Chief Economist
DOUG GRANT, Ph.D., Branch Chief, BRS Regulatory Operations Program
GREG IBACH, Under Secretary, USDA Marketing and Regulatory Programs
BERNADETTE JUAREZ, Deputy Administrator, BRS
IBRAHIM SHAQIR, Associate Deputy Administrator, BRS

PUBLIC COMMENTERS
JANE DeMARCHI, American Seed Trade Association
RAY DOBERT, Bayer Crop Science
TIM EYRICH, Southern Gardens Citrus
JAYDEE HANSON, Center for Food Safety

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

1:07 p.m.

MR. McKALIP: Okay. Good afternoon, everyone, and welcome. And good morning to those who are with us from the West Coast, and from the Pacific Basin.

My name is Doug McKalip. Most of you know me as Senior Policy Advisor at BRS. I'm also currently pinch hitting, and filling in as the Communications Branch Chief for BRS as well.

This is really the stakeholder meeting of many new faces. And I mean that all around. We have a record number of folks registered, and taking part in this stakeholder meeting.

We have nearly 200 folks that are participating on the webinar. And we're hoping that we are able to accommodate everyone who is trying to sign up electronically. I know the capacity it right around 200. So hopefully we're going to be able to get everybody part of the discussion.

This year we want to make sure we have

a chance to have a good discussion, and dialogue, and exchange between our speakers. We've provided a much concise and condensed agenda than maybe what you've been familiar with in years past.

We want to hopefully hit on all of the key biotechnology issues that are happening out there, and provide you some updates on the BRS side. And again, have a chance for questions and answers.

One area that we won't be able to talk about with you this afternoon is the rulemaking. As all of you know, I think, in this room and online, we are currently in the process of updating 7 CFR Part 340.

And the SECURE Rule is still under development, the final rule, that is. So, we won't be able to have a dialogue with you specifically on contents of the rule. But again, we hope to have a very developed dialogue on a whole host of biotechnology issues.

For those of you who want to ask

questions we've got a room mic here on a stand. WE also have a roving mic a few of the BRS staff will be walking around with.

And for those of you participating by webinar, just type your questions into the chat box, and as appropriate we will read those questions for the presenters, and give you a chance to participate that way as well.

If you need restrooms they're just outside the room. And there also is a refreshment location nearby too. If we have time we'll take a break. But if we have a very full plethora of questions we may just work our way straight through the agenda without stopping, as appropriate.

So, I'm very excited to introduce our first speaker. And I've talked to a lot of BRS staff, and no one could remember the last time that we have had the opportunity to have an Under Secretary address our BRS stakeholder meeting.

But I'm really excited to introduce Greg Ibach. He was sworn in as MRP Under

Secretary in October of 2017. And the breadth of programs and missions that he oversees is incredibly large.

He has all the ag marketing service, all of APHIS activities. Now a lot of the grain packers and stockyards piece falls under his purview, as well as some FSA programs historically.

But you think about the gamut of all the checkoff programs, and grading meat and eggs, and the various pieces all of us are familiar with the APHIS does. The organic program. It's just a massive amount of array of programs.

But we've been very pleased to have his unrelenting focus and attention on biotechnology, even given the large scope of the programs that he oversees.

He has been an incredible advocate, and very closely involved in helping, and pushing, and leading on biotechnology policy. I know that we're all grateful for that.

So, with that, Under Secretary Ibach,

we welcome you to the podium, and look forward to your remarks.

UNDER SECRETARY IBACH: So, thank you very much, Doug. And I think that part of, you know, you spend a lot of time talking about all the AMS stuff. But APHIS is equally as diverse and challenging to watch over on a day to day basis.

And Caleb Crosswhite is with me today. Caleb, I stole him from the House Ag Committee, what, six months ago now, maybe, almost? And maybe a little bit longer.

And it's been great to, you know, pay backs are double. You know, he wrote a lot of this crap now that he has to deal with. And so, but it's good to have him, and the insight that he had into the legislative side, and now working with us on the implementation, the regulatory and service side of things as well.

And, you know, I'm very thrilled to be at MRP. And part of that is because of my past experience as director of ag in Nebraska. I was

a customer of most of the programs now that I'm involved with USDA, as the vendor of those programs.

And so, I think it gives me a unique, I've been on both sides of the fence now. And it gives me a unique approach to how I look at some of these issues on the day to day basis.

But more importantly, I think, my, the part that I think grounds me and draws me to the biotechnology side of things, or the BRS issues is the farmer in me.

And we still have an active farm and ranch in central Nebraska. One of my sons is home on a day to day basis watching over the farm. The other one and his wife live in Minneapolis, involved with agriculture as well.

And we have a daughter that lives in Denver that works for the Colorado Farm Bureau as a lobbyist. So, still a family very centered around agriculture and production agriculture.

And so, anything that I do I think helps augment those friends and neighbors back in

our home town in Nebraska, as well as across the United States, being more productive are things that I'm really interested in.

You know, I think that one of the things, as we talk about what BRS is really focused on, and Bernadette will have an opportunity to talk to you about in more of her individual goals.

But, you know, biotechnology provides the opportunity for us to be able to produce safe and affordable food, for agriculture to be more sustainable, for us to add quality to U.S. crops, and for us to, as we're adding that quality, and producing those larger amounts of food that are required, it gives us a chance to be more competitive, or remain competitive on the world wide stage.

And so, that's what you developers in the room are, that's your responsibility. And that's your wheelhouse.

We also have a lot of BRS people listening in, in the room here today, that are

part of the other side of the equation, the regulatory side.

But, and I also like to not necessarily think of us as regulators and innovators, but more as a team working together to be able to bring both sides together and find the solutions that are going to keep brining innovation to farmers and ranchers across our country.

And the, as we look at the road ahead I think biotechnology is only going to grow in prominence. We're going to see more innovation coming to the table. We're going to see more opportunities for Government and industry to work together.

And so, I'm excited in building a team and a framework here at USDA that allows innovation to flow, and doesn't stifle innovation. And encourages entrepreneurs, public and private universities, as well as very large multi-national companies to be part of bringing that innovation to farmers and ranchers.

And so, the other side of things that I think is emerging is, we've had biotechnology very prominent in the plant industry and the plant world for a number of years.

We're now seeing more and more innovation come to the table, and come to the regulatory platform on the animal side of things. And some of the animal groups have called on USDA to be more involved in that regulatory process.

And we're actively involved with conversations to see what our role might be, what FDA's role might be as we move forward, to be able to make sure that animal biotechnology can also make it to farms and ranches in a timely and useful manner as well.

Doug mentioned the SECURE Rule that -- That's okay. I hear, I get feedback right away on what I'm saying. But Doug mentioned that, and that we're working on it.

This is the first time in I think three decades that we're, I think we're going to cross the finish line on updating plant

biotechnology regulations.

That's going to give us the opportunity not only to streamline our regulatory process, based on science and risk. But it's also going to give us the opportunity to do more than streamline, to deregulate some things.

Biotechnology innovation that could be accomplished through a traditional breeding system, only cutting the timeline down through some of the new technologies like CRISPR and TALEN will give us the ability to maybe say, we don't need to look at those if that's something that could occur in nature.

It's also going to give us the opportunity to say if we've already made the risk base analysis, and decided that it's safe and effective, we're not going to continue to require companies to submit there. And we're excited about being able to move forward there.

The initial, on the proposed rule the comment period closed on August 6th. We had about 6,100 comments, which I really, we expected

a lot more, didn't we, Bernadette? We thought we would have maybe hundreds of thousands. But, so 6,100 was a little bit of a surprise.

But I also think that maybe was a result of the process that went through, in that we conducted a very open process. We invited lots of groups and organizations, both supporters of biotechnology, as well as people that were a little bit more skeptical about biotechnology and deregulation, to the table ahead through the process as we were formulating our ideas about how we would write the proposed rule.

And so, I think a lot of the discussion was had in a transparent way ahead of writing that rule. And so, hopefully that influenced some of the comments and feedback that we got back.

I've referred to Bernadette Juarez a couple of times. And I have to tell you how excited we are to have Bernadette here as Deputy Administrator to lead BRS.

I think Bernadette brings some great

experiences with her past assignments here at USDA. And we're just excited to have her and her energy, and that background here. And like I said, she's going to share a little bit more her vision for the future with you here in just a little while.

A couple of things, also we have some other great presenters for you to listen to. We have Dr. Fan-Li Chou is here. And she's going to talk about the Executive Order that came out earlier this spring, that we've worked on over the summer to try to work together with EPA, FDA and USDA to streamline the biotechnology regulatory process overall.

We also have a unique coordinated base that we're going to be releasing, where it's, you can enter into that, and just access all three agencies' regulatory process through one platform. And so, we're excited about that as well. And so, she'll share that a little bit more with you.

I think the other thing that, as you

talk about biotechnology, there's always the issue about trade, and how biotechnology interacts with trade.

Because we know that we live in an environment here in the U.S. that is probably more biotechnology friendly and progressive, where other countries are more skeptical. And we've seen times when biotechnology has actually held up trade, or become a barrier to trade.

So, as we've been working on the SECURE Rule in a new direction, as we've seen CRISPR and TALEN emerge as promising new technologies and gateways for the future, I personally have spent some time working with the Cartagena protocol countries, meeting with them.

I attended a conference in Columbia, soon after the Secretary announced his vision for how we were planning to handle gene editing as a regulatory process.

I've also spent time in Japan to communicate with the Asian countries. We know Japan will be an important cog in that Asian

regulatory wheel, that a lot of countries follow Japan's lead, explaining to them what we, what our vision is here in the U.S., and where we think we're headed to be able to have a more uniform approach internationally.

So, we know that if we get the western hemisphere, where food is produced, unified, if we get Asia, where the bulk of our customers are, unified, I think we have a smoother road ahead on the trade issues that sometimes are hurdles for biotechnology to move forward.

With that I just want to thank all of you for taking time, staff as well as industry, to be here today.

I think one of the biggest things of these stakeholder meetings, and the biggest opportunities that they provide is that opportunity for dialogue, and to listen to each other, and hear each other in a more relaxed fashion, than reading something in the newspaper, or interacting over email. This way you can actually have time to sit down and talk.

Secretary Purdue, one of his first stated goals when he came to USDA was for USDA to be the most efficient, effective, and customer friendly department in the Federal Government.

And I think that these stakeholder meetings provide one of the greatest avenues for us to really deliver on his expectation, is to open the doors, have stakeholders come in, tell us what you're thinking, tell us where we're performing well, and where we're not performing well.

And let's talk about how we can work together, so that we meet those expectations you have for efficiency and effectiveness, and good customer service.

With that I would just wish you well. I guess I'm supposed to take a few questions. And Caleb is here to decide when they get too hard, and I'm out of my zone of ability to answer. And tell me it's, that my time's up. But with that, I would, if it's still appropriate, Doug, I would take a few questions.

MR. McKALIP: If you could use the microphone there on the stand? And also, please identify yourself and any affiliations, so we can make sure that we capture that appropriately as well. Thanks.

MR. HANSON: I'm Jaydee Hanson with the Center for Food Safety, the nonprofit one. One of the things, one of the kinds of biotechnology that you didn't discuss is vaccines.

I've shared with some of your staff. But I think that the USDA is one of the bigger vaccine deniers in the country, because we have vaccines that can work with salmonella. We have vaccines that work with other animal diseases that aren't being required.

They're not all genetically engineered. It would be good if APHIS, on your website made clear how the different vaccines were made. That's kind of a jumble the way it is listed now.

But our friends at the Center for

Science and Public Interest had petitioned the USDA to declare some of the worst kinds of salmonella to be adulterants. And your Secretary Vilsack in the past didn't move on it.

It would be wonderful if you could talk about how you would move on that. I saw today that for swine flu, making progress on vaccines. It doesn't kill people. It does kill pigs fast.

So, what are you doing on the pathogens that kill people? And how are we going to use biotechnology to develop better vaccines for those?

UNDER SECRETARY IBACH: Yes. So, I think that's a great question. Also, some great feedback, and some good challenges for us to take a look at as well.

So, I think that not only what biotechnology does, but what other vaccine development procedures that are more traditional, provides an opportunity for, is for us to try to produce safer food that consumers are desiring.

And that we need to continue to try to serve those needs out there.

That is, on the animal health side of things, we are actually are, have asked for more money. And there's some bills going through the Congress right now that would enhance our budget to be able to review vaccines for animal health, and be able to work them through the system, and make them available in a more timely basis.

That's a area that we've operated with the same amount of staff and budget for over a decade, with no enhancements. And we've seen the growth in the expectations. And the products that we're being asked to review grow by the fold.

So, we are working together to try to provide Congress technical assistance to make sure we have the resources looking into the future, to be able to meet your expectations, as well as farmers' expectations, and ranchers' expectations.

Any other questions? Well, if not,

we'll have plenty of staff around here that you can interact with to, I'm sure you have some questions for individuals around the room, and stuff.

Bernadette will be happy to answer even harder questions than that one. And so, thank you very much.

MR. McKALIP: Thank you again, Mr. Ibach, for spending your valuable time with the team here this afternoon. We really appreciate you joining us. It's really enhanced our meeting.

Our next speaker, Bernadette Juarez, was appointed Deputy Administrator of BRS this August, in August of 2019. Prior to this appointment she served as Deputy Administrator for Animal Care since 2016, where she led the program's many employees in protecting and ensuring the welfare of millions of animals nationwide that are covered under the Animal Welfare Act and Horse Protection Act.

She also worked on preparation for

natural disasters and emergencies, and worked with animal owners on those issues as well.

Ms. Juarez joined APHIS in 2009, and first as an Investigative and Enforcement Services Deputy Director, for five years. And then as the Director of Animal Care, starting in 2013.

Before coming to APHIS Bernadette was a trial attorney in USDA's Office of General Counsel, from 2002 to 2009.

In 1999 she complete her bachelor's degree from the University of New Mexico, and went on to earn a juris doctor from American University, Washington College of Law, in 2002.

I know all of the BRS staff are excited to have her onboard. And we're looking forward to her remarks, as I'm sure all the stakeholders are, in her very first BRS stakeholders meeting. So, please welcome Bernadette to the podium.

MS. JUAREZ: Perfect. Good afternoon, everyone. Wow, it's a really cool audience.

This is really great. So, thank you. Thanks for spending the afternoon with me.

I just wanted to first off let you know how excited I am to lead the incredible team here at BRS. I have a team that has outstanding scientific communication and inspection skills, among many others. And I'm lucky to be part of that.

I inherited this team from Dr. Firko, who many of you know dedicated his career to protecting plant health, and developing others, really.

So now I want to tell you what my vision is for BRS as we move forward together. I want BRS and USDA's biotechnology program to be the very best program in all of Federal Government.

I want to lead a team that stay ahead of the pace of innovation, and ahead of the needs of American agriculture. I want a team that is trusted, both domestically and internationally, to make sound transparent decisions that enable

policy alignment, and the productive use of biotechnology around the world.

Achieving this vision really requires a very delicate balance between two critical functions, program efficiency and quality review. And in my view there is an inherent tension between the two of those.

You want a thorough and careful review. But given the pace and speed of technology it must be efficient. This tension I think is necessary to ensure that we minimize the risks to plant health, while also maximizing the use of innovation.

My role as the leader of BRS is to be aware, and maintain balance of this tension. And as I do that you'll see me do this in a couple of ways.

The first thing that you'll see me do is encourage engagement and communication across the board, both with our regulated community within our own organization, with our federal partners, internationally, and of course with

stakeholders who have an interest in plant health.

A nice example of the type of interaction that I'm looking for, recently has been occurring in connection with our development of an online permitting system.

We've engaged developers to assist us with the development and testing of the system. And we've been able to make refinements that make the system better for both of us.

And that's the exact type of partnership that the Under Secretary was just referencing when he said he wishes for us to not just interact as regulator and developer, but come together to find solutions that actually make us both more productive in the work that we do each day.

You'll also see me expanding my team to make sure that they're able, and more able to have the bandwidth to meet the balance that's necessary between program efficiency and quality review.

Just recently BRS announced the vacancy and hiring of 12 new positions to enable the work that we do. These positions will enable us to build the capacity that's necessary to handle our current and future workload in an efficient way.

In practice this means that we must be thorough and careful in our decisions, and efficient. And make them in a way that you can come to understand in terms of expectation and consistency.

In balancing between program efficiency and quality review we have to work together, and keep in contact and communication, and interact with each other to make sure that we're on the same page moving forward.

Often times you have concepts and ideas that we may not turn to immediately, or be aware of. And when we interact together we can implement solutions that are helpful for everybody.

I really appreciate the opportunity to

lead this program, to step into a new space here at USDA, a space that I think is a leading area in agriculture.

I can't imagine agriculture without biotechnology. And I quite frankly think that it's one of the most special programs here at USDA. So, thank you for the opportunity to lead it.

I also appreciate the opportunity to share my thoughts and my vision with you, so that you know what to come to expect from me, and from my team moving forward.

So, with that, knowing what's in the future, I'll give a quick overview of what's just happened in the past.

Okay. So, in Fiscal Year '19 we had a few primary accomplishments. You heard the Under Secretary say that we focused on issuing a proposed rule involving the SECURE Rule, reviewing 6,100 comments.

The rule remains under review within the department. And the next public facing

document that you'll see in connection with this rule is the posting of an update on the regsinfo.gov website, that indicates that it's been accepted for review by the Office of Management and Budget. So, stay tuned, and refresh that page until you -- see that update.

We also, and I have to say that I really enjoy working with rules. It's been really great to step in and assist BRS to get this to the finish line. We've made several efforts to do that. And I hope to be the one to get it across the line.

With respect to ePermits, I mentioned to you the iterative process that we've engaged with, with developers to start building our new online permitting system.

The system is really important. Because in 2021 APHIS is going to be sunsetting the existing ePermit system that you're familiar with using.

So, BRS is really ahead of the game in developing its online system, and integrating it

with user testing in advance of having an all in approach with that system.

And I'm really appreciate to the work that our team at BRS has done, the developers, and of course our contractor, Accenture.

We've also focused on making sure that as a team in BRS we're working well together. And Dr. Firko was excellent in building a community of great collaboration in BRS. I'm lucky to be part of that now. And also ensuring that we provide excellent customer service.

And when I think of customer service I think of not only the service that we provide to the regulated community, but the service that we're able to provide internationally in developing shared understanding of the uses of biotechnology.

So, in 2019 we had 1,486 authorizations for regulated activity. We authorized these activities at 3,283 sites. And if you look at the phenotypic designations, there are almost 25,000 types that were authorized for

testing in 2019.

And I didn't have a chance to look at what other countries are authorizing in terms of field testing and phenotypic designations. But I'm pretty sure that USDA is ahead of most others.

We also completed three petitions for deregulation. We have one for Texas A&M involving low gossypol cotton, BASF, altered oil profile and herbicide resistant canola, and Verdeca has one too, involving soybean.

We have presently nine petitions pending our review, and two requests for extension that we look forward to completing.

The Am-I-Regulated process is a process by which people can voluntarily ask whether they are regulated or not under Part 340. You can see the statistics, that in 2017 we responded to 14 of those, '18, 14, and in Fiscal Year 2019 so far we've done 12, or we did 12.

We had a slight decrease in the number that we completed because we had to divert some

resources to other projects, like completing the SECURE Rule.

And also, if you look at the last statistic, we received 14 requests under the Am-I-Regulated process since the mid-year. So, there's a tiny bit of a rush to get those in the door, perhaps in anticipation of switching to a new regulatory framework.

We conducted over 600 inspections in person, with partners from PPQ and our state partners as well. A bulk of those inspections, roughly 75 percent of them were actually conducted by BRS staff.

We're really glad over the past several years to be taking on an increasing number of those inspections ourself, though we do appreciate the additional bandwidth that PPQ and our state partners provide.

We did also 53 inspections involving virtual activities, where we're talking on the phone to the developers, and exchanging photographs that we can assess conditions.

We have Doug Grant here from our inspection staff, who will give you a rundown, an incredible rundown of information on inspections later. So, I won't spend much time here.

The Under Secretary also mentioned that we're working to develop a website with our federal partners, EPA and FDA. And USDA has the good fortune of being the one to house that U.S. biotechnology regulations.gov website, or .usda.gov website.

We're very excited to see that launch, which may actually occur later this week, or early next week.

This portal is designed to provide folks with a one stop shop to reach all of the information you may need to determine which regulatory pathway, or pathways are necessary in order for you to commercialize a product.

In addition, it will have a question box that will allow for the submission of questions that will be triaged by the three

federal agencies, to ensure that you get the response that you need.

We also did the soft launch of the online permitting system. I've talked about this a couple of times, how we've had developers engaged in this process, and made refinements to it.

Today you're going to hear an update on this project. And we're encouraging additional folks to begin to move over to this new online permitting system.

If you've ever received a permit in the past, or you're a permit applicant this is a really great time to think about doing this, because eventually everyone's going to be there.

And then we have the SECURE Rule. We've talked a lot about it. Unfortunately I can't give you all the very good secrets that I suspect is driving the large crown here today.

But I can say that everyone is very supportive of seeing this move forward. It's been long in the tooth, in terms of having an

opportunity to update our regulatory framework.

We certainly look forward to launching it. And we hope to see others align with USDA's philosophy on overseeing biotechnology.

So, looking forward into 2020, our number one goal will be seeing the SECURE Rule through. Once you see it posted on the regulations, reginfo.gov website, OMB has by statute 90 days to review the rule. And they may request an extension of an additional 30 days.

So, it could be at OMB for a while. We certainly hope that's not the case. But I just wanted to provide you with some expectations of timeframe, once you see that rule posted for OMB review.

We'll also continue to make sure that we have adequate staffing in the right places in BRS. I mentioned to you that we have incredible skills, and scientific and technical expertise in BRS.

And I am so excited about expanding and building that further, so that we can have

the very best biotechnology team in all of Federal Government.

And of course, I want to maintain the close working relationship that I have with you all, and that Dr. Firko has worked to first establish. And I look forward to expanding.

And I'm glad to be here with you today. I'll be around after the meeting. If you have a chance, please come up and introduce yourself, so I can get to know you. And when I see your email or your telephone message, I'll know who's writing or messaging me. That's it. Now, I get the questions.

MR. McKALIP: So, if folks have question, either put your hand up, and Colleen Wood can bring a roving microphone, or if you want to go up to the mic stand, that would be great.

Bernadette, we did have a question submitted from the webinar from a researcher who does agricultural research here in the U.S., but works a lot with India.

And they would like to know, as the rules change, as we update our rule, what is your vision for ensuring a common understanding on the international community working with nations like India, so that we understand each other's requirements going forward?

MS. JUAREZ: Thank you for that question. That's an area of particular focus and emphasis for me. I worry about the differences in requirements around the world, and look forward to seeing greater alignment sometime in the near future.

Until then we'll be spending plenty of time with our trading partners, talking about the content of the SECURE Rule, and the scientific basis for the changes that we've made to the way that we're evaluating biotechnology.

We also look forward to hosting visitors who come to the United States. I'm looking at Dave Heron, in the back right here. I had the great fortune of sitting in with Dave on a briefing with two Borlaug Fellows from Rwanda,

who were looking to develop the biotech framework in that country.

We'd love to be part of that. We'd love to help countries who are contemplating potential changes to their regulatory framework, or establishing their framework.

I understand that India at one time had a very active biotech program. There was some stepping back for a while. And now India's re-engaging. So, we look forward to working closely with them. Yes.

MR. DOBERT: Hi. Ray Dobert with Bayer Crop Science. So, Bernadette, you mentioned that you have, you're looking to hire about a dozen new staff persons. But you didn't specifically mention what specific areas do you think there's a need for additional staffing?

And what, so I don't know if there's specific plans with those additional folks. But what are the kind of areas that you're staffing up in?

MS. JUAREZ: The 12 positions that I

mentioned are all biological scientists that will help with the evaluations for permits and petitions, or other requests under the rule.

MR. McKALIP: Bernadette, we had another question submitted on the webinar. This one comes from Steve Davies with Agra-Pulse. And he asked, to the extent you are able to share what you believe the timing would be of issuance of the final SECURE Rule? That might be a question for Mr. Ibach, and/or Bernadette.

MS. JUAREZ: We are making wonderful progress on the rule. And I don't wish to jinx it by making any estimate as to its anticipated publication. Although, I will say that I'd be sorely disappointed if I didn't see it happen relatively soon. Any other questions? Yes.

MS. DeMARCHI: Hi. Jane DeMarchi from ASTA. In terms of outreach after the SECURE Rule is finalized, there are going to be maybe some other crops that are less used to coming to BRS that -- Do you guys have plans to do some outreach with additional crop sectors, and other

crop developers?

MS. JUAREZ: Thanks for that question. We're still working out our implementation plan for the SECURE Rule. And I see that outreach will certainly be a strong component of that. We did a lot of that in developing the initial proposed rule.

So, we'll make sure to touch base with folks who may be new to the regulatory framework, or who may be coming through BRS's system for the first time, and make sure that they have the information they need to work with us. Did I screw up? No? Is that it?

MR. McKALIP: Other questions from folks in the room?

MS. JUAREZ: Okay. Well, thank you. Then, I'm finished.

MR. McKALIP: Thanks, Bernadette. We're excited to have Fan-Li Chou join us this morning. I've been lucky enough to know Fan-Li for a number of years, and worked with her, as many of us in the room have in various

capacities.

In her current position, which is Biotechnology Coordinator for USDA, she really is an ombudsman across the department in research in the regulatory side and the communications side, and the international trade piece as well. And we're really lucky to have her in that role.

Dr. Chou has over ten years of experience at USDA, including positions with FAS, and as well with APHIS as well, here in this building.

She has represented USDA in various bilateral and multilateral negotiations, including the Cartagena Protocol on Biosafety. She is a alumni of the AAAS Program, which I know we've got a lot of those in the room here this afternoon as well. So, please join me in welcoming Fan-Li to the podium.

DR. CHOU: Hi, everyone. It's so great to be back in this building. This building has a very special place in my heart, because this is where my career with USDA began as a AAAS

Fellow, knowing absolutely nothing about USDA.

So, it's been such a great pleasure to serve USDA here. And I want to thank the BRS team for inviting me to just give you guys a broad overview from a USDA perspective, and also from a USG perspective what our priorities are moving forward.

And as I was thinking about how to talk about the Executive Order in a more exciting way, rather than just reading about what we have been asked to do, without any additional funding, mind you, I thought about this a lot.

And I think a lot of what we are working towards, I think what Bernadette's team is working on, and what our FDA colleagues, and everyone around here is working towards access and choice.

And from this perspective, I mean, we are here to provide access and choice to U.S. farmers, to U.S. producers. And we want our farmers to have the best available tools to do what they need to do. And to have them have the

ability to make that choice, of using what, the tools that they need for the situations they have at hand.

And we want this access and choice not just to be available to U.S. farmers and producers, but globally to other farmers and producers.

But this access and choice is just not limited to farmers and to producers. It also needs to be centered towards the research community.

And I think this is really important for USDA. Because besides regulatory policy, and trade policy, we have a tremendous amount of research capacity.

So, we want our scientists to be able to use these tools to develop new innovations that our farmers can access. And we want this access and choice available not just to our scientific community, both public and private, but globally as well.

So lastly, I want to talk about access

from the consumer perspective, right. Not just consumer at the supermarket, but consumer along the value chain, your corn refineries, your seed providers, your supermarket manufacturers.

Those producers, they need to have choice and access as well. How do we provide the variety of food that we are so used to in this country? How do we expand that choice, maintain that choice and access in the U.S., and expand that access and choice globally?

So, with that kind of access and choice as our two top kind of major goals in mind, this is kind of how I think about the work that we all do around here.

So, as many of you know, and Under Secretary Ibach mentioned, in the summer of this year a Executive Order came out of the White House. And this was a lot of work, leading up to this Executive Order being published.

And this Executive Order is actually a continuation of a lot of the work that has been done throughout the years. So, in 2017 we

updated our coordinated framework. That has not been updated for many years. We also put out a national strategy on biotechnical regulatory framework.

And this Executive Order kind of carries on that progress of, what do we need to do from a Government perspective, not just USDA, but as a U.S. Government, to create that enabling environment where our farmers, our producers, our customers, our scientists, have that access and choice, right?

So, you can read the Executive Order. But the way I read it there's two major components. One component is regulatory reform.

As Bernadette says, we've been doing this for 30 years. USDA, FDA, EPA, we've had a great and efficient process in putting out, or ensuring that we're delivering safe technological tools to our farmers.

So, what have we learned in those 30 years? And how do we become more efficient in providing that benefit? So, the regulatory

reform part of the Executive Order is doing just that. It's asking USDA, EPA, and FDA to look at our guidances and our regulations, and see how can we improve? How can we do better? How can we be more efficient? How can we be more risk proportionate in our approach? That's one aspect.

It actually specifically calls out genome edited plant products. And I think this was, it's really important. Because as you look at the research community, and the amount of information, and amount of publication that's coming out from there, you can see the great potential that this tool can have across our agricultural sector.

And not just for row crops, but across a great variety of applications. And I think that's where the excitement was. That's why the Executive Order highlighted that specific sector, right.

So, this is kind of the regulatory reform. And the SECURE Rule is USDA's way of

meeting that mandate under the Executive Order. It's very much aligned with that.

And we're a bit ahead of our sister agencies, FDA and EPA. And they are also working under this Executive Order to look at their regulations and their guidance documents, to see where they can make efficiency changes as, based on science, and based on experience.

So, we're looking forward to see our sister agencies kind of catch up with our progress.

The other component of the Executive Order that I want to talk about is this other, the non-regulatory piece. This is more about, you know, as regulators, as scientists we're very confined in our work. We look at the assessment. We look at the risk. And we put out a product.

And whether people want that product has so many different components, right. It's not just about USDA, FDA saying it's safe. It's about a lot of other things that I am not an expert in, and slowly becoming more appreciative

of.

And so, the Executive Order is asking us, and I think this is, our Secretary's also asking us, is actually to be more, he would call out there, to be more extroverted about communicating our story about agriculture.

So, in that way, one, we want to improve our communication with the regulated community. And this is one way the USDA MRP, I think Bernadette's team is leading developing this single platform where anyone, mostly this is aimed at the regulated community, can have one point of access for all the regulatory information, and to have one point of access to ask a question.

And like many, many other, almost all other countries, we have three separate agencies, three separate doors that you may have to, or now always walk through.

This can be quite daunting for folks that do not have 200 regulatory folks like the major companies to walk through. So, for us this

is a mechanism for us to streamline that process.

That you can have one point of entry to ask us questions. And we all can scramble behind the scene and provide you with a consistent and coordinated answer. So, that's one way.

But the regulated community is just one aspect. The Executive Order has tasked USDA to lead in developing a domestic engagement strategy.

And this is building on what FDA is already doing with their Congressional issued mandate. And this actually came with money. Our mandate came with no money.

So, FDA has this initiative that FDA funded, that, sorry, that Congress has funded, to get out there and educate and outreach with the community about how ag biotech is being used in the food sector and the agricultural sector.

And USDA is part of that committee. So, what the Executive Order has asked us to do is go beyond that. Go beyond just talking about

how we have ensured food safety.

USDA is involved in ag biotech across the board. How do we get it there and talk about it? How do we ensure that our community, broader community, the folks that pay taxes that fund USDA research understand how we're using ag biotechnology to solve agricultural problems, to solve food nutrition problems, to solve animal disease problems?

We've got to be more outgoing, to be more extroverted in talking about that. So, I have Paul here, who's been working with me from the Office of Chief Scientist, putting together a program.

But how do we use the resources we have? How do we use our arboretum? How do we use our connection with the land grant universities to be more, to build our story, to talk to, communicate about how agriculture biotechnology has been used by USDA across the board?

So, domestically it's important,

right. We need the tools available to our farmers. We need access and choice for our consumers.

But internationally it's hugely important, as some of the question folks have asked. It's about trade. It's about the international environment.

So, how do we go about creating an international environment? The Executive Order is asking State Department and USDA to develop a outreach and communications strategy internationally.

And this has multiple components. One is to advocate, and I want to say advocate for more consistent regulatory policy around not just what I will call traditional biotech products, but looking forward to the innovations that's coming along. How do we have compatibility globally, right?

This is good for trade. But it's also good for research. As a research scientist, moving product from country to country for your

research collaboration, you need to have a understanding of what the other country's requirements are.

So, compatibility in that sense will smooth research interactions as well. So, that is very important. And I think it's really important for us here in the U.S., and others who have years of experience in safely deploying the technology to really explain the safe history of use that we've had.

And how do other countries like Rwanda, that is standing up their regulatory systems learn from that? Do they really have to have, do things from the beginning? Can they leapfrog us, really?

You know, they don't have to start with a landline to get to the Smartphone. They just go straight to the Smartphone. So, they can just go straight to certain things that we have already learned, right.

So, that's one component of the international communication strategy. The other

part is, how do we use our international partners, our international organizations, to refocus this conversation about innovation in agriculture, and I want to say innovation writ large, back to science based risk proportionate decision making?

Some of these international organizations, especially standard setting organizations, is founded on scientifically based, risk based decision making. So, how do we re-bring that back into those communities?

And finally, the Executive Order is tasking USTR, working with a lot of diverse agencies here, to develop a trade strategy.

And this is for us to use all the tools available to us that include our bilateral relationships, our multilateral relationships, our compliance and enforcement trade tools, to ensure that our products are traded fairly and equally in global marketplaces.

How do we protect our market share? Because this, at the end of the day it's very

important to our farmers' access and choice.

So, all of these Executive Order mandates, if you read them, all acme with an actionable date. This is kind of special for all the other Executive Orders I've worked on, where they ask you to do a thing, but they don't give you a really good deadline.

This one had very, very tight, and very, very specific deadlines. So, the Executive Order was published in June. All the deadlines are going to end up right before Christmas.

So, for a lot of us, you know, we're working hard getting through this. And it will be a nice Christmas Present to the White House when it's all done.

So, I just let you guys know that this is all going to happen soon. So, keep your eyes open. Stay tuned. There will be, I would expect some announcements, if not from the White House, then definitely from USDA about many of the initiatives that USDA have been tasked with.

One with being the website. The other

being our domestic engagement plans, and also out international engagement plans. And so, I'll take any questions.

MR. McKALIP: And if folks have questions, please approach the microphone, or motion, and Colleen Wood can bring you one.

Fan-Li, we did have a question come in over the webinar from William Pilacinski. And this deals with Codex Alimentarius, which as many of you know has important bearing on food safety requirements.

But he asked if in the context of what you had to say, if you see any opportunities in the near future to make any changes to Codex guidelines?

DR. CHOU: So, the Codex, so, for those of you that may not be aware, the Codex has a compendium of guidelines and general principles for food safety that's associated with either plant, food derived from recombinant DNA plants, this is their terminology, or food derived from recombinant DNA microorganisms, or food derived

from recombinant DNA animals.

And these were hard negotiated consensus documents. And they're good guidance documents for, yes, for folks that need to do this.

I think it would be very difficult to renegotiate these things. I think that based on experience that countries had using those guidances as a guidepost of how to do this, there are definitely ways to be more efficient, based on our understanding.

For example, I think we have looked at hundreds and hundreds, not just we from U.S. Government, but around the world. Many, many glyphosate resistant soybean food safety assessments, you know. Do you we really need to do another one?

I think that's a good question for the food safety experts out there. Do we need to look at, you know, another Bt corn? We've looked at hundreds and hundreds of them.

And everybody has come to the same

conclusion. It's just inefficient use of your regulatory resources. But those can be handled without reopening the Codex guidelines. Sir.

MR. EYRICH: Yes. Tim Eyrich, Southern Gardens Citrus. Can you unpack a little bit more on this domestic engagement --

DR. CHOU: Sure.

MR. EYRICH: -- initiative? Your words are outreach on how biotech is used. That's a confusing message to the consumer anyways.

DR. CHOU: Right.

MR. EYRICH: If you're involved in it, to try to figure out what your strategy is going to be, it's highly confusing. So, how are you, are you going to work with industry across this? Are you going to have industry participating on a unified message on how biotech's used? Again, can you, from a small company, we just don't have the resources --

DR. CHOU: Right.

MR. EYRICH: -- to market like others.

So, can you unpack a little bit more about that?

DR. CHOU: Sure. I think for us too is, there's lots of already private sector communication on this. There's lots of, you know, Governmental organization involved in this space.

And for us it's thinking about what value does the U.S. Government, or USDA have in this space? You know, we can all get out there and say the same thing. Does that add any value?

And I think where USDA add value is not to talk about biotechnology in isolation. I don't think that works really well, coming from someone who is not from a agricultural background.

Like, you can't start the conversation with like, this is biotechnology, and this is how it's used. It's about how it's using context updates. And USDA uses them in many different ways.

I think it's very important for us to get out there and say how are scientists using

this. How are we, is citrus important to you in Florida, right?

We don't, is plum pox resistant trees important to you in California? Is papaya important to you in Hawaii? Is potato important you to in Idaho? And how does technology help solve some of the problems that are important to you?

As a mother, as a suburban person, I want to have strawberries in the middle of November that taste like strawberries. How does technology help me with that?

If you're curious about how we're going to get to Mars, how does biotechnology get us there? How is USDA working with NASA on those problems?

So, things that people don't traditionally associate with biotech, how do you bring those stories to the forefront, so people actually have a context, and you're not just talking in isolation about a technology?

And in that way I think USDA is in a

very special place. Because we have special partnerships. But also, I think it's really, as part of our domestic strategy we really want to use the state ag resources, the universities.

So, how do you have that conversation in your community? Because your conversation in your community is going to be very different from the conversation in my community.

My community at Bethesda, Maryland is interested in buying, you know, good nutritious food for my children that I feel safe about. And we don't know anything, really about farms.

If you're in Idaho do you have different conversations? And how, and what's important to you? What are the questions?

So, from USDA we're thinking about how to build tools, working with our state partners, working with our university partners, working with our private sector commodity partners, to figure out how to have conversations around, what is important in that community?

How do we build tools so people can

take that toolbox to have that communication in their community about how ag biotech, or innovation in general is useful in the agricultural space? All right. That was relatively easy. Oh no, Ray.

MR. DOBERT: Ray Dobert, Bayer Crop Science, so no one has mentioned something that's going to be pretty impactful in about two years from now. It'll be the implementation of the Bioengineered Food Disclosure Act.

DR. CHOU: Yes.

MR. DOBERT: And in terms of communicating, because obviously that would be one way that the public will get information with regard to what foods do and do not contain bioengineered ingredients.

Is anything that you're considering, with regard to this outreach and this engagement exercise, at all mindful of the fact that there is this overarching disclosure provisions that will be implemented on less than two years, or about two years?

DR. CHOU: Right. So this is all under Under Secretary Ibach. And he should have left --

(Laughter.)

DR. CHOU: -- so we can ask him. I think, as Bernadette has mentioned, we're going to have this unified web platform for the regulators. Or how do you approach the regulation information at a one-stop-shop?

USDA would have all this different pieces about biotech. And how do people find out that information? So we do actually have a usda.gov/biotech planning page at the Secretary, at the Departmental level. And we are revamping that. Because that is ancient.

And we're trying to figure out how to streamline consumer access to information that USDA has about biotechnology's use writ large. And that would be our disclosure standard, even our organic program, all of these touches there.

So want to have a place where we can streamline access to this information and have a

place that people can have a wholesome or fulsome, a holistic conversation about this, right. Sir?

UNDER SECRETARY IBACH: So AMS was the agency that actually worked on the bioengineered food disclosure regulations. And they were really kind of the model that we used when we set out to start working on the proposed SECURE Rule. Because we spent a lot of time doing the same thing as we wrote those regulations. We opened the doors, we had lots of people come in, we had lots of conversations. Arthur Neil led that charge for us on the AMS side and did an excellent job.

And there's another example of where we anticipated that whatever we came out with would be controversial. And at the end of the day, because of the transparent process we went through, we really had a surprising embrace of that final rule when it came out.

You're going to start seeing it. It ramps up, it phases in over this year and into

next year. And so you're going to start seeing some of those logos or the sign show up on food products.

And we're prepared to try to address, if necessary, questions that consumers have. But it also provides an opportunity for food companies to really, you know, kind of self-provide that educational process as well.

And, you know, I'm somewhat anticipating that that issue, the consumers had their opportunity, they were interested in it. They know there's a solution out there that provides the transparency forum.

I don't think we're going to see a lot of new renewed interest. The consumer groups that were interested in that accomplished their goal, have that transparency out there, and I think that we've kind of gotten over that interest level.

MR. McKALIP: Under Secretary Ibach, while we have you up there, we had a question come in on the webinar for you. And they're

looking for advice on balancing messages. Because you talk to a lot of farmers, you talk to a lot of consumers from all backgrounds.

They're interested in any thoughts on how you can balance messages, or dealing with producers, and productivity with technological innovations, with what's happening on the regulatory front in trade, and how you kind of balance those messages for various audiences when you're meeting with them.

UNDER SECRETARY IBACH: I think the key is to approach the audience trying to understand what their questions are, or their understanding gap is, and to try to have that conversation in that context.

I think no matter who you're talking to, there's the challenge of making what's unfamiliar to them familiar. And whether it's out in a foreign country trying to talk about American agriculture, and why you should be comfortable buying food from our family farm and ranchers, 90 percent of our farmers and ranchers

are family farms and ranches.

And communicating that understanding that we are not America factory farms or industrial agriculture, to talking to a consumer about why they should be comfortable with the regulatory processes we have in place to assure that the food that meets their table is going to be safe, and wholesome, and most importantly affordable as well, and so I think that's the challenge that we face, is trying to shape those messages that the family is talking about to be able to make what's unfamiliar to that audience familiar and make them comfortable with it. Okay, thank you very much.

(Applause.)

MR. McKALIP: Thank you again, Under Secretary Ibach, for spending your time with us here this afternoon. And thank you, Fan-Li, for your remarks and being willing to answer questions as well.

We're going to switch gears now. We're sort of at the half-time point of the

stakeholder meeting. You've heard a lot of the global issues happening at the administration level, at the departmental level, sort of an overview on policy.

We're going to shift gears not to talk a little bit in specifics about specific BRS oversight work over the course of FY 2018 and '19 and looking ahead to 2020, as well.

I think last year at our stakeholder meeting we didn't necessarily dig into some 2018 data. So we're going to make sure that we bring you up to date on the oversight and compliance information.

So we'll have Doug Grant come up to the podium. Doug is the chief of our BRS Western Compliance Assurance Branch. He's located in Fort Collins, Colorado, normally. Although he's willing to come in here to provide the update.

Doug has a Ph.D. in plant ecology from Colorado State University. He grew up in Ohio and then moved to Colorado when he went to college. And he joined APHIS in 2005 and worked

in our crops research laboratory at ARS from 1999 to 2005. Doug Grant.

(Applause.)

DR. GRANT: Thanks, everybody, for coming today. And thank you for having me here. I appreciate the opportunity to share some data with you for our compliance and inspection program and the regulatory operations program of BRS.

I also want to say thank you to some folks that helped me with some of the data and maps for the slides. So thanks, Heather Brown, Deshui Zhang, and Meghan Dexter. I appreciate it.

So looking, for the last couple of years we've had, you know, quite a few field trials, but the numbers have been sort of coming down. so I'm going to provide, some FY '18 and FY '19 data. And we'll also look at some trends.

We had about 4,500 release sites that were authorized in FY '18, and then it dropped down to about 3,300 release sites authorized in

FY '19. And you can see the number of phenotypic designation crop-trait combinations up there as well which is a very high number. A lot of field trials that we see out there have a lot of different combinations that are planted.

So looking at the number of release authorizations going back 30 years or so, you can see that we sort of hit a peak there in the early 2000s with almost 12,000, I'm sorry, 1,200 authorizations in that year. And then we've come down gradually over time. And over the last half-dozen years or so, we've had between 350 and 550 or so authorizations.

Now, in terms of the number of field release sites, that number has a little bit of a different trend, where we actually saw a peak about five or six years ago where we had, you know, a lot more authorized sites than we currently have. So we reached a peak of about 11,000. And now we're down to about 3,300 in FY '19.

So for those of us in the Regulatory

Operations Program, you know, the Biotechnology Risk Analysis Program has to look at all of those different authorizations and all of those different release sites.

In the Regulatory Operations Program, we're really looking at what actually was planted. So we're focusing on the sites that ended up being planted, not just everything that was authorized.

And so what do we do to decide what to inspect? There's a lot of stuff out there. And we first and foremost rely on the data that we get from you, all right, the data in the application to tell us exactly what's being put out there, but then the data that comes through in the planting reports.

And so we take that information that we get from you, we put it into spreadsheets and databases. We put it into geographic information systems. And then we use that information, and also looking at compliance history or other issues, to determine which one should we sort of

prioritize for inspection.

And, you know, some of the species that Fan-Li just mentioned are some of the types of species that we see out there. It's not just corn and soybeans. It's also camelina, cotton, canola, strawberries, grapes, walnuts. There's poplars, pineapples, potatoes. So it's a really broad range in terms of the number of species that we actually authorize each year. So we have got to make some decisions about what to inspect.

So for those lower risk authorizations, you know, primarily notifications, what we're looking at is sort of a random selection of what's been planted. And we also want to try to get good geographic distribution in terms of where those inspections are occurring.

With the higher risk authorizations, we have a standard policy that we're going to inspect at least once in each state where there's release each year, at a minimum. With perennial trials like poplars, switchgrass, alfalfa, things

like that, we want to look at those every single year.

And then we also still continue to have a few pharmaceutical, plant-made pharmaceutical or industrial trials. And in those, we look at those multiple times every site, every year.

So what do we do when we decide we're going to inspect somebody, most of our inspections are scheduled inspections. We'll contact you ahead of time, tell you which site we want to look at, and then we'll make a plan when it works with your schedule to meet you out there.

We do do some of our inspections as unannounced. And those could also be thought of as same-day inspections. So we'll contact you in the morning and say we'd like to meet you out there this afternoon and take a look at your trial site.

We've also been moving towards, and Bernadette mentioned this, some virtual

inspections. And another name that we have for those are MEIs or monitoring and evaluation interviews. And that basically consists of a phone interview and some document exchange through email looking at some photos of the site. And those generally occur with trials that have already been harvested.

So a lot of those types of inspections are occurring during the, you know, winter months rather than during the growing season. And we do want to place an emphasis on species that have some sort of heightened concern, whether that be perennials or other things that might have a higher likelihood to persist in the environment.

Now, looking at the compliance rates, you know, generally we see really good compliance with the inspections that we do. And in FY '18, the rate of compliance was 92 percent. And in FY '19, the rate of compliance was 97 percent.

Now, those are based on the things that we've actually inspected. There are also other compliance issues that come up. And I'll

talk a little bit about those later on. So now looking at a map of where are these authorized sites, and where do we conduct our inspections, I wanted to provide some visuals for you so you can see kind of the distribution across the US.

And basically, this is showing anything that was valid in FY '18. The next slide shows anything that was valid in FY '19. So that might mean it was only valid for three days at the beginning of the fiscal year, or the entire fiscal year, or three days at the end of the fiscal year. That's why you see these numbers are about twice as high as the number of sites that we authorize each year.

But there are big concentrations in certain areas. In the Midwest, places like Nebraska, Kansas, Iowa, Illinois, we see a lot of corn and soybeans. In the winter nursery locations like Hawaii and Puerto Rico, they've got field trials going on year-round.

And then there are places like California where you have anything you can think

of being grown out there from, you know, strawberries, to walnuts, to corn, to wheat. We've got citrus in the southeast, you know, we've got poplars in the northwest. So things vary depending on where you are in the country.

And then this is looking at FY '19, so a similar number of valid release sites, about 7,800. But then of those, which ones were actually planted? So in FY '18, you can see the concentration is also similar to where they're authorized. So we have pretty high concentrations in the Midwest, also on the coasts, and then in the winter nursery locations in Hawaii and Puerto Rico.

And of those 1,300 unique plants at locations, some of which have multiple plantings at the location through the year, we inspected 700, we did 706 inspections. So we're inspecting a little bit more than half of the sites that are planted out there in the US. And, you know, we concentrate in those areas where there are more plantings, like Hawaii, Puerto Rico, Illinois,

Iowa, California.

In FY '19, the numbers came down a little bit, so we had about 1,100 plantings, I'm sorry, sites, unique sites across the United States. And we did 636 inspections, so slightly more than half of the sites out there we inspect.

And some of the numbers are different depending on the state. So if you have a state where you have some pharmaceutical industrial trials, there may be more inspections than there actually were plantings, because we're going out there multiple times, or places where there are perennials, or things like that.

So this is just to try to give you an overall idea of where things are generally being planted across the United States that we have to inspect.

Now, who does those inspections? They are primarily done by employees of Biotechnology Regulatory Services. But that hasn't always been the case. Going back a half-dozen years, we have been partnering with APHIS plant protection and

quarantine for a long time.

They've been conducting inspections of biotech crops since before there was a thing called BRS, which BRS just came into being in 2002. So some of the people who work on my team have actually been doing inspections going back to, you know, the late '90s.

So we used to have them do the vast majority of the inspections going back to FY '14. PPQ did about 85 percent of the inspections. We also have partnerships with a bunch of states, and their state departments of agriculture will actually conduct inspections on behalf of Biotechnology Regulatory Services. And so through that agreement, they are providing oversight in a lot of those locations.

And as we've built our own inspection workforce, those numbers have been rising and have sort of leveled off the last three fiscal years where BRS employees are doing about 70 percent of those inspections. PPQ employees are doing about 25 percent, and the states are doing

between 5 and 10 percent of the inspections each year.

So of those inspections, we already talked about the total inspection numbers, what about the unannounced? Well, we're doing about 10 percent of the inspections that are conducted by BRS employees as unannounced each year. And, you know, almost ironically, we had 43 in FY '18 and FY '19. And I double-checked the slide, because I thought maybe I messed up the data.

In terms of virtual inspections, those are the things that we're doing over the phone, the monitoring and evaluation interviews. And most of our inspections occur in season. And so the vast majority really occur in Q3 and Q4 of the fiscal year, because that's the primary growing season in the Continental US.

So more than half of our inspections are done in Q4, and a large number in Q3. But those virtual inspections tend to happen in Q1 and Q2. And we've been sort of increasing the number of virtual inspections we've been doing

the last of years since we piloted it.

All right, what about reports and notices? We have been meeting with different members of the regulating community, and we've gotten some feedback. We changed some supplemental permit conditions, and they're kind of going, what's the deal with these changes? Why are you asking for these additional types of reports and notices?

And we've always required certain reports and notices, and we've added requirements for a couple of different ones such as storage reports. But we have planting reports which tell us when the material goes in the ground. And then after the material is harvested, we have volunteer monitoring reports. After the trial has been completed, and all of the data has been collected, we have field test data reports.

And, you know, we are really interested in your feedback to hear what we can do better into modifying and tweaking those supplemental permit conditions to try to make

them better so that they work for everyone.

We had an OIG audit back in 2015, and one of the things that they told us was they basically wanted us to be able to track the fate of all the regulated material. And so it's like the, you know, slogan that they use in real estate, location, location, location. They want to know where it is from the time that it was taken out of the lab, or out of the greenhouse, and put into the field, to the time that it's devitalized and disposed of.

So that's why we're asking you for those reports. We're trying to make sure that we have a good idea of where the material ends up after everything is said and done. And it's really important to us that you please try to get those reports submitted to us in a timely manner as indicated in the supplemental permit conditions.

And we know it's a lot of work, and we appreciate that work. And we're willing to work with you if things come up. You know, we

understand that not everything happens like clockwork all the time.

So most of those can be sent electronically, some of them you can still send hard copy. You can also send them to our BRS compliance inbox via email. But, you know, right now, everything should work through ePermits. And we're working on making it so that all of that stuff will work in eFile as well.

So speaking of eFile, we've been working really hard in the Regulatory Operations Program on the I&C, the Inspection and Compliance workflow within eFile, and working with Accenture and really trying to make that happen.

We've also had several other smaller projects that are sort of going on in the background in FY '19. So I'd like to point out a couple of those that you might be interested in.

APHIS has been making a big push to work on what is called the GIS portal which is basically mapping that's done in the cloud. So all of that GIS data, instead of existing on

someone's hard drive, or on a remote drive, is existing in the cloud. And that's all of the information that we get from you when you submit an application about where your trials will be located. All that geospatial data goes into the mapping.

And then we also do mapping with all the information that we collect during inspections. And so BRS has been doing a really great job being part of this APHIS-wide effort.

And everything that is involved is secure, so I just want to reassure you. When you submit your data to us, and we put it in the portal, it's completely secure, it's all FedRAMP authorized, or approved, or whatever the right term is for that. But basically, we can't use any software or anything in USDA that's not approved at the federal level.

We also were partnering with ESRI, through the use of the GIS portal, to create a mobile app to collect data. So basically, other parts of APHIS are using this already. PPQ and

VS use the collector app when they go out and do surveys, and check traps, and things like that.

And we started beta testing that the past growing season where you could basically just take your phone or your iPad out into the field. You could collect coordinates, enter other information, and then it will be uploaded and synched directly to the porta.

And this is really cool for us to try to make our processes more efficient. And also, in the not too distant future hopefully, this will be integrated so that portal will work directly with eFile. So we're excited about that.

Another thing that we continually work on is trying to make sure that we are reminding folks about notifying us when there happens to be some sort of an incident. And incidents might be discovered through different paths. It's not necessarily just during an inspection.

It could be a self-report where you realize that confinement was lost on a field

trial. It could be through a third party report. It could be somebody reports it to the state department of agriculture, and then they come and notify APHIS.

So if you have an incident of some kind, in particular part of our regulations say that if you have an accidental or unauthorized release, if material end up being planted in a field that was not authorized or, you know, accidentally released in the environment for some other reason, you need to notify us. And you can do that sending an email to the BRS compliance inbox. And there's also a BRS compliance hotline, and that is checked every day to see if we have any reports of incidents.

And we did have one incident in FY '19 that I'd like to talk a little bit more about. As some of you are probably aware, we had an incident where some regulated herbicide-tolerant wheat ended up appearing in a field in the Pacific Northwest. And it wasn't a fallow field.

This isn't the field, this is just a

picture of wheat stubble. But it is important for us. Because one of the things that Mr. Ibach said was, you know, we want to protect and facilitate trade, and most of the wheat that is grown in the Pacific Northwest is exported to markets in Asia. And they have a very low tolerance for anything that's genetically engineered. And we've never deregulated any genetically engineered wheat.

So when we were notified about this, we took swift action to get out there to the field to collect samples, to identify the material, and to delimit the area that was affected, and also to make sure that this material was not ending up in commerce.

So in terms of just sort of the summary of the wheat incident, we received a report that some wheat had survived the glyphosate treatment in a fallow field in Washington. And that report came into us in late May. And we were out there working in the field also, you know, had folks from APHIS, PPQ out

there working in the field all the way through the month of June through early July.

And we had excellent communication, which was really the key to success in terms of figuring out the extent of the incident and making sure that things did not enter commerce. But not only did we have really good cooperation from the developer and the grower, but we also had really good communication and cooperation with the Washington State Department of Agriculture.

We got mitigation plans in place in terms of how to handle the site going forward, and got a compliance agreement in place with the grower. There was really no evidence in all the places that we looked, and we did look hard in the state of Washington, also looked hard at the seed sources in terms of that foundation seed, the certified seed, the seed that's planted by wheat farmers.

We didn't find any evidence that there's any genetically engineered wheat in those

materials that are planted in the field or that ended up entering commerce in any of the shipments or anywhere in that pathway.

So most recently, we also collaborated with Washington State University to develop some best management practices, guidance for wheat growers. And, you know, we'll continue to be paying very close attention and trying to keep our fingers crossed and hope, through those best management practices, that we don't have future incidents like that.

So with that, I'll be happy to take some questions. And thank you.

MR. McKALIP: Doug, we had a question come in on the webinar dealing specifically with the Midwest. And if you could share with the folks, according to weather, if their particular concerns on regulatory oversight in any of your experiences there from this past year, that you think the group would benefit from?

DR. GRANT: Well, we did have, you know, the severe flooding events that occurred in

the Midwest this year. We had some other weather events, you know, such as hurricanes that impacted other parts of the country.

In terms of those flooding events that occurred and impacted a lot of farmers, we look very carefully, and we do send out reminders to folks who have regulated plantings in those locations that are impacted during a severe weather event. And it was sort of lucky that we found that none of the locations where there were regulated trials had actually been impacted by those floods in Nebraska and other parts of the Midwest.

So we've got a lot of corn and soybean trials in those areas, and other types of trials as well. But I don't think we've had any, you know, major compliance issues in the Midwest in the last couple of years.

MR. McKALIP: Another question from Genna Jenkins with Ventria. She asks about PMPIs or plant made pharmaceuticals and industrials, and if you have any kind of rough estimate in

your region of what level of business, or what percentage of your business and oversight work would be PMPI-related?

DR. GRANT: I, you know, don't know. I could guess at it, but it'd be a really rough guess. It'd be a fairly small percentage. We don't really have that many PMPI types of trials going on.

But those that we do have, we make sure to look at every site and work with those developers to make sure that everything is isolated away from any commercial material. But it is a rather small percentage of the overall number of sites that we see planted.

MR. McKALIP: That's good for an eyeball guestimate. We can follow-up with maybe some data from your branch as well as the Eastern Compliance Branch.

DR. GRANT: Yes. We'd have to crunch some numbers.

MR. McKALIP: Okay. Another question comes from DTN Progressive Farmer. Emily

Unglesbee asks a question you may or may not be able to respond to, but she wanted to know if there was any determination on how the GE wheat got into the field there.

DR. GRANT: You know, we have had very little success in the area of trying to find a particular smoking gun when it's related to our various GE wheat incidents. And so we don't know exactly how it ended up there.

We do believe it's isolated to one grower's field in Washington State. But no, that's not something that we have an exact answer to. And we've looked. And we've tried, but we really don't know exactly how it ended up there.

MR. McKALIP: But as you described, your major focus of resources is then dealing with the follow-up in doing those steps appropriately.

DR. GRANT: Right, making sure we have good mitigation plans in place to make sure that doesn't persist.

MR. McKALIP: Okay. Questions from

folks in the room, either wave your hand or step up to the mic for Doug.

Okay, I don't think we have any more questions come in over the line, but Doug will be available throughout the afternoon if folks want to grab him and ask additional questions as well.

DR. GRANT: Thank you.

(Applause.)

MR. McKALIP: As you know, a major initiative for BRS this year was the successful pilot launch of eFile. And I'm going to invite Ibrahim Shaqir to come up and provide us with an overview of where we currently stand.

Ibrahim is no stranger to all the folks in the room and on the call. He serves as our Associate Deputy Administrator, focuses on many areas. One in particular is international biotechnology.

He represents APHIS, many departmental working groups, and across the federal government as well, providing international technical assistance on standards for biotech and providing

his expertise to countries around the world in biotechnology.

Prior to joining us, Ibrahim was the Director of International Research over at ARS. In 2012, he was selected as in residency with the U.S. Institute for Peace as well. He's an alumni of the University of Maryland, has a B.S. degree as well from the University of Rutgers, and is a graduate of the Harvard Kennedy School, Senior Executive Fellows Program. And we're looking forward to having Ibrahim's update on eFile. Ibrahim?

(Applause.)

MR. SHAQIR: Well, thank you very much, Doug. That's a very generous introduction. Well, eFile you've heard a lot about it. Bernadette is so passionate about it, I feel I don't have to present. But nonetheless ---

(Laughter.)

MR. SHAQIR: -- we are lucky in that regard. We have a great team. Bernadette, from her previous experience with Animal Care, she was

also thoroughly engaged in and involved in the whole process from the Animal Care side. And when she joined us, also she devoted the same passion about it.

We reported to you, you know, the great progress we're making. But behind that, we have a great team that's working to support this important system of the permitting system of APHIS.

Miranda Wanex, probably you've heard, many of you, she's been leading this for us from the BRS side. And we have a great team here in BRS that collaborates closely with the developer, Accenture, but also all the support. And anytime we need added funding, of course, the Office of Administrator. And Dr. Mike Watson is here, our Associate Administrator. We thank you for coming.

And so in brief, I just would like to provide you with a quick update about eFile. Last year, we shared with you a demo of how eFile

will look like. And we devoted, I believe, an entire afternoon specifically for that. And we promise that we will continue to engage you. And we were able to basically continue that dialogue with you, developers, throughout the process.

But back in July, on July 23rd, we were ready to go and pilot eFile. And we invited selected developers to participate, and not only participate but also provide us with valuable feedback that can help us in the process.

As a result, we have received about 76 comments and important feedback from developers. We were able address, and create, establish some kind of enhancement about almost 31 of them. And that's tremendous progress, I believe.

So you can see that we value your feedback and input. Even though we are in pilot, we are truly committed to providing you with an excellent alternative to ePermit, to our current permitting system. And with eFile, as we transition and move forward, we want to provide you with a fantastic system that we all can be

proud of, okay.

So we will continue to engage, and we will continue to work on our system, and we will open it up. And I will mention that later on you have a flyer we attached to the agenda that we'd like you to take with you.

And from that, we just provide you with added information and who basically will be a good developer, customer to take advantage of that. Anyone who already previously submitted an application for an authorization for a permit will qualify to be part of the pilot.

The next, basically the step now, we are opening up to larger developers. And we hope to give you much more substantial update summer of 2020.

I just want to give you a quick example of the certain, how the collaboration, close collaboration with developers helped us in the process.

There was an issue with the previously submitted construct where developers could not

take advantage of that with eFile, because we had an issue with XML. And because we were able to communicate that early on in the process, we were able to devote resources, human capital resources, as well as financial resources, to address this important issue.

And we created some kind of a tiger team, as we refer to it, with an important and appropriate surge to address this very issue. And we have good news that I think, I'm not going to commit tomorrow, but by early, as soon as possible, it will be ready for, basically for developers to take advantage of it.

Miranda, is there any -- do you have a specific date when?

MS. WANEX: No date just yet.

MR. SHAQIR: Not yet, okay. And so we're excited that we will be able to share with you sooner than later on how this, when will be available to you. And that, again, wouldn't have been possible without the continuous dialogue with you.

So we open it up for all of you, again, people who already have, we issued a permit for you in the past. You were able to join us and take advantage of this important and really exciting system that we have in place.

And you cannot, if you want a multi-year permit, you will have, I think it will be important for you to come to eFile, okay. And we shared with you the organizational access feature that we, it's only unique to eFile.

We demo'd that last year, where a company, a developer can provide one administrator key to provide access to multi-users in the company to access that and provide either part of the permitting process or the compliance aspect. And so again, that's basically the feature that we are excited about. And I'm sure you will be happy to be part of that.

The exciting other XML compliance is for reporting, and we hope this will be ready as soon as possible for the compliance aspect. And

I believe the planting reporting will be first, and then the other reporting will be available to you as well.

So we invite you to please communicate with us. And now we're moving forward. Even though we're in a pilot stage, we will continue to modify and enhance so we have a great system that we all can be proud of. With that, thank you very much. And I look forward to if you have any questions.

Excellent, you're all happy with eFile.

(Laughter.)

(Applause.)

MR. McKALIP: Thank you very much, Ibrahim. This brings us to the final item on our agenda but by no means the least important. Maybe in many cases for the regulating community here in the room this afternoon, it could be one of the most important pieces.

We wanted to have a chance for Maxine Ball to come up and talk through some of the

administrative pieces that go along in terms of requirements with documents submitted to BRS. And we've had a couple instances within even just the past couple of weeks where we have had to return a document, either because of lack of signature or other technicalities.

Obviously, it's not something we like doing, we don't feel good about it. And clearly, for the regulating community, it's a good use of your time and resources either. So we would love to avoid these if possible. I'm sure you would too. So that's what this agenda item is all about.

Now, many of you, as you work through the petition process under the current regulation, are familiar with whether the document is technically complete. This step we're going to talk about in this final agenda item is actually making sure whether the document is administratively complete.

And that's important, because you can't get to that technical analysis and

evaluation if you haven't already passed the basic requirements in making sure that your document has all the administrative pieces completed before that stage.

So I'm going to invite Maxine Ball to come up. Maxine started with the federal government in 2012. She actually worked in the APHIS Investigative and Enforcement Services Branch initially while she was working on her master's degree.

And four months before she graduated, BRS was able to recruit her over and get her as an analyst for BRS. Her major responsibilities within BRS are analyzing the FOIA requests that come in. She assists in records management for BRS, and she works on processing incoming permits, and petitions, and notifications.

So she sees a lot of these things, so she knows a few things about these. So, Maxine, welcome you to come up and talk about the administrative requirements.

(Applause.)

MS. BALL: Thank you, Doug, and thank all of you for this opportunity to talk with you about the procedures and formatting for petitions.

As Doug mentioned, there are some things that we have been seeing. And we just want to make sure that we're providing everything that we can to ensure that your petitions are being reviewed and getting them over to the technological side so that your petitions can be expedited and issued.

So I'm kind of new at this, and I'm going to see if this works. Okay, all right. I think I've got it.

So what we will cover today, we'll be looking at when you're submitting your petitions, the number of copies you should be sending, the structure and the formatting of them, certification statements and the importance of signatures, the completeness of the package or what we call administratively complete, how to mark your CBI information, and then guidelines.

There will be actually a couple of examples, and it should be also in your packet of examples of each of the, whether your petition is a CBI copy, it's your CBI-deleted copy, and then also the no-CBI.

So first of all, the number of copies to send. So when submitting petitions, send two copies of the petition, and that's going to go to my team leader who is Cindy Eck. Cindy is our BRS Document Control Officer.

This means if you have a petition with confidential business information, which we name CBI, you should send us two copies of the CBI version and then two copies of the CBI-deleted version.

If there is no CBI information that's claimed in your document, then you would just send the two copies with a statement, no-CBI. And the same is true if you're sending an amended petition as well as extensions.

Our regulations under 7 C.F.R. 340.6(b) require the petition to be structured in

a certain way. On the cover of the page, you need to date the petition and provide the following statement and a signature. The undersigned submits this petition under 7 C.F.R. 340.6 to request that the administrator makes a determination that the article should not be regulated under 7 C.F.R. Part 340.

Our regulations were written before the time of electronic signatures, so the intent was to require a wet signature.

Okay, so that's right there. That's why that's highlighted. This I one of the main things that we have been seeing, is to make sure, and we wanted to highlight that the signature is there.

So following the required submission statement and signature, you need to provide a statement of grounds. And that just basically means that you need to provide an explanation as to why the organism should not be regulated under 7 C.F.R. 340.6.

On the certification statement and

signature required, so below the statement of grounds our regulations require the following certification statement. The undersigned certifies that, to the best and belief of the undersigned, this petition includes all information and views on which to base a determination, and that it includes relevant data and information known to the petitioner which are unfavorable to the petition.

Below the certification, you need to provide another signature, so there's actually two signatures that are required on the petitions, the individual petitioner's name, a mailing address, and telephone number.

Again, these are all items that are spelled out in the regulations, and we will kindly ask you to provide an email even though it's not mandatory or required. But email addresses were not around as widely used at the time the current regulations were under 340.

So additionally, our regulations also state that if there is any known unfavorable

information to a petition it should be made known. And if there is no unfavorable information, we just ask that you put none, just add none, that clause.

So again, I want to highlight petition requires two signatures on the first page and also on the certification page.

Administratively complete, so in order for us, BRS, to make a determination of regulatory status, we must see that you have provided at least the items that are required in our regulations. And a complete list of all items required to submit a petition can be found in Paragraph (c) of 7 CFR 340.6.

Our regulations say you will need to include copies of scientific literature, copies of unpublished studies, when available to you, and data from tests performed upon which BRS can base a determination that the organism no longer needs to be regulated under 7 CFR 304.6. So any cited literature that you use in the petition, it should be submitted along with the petition

package.

And so now we get down to really the nitty gritty. And this is where lots of sometimes confusion as to how to actually format the CBI in your document.

So if you are providing us a petition that contains confidential business information, again CBI, you must also provide us a CBI-deleted version of that same petition. Our regulations require that, if portions of the petition contain trade secret or confidential business information, each page of the petition containing CBI information should be marked CBI-copy and marked on each page where CBI is cited. And I'll show you that in a moment.

Each page of the petition where CBI information was deleted should be marked CBI-deleted and marked on each page where the CBI was deleted. If a petition does not contain CBI, the first page of both copies shall be marked no-CBI. Or sometimes we just see it spelled out, no confidential business information.

Okay, so here we go. all right, so this is a copy of the CBI-copy. And each page of the petition containing CBI must have CBI marked in the upper right-hand corner.

Okay, well if you look in your package, if everyone will look in their package while she's working to try to get that back up. And you should be looking at the copy that says CBI-copy. So if you have your copy, you can see, in the upper right-hand side of the document, it says CBI-copy right where there is the little yellow arrow. Does everybody see that?

Oh, okay. Oh, there it goes. Okay, so right there, CBI-copy, in that upper right-hand corner. And a lot of times this right here is actually missing. And it will cause a deficiency and would have to go back.

Also, so that's the CBI-copy, and then for all the information that you are claiming to be CBI --- okay, so all the information that you are claiming as CBI, it has to be CBI in the right margin identifying the information in

brackets --- I just can't really see it.

Okay, so your information is bracketed here. Can you make that bigger, is there any way to make that bigger? No? Okay. All right, so it's a bracket here and there should be an open bracket right here, okay.

So right here is the information that you claim as CBI, CBI in the right margin, and then the closed brackets for CBI here. So every place that you are actually marking as CBI with those brackets, you should be making sure that that information, you have an open bracket, and you have a closed bracket, and then the CBI in the right margin.

Okay, the second one is your CBI-deleted copy which also each page must contain, in that same upper right-hand margin, CBI-deleted, mark up in the upper right-hand corner.

And then on the CBI-deleted version, you replace blank spaces. For that information that you're claiming as CBI, it should be redacted or just white space in between the open

bracket and the closed bracket.

The CBI-deleted version should be identical to the CBI version except the difference being, again, blank spaces between the brackets and then also CBI-deleted copy at the top, and then CBI-deleted for every instance where you have information that has been redacted.

The CBI-deleted version must be paginated identically to the CBI-copy as well. The CBI-deleted version should be made directly from the same document. You find that's going to be the most easily to keep your pages in order as well as your brackets lining up from the CBI-copy.

We ask that you do not insert additional text, transitions, paraphrasing, or generic substitutions into the spaces where you have redacted the information.

One thing also to remember on your published references, if they appear in your CBI-copy, make sure that also the reference list is

in the CBI-deleted copy as well.

And then lastly, each page of a petition that does not contain any CBI, then no CBI should be marked also in that same upper right-hand corner. So those are the things that we're actually looking for when we first get the document to start to analyze them and review them.

We're looking for the formatting, and that is what helps move the petition through the process quickly when all of the documents are formatted properly and we can, as I said, just move the petition on.

So this concludes my reminders. And our final recommendation is to contact us directly before you submit it. And as we said, customer service is important to us. And so we want to be able available to answer any questions that you may have.

If you have difficulty in trying to format the petition, we can go over that information with you before you submit it. And

that way, when we get it, it will expedite moving it through the process.

So on this slide, this is where you can do, if you have any follow-up questions to what I've presented today, you can reach out to us, again, Cynthia Eck, who is the document control officer of BRS, along with myself, a management analyst, and my colleague, Helena Johnson. And I thank you for your time.

(Applause.)

MR. McKALIP: Thanks so much, Maxine. And our goal with that module was not to talk too much on the bureaucrat side, but our key really for BRS is we want to streamline, provide efficient service, provide timely service. We just want to make sure that we get past a couple hurdles that have to be surmounted to get you to the right part of the implementation process.

So with that, that brings us, really, to the close of our agenda for this afternoon. As you heard Bernadette mention, many of us will be around and want to have a chance to visit with

you. If you haven't introduced yourself, please do so.

All of our presenters, Doug Grant, Ibrahim Shaquir, Maxine, are available to answer questions and help you with any technical details that maybe we weren't able to cover in the actual presentations or in the Q&A portion.

I also wanted to mention, you know, in the theme of new faces, there are many new faces in BRS leadership who are here in the room who either weren't in the exact same position at this time last year. And it's a good chance to maybe catch up with folks and to know who they are.

Dr. Alan Pearson, if you'd stand up? Alan is in the role that many of you were familiar with previously, Sid Abel, our associate deputy administrator. Mary, are you still in the room? Mary Fleming, our chief of staff, is here. Many folks are in positions this December that maybe they weren't in that exact role last year, even if you know who they are. So this is a good

chance just to connect with folks.

Again, if you have questions that we weren't able to answer, many of the BRS team are here. And we really do welcome your questions and your feedback to help us as well.

Most importantly, Bernadette actually sponsored the coffee in the back of the room, so please grab some refreshments and make sure that we take advantage of her generosity in providing refreshments for the room.

So any members of the BRS team have any closing messages that I might have missed or any items that we need to make sure that we cover?

Dr. Watson, we're happy you're here too, hopefully you can stick around for a few minutes too.

So with that, and for the folks on the webinar, we appreciate your participation as well. We had a few items that I think we're going to follow-up with in writing. The slide decks can all be downloaded from the same site

where the webinar is located. So all those materials are available.

If you are interested in signing up for being a participant with us on eFile, the paper copies are on all the tables, but there also is an electronic means of signing up. And we have sign-up sheets here on this front table as well. So if you haven't signed up to work with us on eFile and are interested, we would love to have your participation and your help on that effort.

So with that, thank you so much for being part of the discussion. And please, we hope that you will hang around and spend some time with us more this afternoon. Thank you very much.

(Applause.)

(Whereupon, the above-entitled matter went off the record at 3:09 p.m.)

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Place: Riverdale, MD

was duly recorded and accurately transcribed under my direction; further, that said transcript is a true and accurate record of the proceedings.

Neal R Gross

Court Reporter