Transcript—BRS Stakeholder Meeting November 18, 2021

Adam: Welcome ladies and gentlemen. Thank you for joining today's Biotechnology Regulatory Services Stakeholder Meeting. Before we begin, please ensure you have opened the chat panel located in the bottom right-hand corner of your screen. If you require technical assistance, please send a chat to the event producer. If you wish to submit a written question during the presentation, please direct it to all panelists via the chat drop-down menu, and it will be answered of the designated Q&A periods. With that, I'll turn the call over to Alan Pearson. Alan, please go ahead.

Alan Pearson: Thank you. If you could advance to the next slide. Good afternoon. I'm Alan Pearson. I'm the Assistant Deputy Administrator for BRS, and I welcome you to the 2021 BRS Stakeholder Meeting. We're glad so many of you could join us today, and we wish we could have seen you in person. Hopefully next year, we'll be able to gather in-person together again. Next slide, please. We have a full agenda this year for the meeting. As you know, we've now fully implemented our revised biotechnology regulations, and you'll hear updates today on how that's been going, and on our plans for the year ahead. After reviewing our activities in FY 21 and, and our plans for FY 22, you'll receive updates from our Biotechnology Risk Analysis Programs and our Regulatory Operations Programs, as well as updates on APHIS eFile. You'll also hear about our international activities, and you'll hear from the USDA biotechnology coordinator.

Following this meeting, we're also holding a breakout session where people who are interested can hear more details about eFile developments. In addition to the information that you'll hear today, we also have two handouts available on our website, and we'll be posting these presentations online after the meeting. Before we start, I want to share a couple of additional points about logistics for the meeting. The agenda indicates, when there will be time, Q&A sessions. If you want, you can enter your questions into the chat box, as you think of them, and then we'll read them to the appropriate presenter during the Q&A sessions. We'll also take questions orally during each Q&A session. We'll have about 15 minutes for the first Q&A session, and we ask that you limit yourself to one question at a time, so everyone will have a chance to ask questions. If there are any unanswered questions at the end of this meeting, we'll be posting answers on our website in a Q&A document. And with that, I'd like to turn the meeting over to Bernadette Juarez, our Deputy Administrator for Biotechnology Regulatory Services. Bernadette?

Bernadette Juarez: Thanks Alan, it's really great to see everybody. Next slide, please. Another one, please. I wanted to just provide a real rapid recap of where we've been this year. Like you, we've had an incredibly productive year here in BRS, despite being pulled between a variety of other priorities related to the pandemic. We really focused in three big buckets that you'll hear more about as we go on into this presentation. So I won't belabor them here, but in terms of the past, we've worked to retire the legacy regulations. Over the year, you've seen us issue

petitions and retire the notification process that existed under the legacy regulations. We have a handful of petitions that remain in the process and look forward to completing those over the next year or two, and fully retiring those regulations.

As the present continues, we've worked to implement the revised regulations. Throughout the year, you've seen us take steps, first by making the permitting regulations and requirement active in April of 2021, along with the Regulatory Status Review Process for certain plants. Then we made the Regulatory Status Review Process available to all plants by the end of the fiscal year. In the intervening period, also set up a confirmation process, so developers who would seek a determination about whether their plants meet the criteria for exemption from regulation. All of those processes are up and running. Thank you for using them. Thank you for reaching out to us before your first submissions, so that we could have consultations and ensure a smooth transition to these new regulations.

This year we also thought about the future of Biotech with the issuance of an advanced notice of proposed rule-making in connection with an animal biotechnology regulatory framework. We appreciate the vigorous comments that we received in response to that advanced notice of proposed rulemaking, and the many conversations that we had with interested stakeholders. We continue to analyze the comments and feedback that we received, and think about next steps, in terms of animal biotechnology. So thank you for that insight. It's been helpful. Next slide.

One of the things I wanted to share with you are the Secretary's priorities for USDA in fiscal year 2022. He's really focused on Climate Change and Climate Smart Solutions using agriculture and forestry. We've seen some developers already beginning to think about Climate Smart Solutions for their own business processes, and to the extent that they may have an impact or touch on our regulatory processes here at BRS. You've sought consultations so that we can make any necessary adjustments. We appreciate that, and encourage that continued work collaboration. The Department's also focused on advancing racial justice, equity, and opportunity, creating more and better market opportunities, which you'll hear about in the presentation today, too, tackling food and nutrition insecurity and making USDA a great place to work for everyone. This is going to be especially important to us as we move into the next year and begin to return to our office spaces to work. Next slide.

I wanted to share with you a few of the BRS priorities. As I mentioned, we are preparing to return to our offices, the senior executives and senior leaders within USDA will begin returning to the office in December. So we look forward to reacclimating to that environment. The rest of our staff members will begin to join us in January 2022, and we'll have a phased return through March 14th,

2022. At which point we would expect to begin resuming more normal-type meetings in-person, like we did prior to the pandemic. So hopefully you will be seeing us in-person in 2022 at some point. We will also work to continue with the implementation of the revised regulations. One of the things that we shared with you last year was our thoughts on a potential [inaudible 00:07:22] plants that would be exempt from regulations because they contain modification [inaudible 00:07:28]. What may be accomplished through conventional breeding. We appreciate your comments on that proposal, and we continue to review those. I want you to know that they remain on our radar screen.

This year we'll also be dedicating some resources to litigation in the Ninth Circuit that is challenging the implementation, or excuse me, the adoption of the revised regulations. Throughout this period of litigation, we continue to implement the revised regulations, and are operating under the new 7 CFR part 340. We also want to make sure you're aware of an upcoming opportunity, likely in the New Year, in January or February, where we'll host a meeting of our Biotechnology Quality Management system. We've refined our system to align with the requirements in the new, excuse me, in the revised regulations. And we really want use this workshop as an opportunity to help developers establish systems and practices that support compliance with the regulations.

So you'll be hearing more about that in the near future. We'll send out stakeholder messages, and solicit participation and registration as we've done in the past. And finally, to restate what I mentioned earlier, we also will spend some energy and resources focused on animal biotechnology, and how USDA may play a role in that space in the future. You'll hear a lot more from my team as we move on into this presentation, I'm extremely proud of the work that they've accomplished this year, and the number of projects they are willing to take on with strong enthusiasm, while continuing to deliver outstanding service. So with that, I'm going to pass it back to Alan.

Alan Pearson: Thank you, Bernadette. Before we move on to the next presentation, I just want to let you know that this slide set, and the handouts, are now available on the BRS website, and remind you that if you have questions, you can enter them into the chat box. Next, we'll be hearing from Subray Hegde, the Director of the Biotechnology Risk Analysis Programs. Subray.

Subray Hegde: Thank you, Alan. Can I go to my first slide, please? It still shows me FY2022 BRS Priorities. Yeah, thank you. My name is Subray Hegde, the Director of Biotechnology Risk Analysis Programs. Today I am going to provide, I would like to highlight a few of our accomplishments, and provide you with some updates on confirmation request, regulatory status review, and permits. Next slide, please. With some of our accomplishments in the last year, regarding petitions, we provided determination on six petitions. As you see in the list, one was Monsanto insect protected cotton, and Westhoff orange-colored petunia, and

three maize events: Pioneer's enhanced yield maize, Pioneer's seed production technology for Africa maize, the Agrivida phytase maize, and finally, an extension from Okanagan on non-browning apple. Next slide, please.

We received 24 confirmation requests, whether they qualify for exemptions. We completed review 13, and provided confirmation request on seven. Means some of them are either not qualified, or not necessary to ask for exemption. And currently, we have 11 confirmation requests in the queue. Next slide, please.

Authorizations. Our last year, we had a two permitting platform. One is ePermits, and eFiles. ePermits will be decommissioned, and will not be available after a few months. Currently, all permits are received in eFile. Last year, we authorized 450 applications in ePermits, and 304 in eFile. Next, please.

Regarding Regulatory Status Review, a draft guidance. We published a draft guidance for public review on, I think, August 25th for a 60-day public review and comment. We also provided a webinar presentation to stakeholders on September 28th, 2021. There were 107 unique attendees, the participants. The recording of question and answer will be available soon on the APHIS website. Next, please.

We received public comments. We counted nine unique comments, and I highlighted some of the substantive comments on different sections of RSR, the draft guidance. There were requests for publication of the RSR risk evaluation model. Also, some people suggested how we should handle Plant-Incorporated Protectants. And there were some concerns raised, regarding RSR. That RSR is focused too broadly and will overregulate. On the contrary, we also received concern, regarding the RSR is focused too narrowly and will miss risk. People also requested clarification about information/data requirement. Also, there is concern regarding how APHIS would handle CBI in their RSR request, and some developers requested clarification about NEPA analysis in RSR. Next slide, please.

Update on Confirmation Request Process. We are working to revise CR guidance to provide more clarification for the requesters. Also, we are updating our Confirmation Request Frequently Asked Questions. Also, we are, as with any other processes in BRS, tracking internal steps to monitor efficiency. For CR, the due date are the number of days we can take to respond to a request is 120 days. So far, we have provided response on average within 45 days on all those requests which are sufficiently detailed in them. That is, when they are technically complete, we took 45 days to provide responses. Next slide, please.

Guidance on Permits. There are Permit Guidance were always there on our website earlier, but we had to revise some of the sections in Permit Guidance.

This revision is stemmed from to reflect revise regulatory requirements and the capabilities of our new permitting system that is eFile, is also new platform for application permits, submitting permits. So our permit guidance, what we are revising, is to reflect both revise regulation and also eFile requirement. We are also developing an optional template for Standard Operating Procedures. The people who submit earlier used to submit a design protocol regarding containment confinement of their [inaudible 00:17:15] research. For eFile permits, the applicants have to submit their Standard Operating Procedure. Sometime developers and the applicants want information. What exactly they have to provide in this SOP? Both for consistency purposes across permit applications, and also to help our stakeholders, we are developing a template, and showing what are the minimum information required for us to review a permit application. Next slide, please.

A few updates on Supplemental Permit Conditions. So there are two types of conditions. If you remember, one is standard permit conditions, which are listed in our regulation. Second one, supplemental permit condition, depending on the crop, the location, and the trait. We have changed certain terminologies here in the revised regulation and reflecting the changes in revised regulation. There is no term called regulated article now. Instead, it has been called a modified organism, a regulated organism, a regulated material. As you can see, the word article is not there anymore. References to renewable is removed. That doesn't mean there are no renewals. Instead, an applicant can ask for new authorization instead of a renewal. They can have an appropriate discussion how to continue their field trial. This especially true for most of the perennial plants. And we removed the variance references to align with revised regulations for shipping requirement. Instead of responsible person or their agents, now we use the term permittee or permit holder. Next slide, please.

There are some updates and reports, and some of the name changes in the reports. Instead of Planting Report, now it is called Environmental Release Report. Similarly, Planting Unique ID is called Environmental Release ID. Finally, Field Test Report is now termed as Final Environmental Release Report. Next slide, please.

Some of our major focus for, and then this year, FY22, develop a guidance for microbial permits. In the revised the regulation, we set three criteria to decide whether a modified microbial requires a permit to move. Our developers really want how to interpret those criteria, so we are developing a guidance for our stakeholders. It might be useful, and make their decision making easier to decide whether the modified microbe requires a permit from APHIS. We are continue reviewing the pending petitions, and confirmation requests, and RSRs. Next slide please. Next one.

Yeah, okay. If you have questions or comments, and I listed some names here, these are the supervisors or branch chiefs in Biotechnology Risk Analysis Programs. You can contact them. You can contact Deshui Zhang for Permits and Confirmation Request, Suma Chakravarthy on Regulatory Status Review, and Martha Malapi-Wight on Microbial Permits. Thank you.

Alan Pearson: Thank you, Subray. Next, we're going to hear from Doug Grant and Phil Mason, from our Regulatory Operations Program. It's my pleasure today to introduce Phil to you. He is our new Branch Chief in our Western Compliance Assurance branch, is joining us after having spent many years in PPQ. I'll turn the mic over to Doug and Phil. (silence) Doug you're muted.

Adam: I'll just take Doug off mute. (silence) Hi Doug. We still can't hear you.

Doug Grant: Can you hear me? Adam?

Adam: Yes we can.

Doug Grant: All right, thank you very much. Sorry about that folks. Good afternoon, I'm Doug Grant and I'm the Director of Regulatory Operations Programs for BRS. Can we go ahead and move two slides ahead? Phil Mason will be joining me in this presentation to present some information a little bit longer. Next slide? A little bit later. I want to share with you some of the important projects ROP worked on during FY21, as part of our ConOps, or Concepts of Operations, to align with the revised regulations. We had to provide oversight of authorizations issued under both the legacy and current 340 regulations. So we carefully tracked authorizations, in both ePermits and eFile, to ensure appropriate inspection worksheets and compliance evaluations were used for each inspection and compliance case we handled.

We also worked to streamline some of our processes to reduce hand-offs and time-in-process for compliance determinations, to improve timeliness with delivery of our compliance outcome letters, so that regulated entities know the compliance outcomes of inspections, and can perform any necessary corrective actions in a timely manner. In addition, we engaged with stakeholders to resolve issues and answer questions about how things may be different under the current regulations than the legacy regulations. Next slide.

We also continued to conduct many of our inspections using a virtual format in FY21. These virtual inspections known as Monitoring and Evaluation Interviews, or MEIs, involve exchanging documents, such as records associated with the trial, and photos of the trial site, with the permit holder or site cooperator, before the virtual inspection begins. We used video conferencing technology to help with remote visualization during many of these virtual inspections, and we

used Remote Sensing, such as satellite imagery, to help verify information gathered and evaluated during virtual inspections. Next slide.

As we mentioned during last year's stakeholder meeting, we've been working to analyze geospatial data to help with compliance oversight and evaluation. This involves mapping of GPS coordinates from the permit application, planting reports, and coordinates collected during inspections, to assure all regulated activities occur within the authorized trial area. And we continued to use Remote Sensing to evaluate what has happened on the ground. We select the best satellite imagery dates to support our inspection and compliance work, to verify things like planting and harvest dates, and acreage planted. This provides us with more context to verify information gathered during virtual inspections. Next slide.

So looking at the map of inspections by State in FY21, we conducted a total of 708 inspections. You can see in the middle here, with the darker colors representing States with higher numbers of inspections, we had a high concentration of field trials and inspections in Midwestern States like Iowa and Illinois, as usual, and along the coast in places like California, Texas, and Florida. In addition, we had a fairly high number of trials and inspections in our winter nursery locations, where trials occur year-round, like Hawaii and Puerto Rico. Next slide.

Looking at who conducted the inspections over the last three fiscal years, most of the inspections are conducted by BRS personnel, but a significant number performed by our sister APHIS program, Plant Protection and Quarantine, or PPQ, and some are conducted by State Departments of Agriculture on our behalf. Last year, since most of our inspections were conducted virtually, BRS performed 95.6% of the inspections in FY20. Towards the end of last year, we trained a number of PPQ inspectors to conduct virtual inspections, and were able to return to doing some in-person inspections this past summer, as the travel restrictions eased a little bit.

So the number of inspections performed by PPQ in states went up again this year, compared to last year, getting back closer to the percentages done in 2019, before the pandemic. Overall, in FY21, BRS conducted 86.4% of the inspections, while PPQ conducted 11%, and our State partners conducted 2.6% of the inspections. Next slide.

Looking at the breakdown of inspections by Quarter, 165 inspections were conducted in Q1 of the fiscal year, and these were primarily post-harvest inspections occurring between the months of October and December. 97 inspections were conducted in Q2, and 158 inspections were conducted in Q3, as we entered the new growing season. Our busiest Quarter, which is pretty similar to other years, we tend to have the highest number of inspections in Q4

after most of the trials have been planted for the year. So we had 288 inspections conducted in Q4 for that total of 708. Moving on to the next slide. And with that, I will hand it over to Dr. Phil Mason, to tell you a little bit about inspection outcomes, compliance trends, and some of our priority projects for this year. Thank you.

Phil Mason: Thanks Doug. Let's see here. So looking at the resumption of in-person inspections, we see that resumption began about midyear FY21 as we began to ease some travel restrictions. So BRS along with our federal and state partners conducted approximately 82 in-person inspections. That was about 11% of our total inspections for the year.

We focused on high risk trials, things like plant made pharmaceuticals and industrials, and it's what we referred to as PMPI trials. We also focused on species with higher likelihood of persistence and also trials that had common compliance issues. And in FY22, we're going to continue to use both virtual and in-person inspections as we evaluate compliance. Next slide please. Next slide please. Can anyone hear me?

Miranda Wanex: We can hear you. I think we can go back.

Phil Mason: Started to... I was like, oh my goodness. I must not be on. Ok. Thank you very much. Compliance inspection outcomes. When we look at compliance rates for FY20, we see that we were very similar in 21. We increased slightly to 98% of those.

And when we look at the notices that were sent out in FY 21, 98% of those were compliant, approximately 2% were non-compliant. So as we look at these first two bullets, we see that they make up approximately 50% of all our compliance issues.

Those being things like late planting reports, late field test reports and failure to comply with supplemental permit conditions. And that was followed by things like failure to comply with the standard permit conditions. Also we had a few instances of releases and areas where in quantities that weren't authorized.

And then finally, we had a few that were failure to obtain or maintain authorizations. And it's just kind of a reminder that to the permit holders that if you have a multi-year trial, that's something you don't want to delay submitting a new application for, you want to get those in early. So we don't have any problems with a multi-year trial. Next slide please.

And that one was already covered. So next slide. Let's see. And so looking at projects within the Regulatory Operations Program or what we refer to as ROP,

for FY 22, we have multiple projects this year, including developing a guide for permit holders, for submitting and required reports and notices.

We're also going to be integrating within our compliance database, going to integrate the compliance database components within the APHIS eFile system. And additionally, we're going to be updating the BRS inspection manual to align with the new worksheets, the new special permit conditions and the revised regulations.

And finally, we're going to be developing a GIS dashboard to inform on decision making. Next slide, please. So if you have questions or comments or need support listed here, the branch chiefs, Nathaniel Yates, Christy Bertone and myself, where you can call us anytime with questions or comments, or please utilize the BRS compliance inbox that address listed below BRS compliance@usda.gov. Next slide. And I will hand it back to Alan. Thank you.

Alan Pearson: Thank you, Doug and Phil. Next, we're going to hear from Miranda Wanex who will give us a update on APHIS eFile Miranda.

Miranda Wanex: Thank you, Alan. Good afternoon everyone. My name is Miranda Wanex and I'm a management analyst with BRS' communications group. I'm also BRS' project lead who oversees continued development and improvement to the new APHIS eFile system. Next slide, please.

For this portion of the meeting, I'd like to share some updates about the new features that we rolled out in fiscal year 21, as well as brief overview of the enhancements coming out in fiscal year 22. A summary of this information is contained in the meeting handouts, which are available on BRS' website.

Since all attendees may not be interested in learning about our permitting system, BRS is holding a breakout session after the meeting has concluded where I'll be back to share a demonstration of a new feature, and we'll share more information about the system enhancements that are on the way.

All participants are welcome to stay for this portion, but those details are mostly relevant to applicants who submit or plan to submit biotechnology permits under BRS' revised regulations with that, let's get started. Next slide please.

April 5th, 2021, was a key date listed in the revised regulations as the updated permitting processes officially went into effect. Also on that day, BRS began requiring that all new applications be submitted through APHIS eFile.

Since applicants could submit permit and notifications, any permits until end of day on April 4th, there's a period of time that BRS continued to process pending

applications in the old system. Several of those authorizations remain effective until later next year.

So those permits and notifications still have reports to be filed. Plus many applicants still submit permits to PPQ. So the ePermit system remains open for applicants to log in and access their BRS records as well as submit compliance reports.

There are no upcoming plans to restrict access at this time. In tandem with this release, BRS prepared a number of resources for applicants on how to use the new permitting system. These documents can be accessed with, or without an active APHIS eFile account by navigating to the website homepage, which is linked here, then clicking the help link in the top right, then accessing the training tab on the following page. Next slide, please.

Also on April 5th, BRS implemented several changes as a result of the revised regulations, which included the discontinuation of notifications as these authorization types are no longer applicable in the updated permitting regulations; two, the alignment of terminology many of which were outlined by presenters earlier in the meeting.

Three, the implementation of new required information such as job titles for applicants, supplier developers and agents, AKA location contact personnel, and finally some adjustments were made to the review processes to ensure adherence to the updated regulations. Next slide please.

One key feature included in the April 5th release was a new tool called the BRS Permitting Assistant. This tool provides stakeholders with an interactive way to navigate BRS's updated regulations and easily determine whether a permit is required for the organism's movement.

This tool also indicates whether an activity is potentially eligible for an exemption or for a regulatory status review. You can use this tool as a guest of the site, meaning you don't have to register to try it out. And if you'd like to see this tool in action, stick around for the breakout session where we will share a demo for participants. Next slide, please.

Finally, this fiscal year, we are releasing a system update that will help streamline and address feedback received on the BRS Permit Application interface, as well as improved PDF generation and large application submission and processing.

This update is expected in late March 2022 and we will have more information to share regarding these changes in the breakout session. Next slide, please. For now thank you very much for your time and attention.

On the slide here we have a few key links for stakeholders. One is the homepage for APHIS eFile, which can be explored as an unregistered user or can be used to get signed up and submit permit applications. We've also linked BRS eFile help desk here, where stakeholders are welcome to ask questions and get help on any applications they're preparing or have submitted.

Finally, anyone who intends to register in the APHIS eFile system must have an identity verified e-authentication account to do so. So please make sure you've created an account or have your existing credentials handy before you sign up in the new system. Thank you guys very much. And I'll be back at the end of the meeting to share more information in the breakout session.

Alan Pearson: Thank you Miranda. Now we will have our first question and answer session. As a reminder, you can put your questions into the chat box, or you can ask them orally. We'll start with questions that have been added to the chat box. And then move on to take questions over the phone.

The first question will be for Subray and the question is that, Subray you mentioned updates on the confirmation request guidance on FAQs, new permit guidance and guidance on microbial permits. Are there specific timelines for when those documents are expected to be released and will they be released as draft documents with an opportunity for input on the draft documents?

Subray Hegde: Thank you Alan. Thank you for the question. I think I misspoke when I used the word draft, all those documents, FAQs are not draft. This is based on the questions we received. We prepare answer and we add it to the list so that our stakeholders can see how we answer it. And regarding other documents, confirmation request guidance document, revisions are minor.

So we are not publishing it for public input on those documents either. And the third one is I'm missing something, permit. Permit guidance document. I think we have a guidance document or we had it on our website, with permit guidance document.

What we are changing is, we are only changing to align with revised regulation in APHIS eFile. There are no major changes, so that will not be in a published for public input or comment. I hope I answered all the sub-questions Alan, or did I miss anything?

Alan Pearson: Their questions are pouring in here on the chat box. Let me go for the second question to Doug. That question is, is there a BRS list of crops that are considered to pose a quote higher likelihood of persistence?

Doug Grant: Yeah. Thank you for the question. We do use a list and that list is used to inform our inspection selection. So we select the species with a higher likelihood of

persistence at a higher frequency for inspection, and things on the list and include perennials and some species that are annuals like sorghum, canola, and wheat that also have longer volunteer monitoring requirements associated with those permits.

Alan Pearson: Thank you. The next question... Excuse me is on October 25th, the comment period ended for comments on the draft RSR guidance and BRS received only nine unique comments. Will BRS continue to accept comments on the guidance document, even though the comment period closed, if not will we provide opportunities for providing comments on the guidance, the RSR procedure, and as well as additional considerations for identifying organisms that be subject to part 340? I would turn that one over to either Subray or Bernadette, whichever one of you wants to take that question.

Subray Hegde: I will ask Bernadette to respond to that question.

Bernadette Juarez: Okay, thanks. So it was a multi-part question. So I'll start with the first part. The comment period has closed in, although we received nine unique comments they were quite substantial in nature. So we have good amount of feedback to work on to refine and finalize that data... Or excuse me, that guidance document.

When we posted it, it will be posted in final form with the understanding that we will continue to make periodic updates for clarification. If after we post the final version of this RSR guide, you continue to believe that there are areas that require greater clarification, you can message the email associated with the RSR.

Miranda or Robin, if you would drop that into the chat. So people have the RSR email box where they can send any questions they might have, or thoughts for additional clarification after the RSR guide is posted. There was also another question, Alan about the availability to comment on whether a plant should fall under our regulations. Is that right?

Alan Pearson: Yes. The question was, will we provide opportunities providing comments on additional considerations for identifying organisms that should not be subject to [inaudible 00:45:56]?

Bernadette Juarez: So I read organisms to be broader than plants. So I'm going to take this in two parts, just in case my reading is not correct. First we did, as I mentioned propose to exempt additional plants with modifications that could be achieved through conventional breeding practices and received a number of comments on that.

We continue to consider those comments in our next steps. There is always a process that is in the existing regulations for submitting proposals, for plants

that you think contain modifications that could be achieved through conventional breeding and should be exempt from regulation for that purpose.

With respect to other organisms, non-plant organisms. When we published our proposed rule back in 2018, we noted or asked whether there was interest in establishing a framework for non-plant organisms that were similar or is similar to what exists for the regulatory status review process for plants.

In response to that question, we did receive comments that were very supportive of establishing a framework like that, although we were not able to do so in the final rule, because we didn't have a framework for you to comment on in the proposal.

So it would not have been appropriate for us to jump to that endpoint in the final rule. So we've noted this as an area of interest for future rulemaking in connection with the existing revised regulations and understand that there remains strong interest in that area.

At this point, it's not been identified as a rulemaking that would occur on the regulatory agenda for this administration, but it is on our radar screen as a strong area of interest for developers.

Alan Pearson: Okay. I'll do a couple of more written questions and then we'll go to the phone lines. There's two questions related to for CRs for Subray one is, if CRS are taking 45 days on average for response after they're technically complete, how long is it taking to get feedback on if the request is complete?

And the second question is how long does it take for responses to be posted online? You mentioned 13 responses, but only seven are currently posted on the website. If I can clarify that last question before Subray addresses, the first one. We have considered 13, we only post responses when we are confirming an exemption. So those are the seven that are posted on the website. Subray, do you want to take the first question?

Subray Hegde: Yeah Alan [inaudible 00:48:49] mention how long it takes to go on a website. That is the question, that was second part after we make a decision?

Alan Pearson: Yes. Okay. The first one I gave example of an average; we took 43 sample size is just seven or 13 it's too small. But from the data of received of a confirmation request and the responses for all these seven, we took around 73, days. That is a certain time is really spent reviewing to see whether it is technically complete.

Yeah, that is the average from the data received, date of response still it is within a 120 days at the time align, which are given to provide a response.

Alan Pearson: Okay. Why don't we turn to the telephone? See if there's any questions coming in over the phone.

Adam: Sounds like a plan. Thank you. And I should remind everyone, ladies and gentlemen, if you wish to ask a question verbally, there are two ways you can do this. If you are connected primarily through the WebEx, you can use the raise hand function located in the top right hand corner of the chat window to enter the queue. If you dialed in using a phone only line, you can press pound two on your telephone keypad to enter the verbal question queue. And I do see we have a question on the verbal line.

Speaker 1: Can you hear me?

Adam: Yes, we can hear you.

Speaker 1: Can you hear me? Very good. Thanks for taking my question. It's in reference to the September 28th public meeting, there was a question asked on the deregulated status when two stacked traits are approved for deregulated status, can that genome have more traits added to it and then requested to be deregulated status still? And I was hoping I could get clarification. So if a organism is found to be deregulated, can that same organism, now go through the process again and be resubmitted?

Subray Hegde: Alan, you are taking that question, right?

Alan Pearson: Well, I can take that question. If an organism has already gone through the process and been found to not be subject to the regulation, there would be no need for it to go through the process to reach the same finding again.

Speaker 1: Well, so let's say it gets two traits it's found to be deregulated can it undergo the process again with two more stack traits to that plant or to the genome.

Alan Pearson: If you're adding additional traits that haven't been reviewed yet, then yes, it would go through that process again. If you'd like to follow up with us after the meeting on more, very specific questions like that, we'd be happy to do that. Subray provided contact information in his slides for Suma Chakravarty where you could follow up with on questions around RSR.

Speaker 1: Right. Ok. Well, but before it had said, just to clarify, it was said it was you'd have to wait six months. And then if that was the case, if you wait six months, would you still be looking at the other traits as well as the new traits inserted? You know I'm just curious for clarification on that.

Bernadette Juarez: Alan, I'm going to weigh in here real quickly. I think there may be some confusion about the answer that we provided during the regulatory status

review seminar. One thing I will flag for listeners is that we do intend to release the question and answers from that session in the coming days on our website.

So we'll make sure that those who are registered for this session receive the link to those answers, which may help in part. I do think that one of the challenges with the question that we receive is we've just listened to, is that as I understand it you wish to cross or connect two traits that have previously been deregulated.

And the first question we would need to ask is whether you've done it through conventional breeding or molecular stacks. So there's a number of, of questions that we would need to follow up on in order to provide you with a solid answer, which is why Dr. Pearson has suggested that you reach out to our team for more information on your specific topic.

Speaker 1: Okay. And just so I don't lose it, who would I be reaching out to? Is there a name you can give me?

Bernadette Juarez: Sure. These slides will be posted on our website and in the biotechnology regulatory or biotechnology analysis programs area at the end of the slide, Dr. Hegde provided the listing for three of his branch chiefs. Any one of those will help you get to the right spot. Otherwise Dr. Hegde can help you.

Speaker 1: Thanks.

Adam: All right. I do not see any additional questions in the verbal queue at this time.

Alan Pearson: Okay. Well, we're approaching about 15 minutes for this session and we can always take more questions at the next session, Q and A session. I'll wrap it up with just two more questions. Both for Subray, then get back to the guidance documents. One was, can you clarify if the guidance document for microbial permits in FY 22 will have an option for public comment, and will it clarify what's actually subject to regulations, and options to not regulated if it is subject to regulation. And the other question is there an estimate of when the RSR guidance document will be finalized and posted in FY 22? Subray.

Subray Hegde: Un-mute, start video. Microbial permit guidance. Yes, we plan to publish a draft permit guidance on microbial for public review and comment. Then second one is, will we clarify what is actually subject to regulation? Yes

We would like to develop some kind of... What do you call it? Decision tree or criteria to use, to decide whether a permit is required, but still regulators, developers can always contact us with their questions.

Regarding RSR guidance, yes we started analyzing, assessing all the comments and we are planning to publish a final one in the third quarter of this fiscal year. That is our expectation.

Alan Pearson: Okay. Thank you. We like I said, there are some additional questions in the chat box and people may have additional questions after the next couple of presentations, but just to make sure that we have adequate time for the presentations, we'll move on to the next items on the agenda and then have another Q and A session after that. So next up will be our associate deputy administrator, Jessica Mahalingappa, who will talk to us about BRS's international activities. Jessica.

Jessica Mahalingappa: Thank you Alan. It's great to have a chance to talk with all of you this afternoon. Next slide, please. Actually probably two slides forward, please. Yeah, there you go.

Jessica Mahalingappa: Actually, probably two slides forward, please. Yeah, there you go. Okay, in fiscal year 2021, we overcame travel and in-person visit limitations to be able to host or participate in over 20 international engagements. We worked with interagency partners to prioritize engagements with important trading partners, both those importing and exporting products of biotechnology, and also countries that are in the process of developing their regulations or legislation. We also continued our collaborations to work with multilateral organizations to establish common ground and understanding among regulators of products of biotechnology. We maintained many past collaborations with neighboring countries, such as Canada and Mexico, and also built on some existing relationships to deepen our understanding of the biotechnology regulations in other countries, such as Korea, Spain, Portugal, the UK, European Union, and Brazil, to name a few. And lastly, we developed an international strategy recognizing the priorities for our stakeholders, but also, our own priorities going forward. I'm going to talk a little bit more about that strategy. Next slide, Adam, please.

So in developing this strategy, we took a step back to consider our goals in international engagements. We examined the changing regulatory landscape, not only our new regulations, but other countries and our interagency partners. We applied feedback that we received from other U.S. government agencies, as well as our stakeholder meetings. We considered potential implications of our regulations on U.S. producers, both those producing biotech products of biotechnology, as well as conventional crops, those who wish to export overseas. We also thought about the potential difficulties facing regulators in other countries, trying to navigate products developed there, or U.S. products, and what we could do to clarify our role, the science behind our decisions. We wanted to do our best to ensure a level regulatory playing field for all the products that we regulate. So we divided our strategy into three parts.

Our main goals are to provide assurance of the credibility of BRS' regulations and the regulatory processes internationally, we wanted to build capacity in other countries for regulating agricultural organisms developed using genetic engineering, and we wanted to promote harmonization in risk-based approaches to agricultural biotechnology regulatory systems globally. Next slide, please.

Key points in the strategy are that we clearly have a role that is distinct from other U.S. government or private sector entities that work with our counterpart regulators. We need to listen to any concerns that they have and explain our regulations as well. So, we want to continue to engage with those international regulators, some that we've built relationships with over years, because we have that unique relationship. We're also willing to work with our interagency partners and non-governmental entities to identify priority engagements. We'll continue to provide technical assistance to trade agencies or other foreign affairs agencies that are interested in safeguarding trade, minimizing disruptions in the global marketplace, and we want to continue to participate in engagements through international organizations. For example, the OECD, or Organization for Economic Cooperation and Development, has been an effective forum for discussing changes in technologies and setting standards among member countries for decades.

We're also building on past work with some regional bodies that have been doing work with biotechnology, as well as some other multilateral fora. For example, the Inter-American Institute for Cooperation on Agriculture that works in the Americas, they recently completed an important review of biotechnology among countries in the Americas and we're very excited to receive this report and identify some key partners that we might reach out to in the coming few years. We're also continuing on past engagements with Asia-Pacific Economic Cooperation or APEC, as well as the World Trade Organization, as they discuss discussions on the potential impacts of biotechnology on trade, and we're willing to provide our expertise in any of these fora, where appropriate. Next slide, please.

So in conclusion, looking ahead, we already have some engagements planned for fiscal year '22, for example, with Canada and Mexico, but we're also interested in working with countries that are reviewing products in a similar way and developing biotechnology within their countries, and also those who might have more limited exposure. We're interested in developing new partnerships with countries that are considering how to develop regulations that are appropriate for them, the way that we have. And we're also looking to welcome your feedback on any potential outreach that is needed, as well as any comments that you might have on our strategic goals. Next slide, please. Here, you can see my contact information directly. So any questions that aren't answered today, feel free to reach out to me and I'd love to hear your feedback,

as well as any questions or requests for engagement with our international partners. Back to you, Alan.

Alan Pearson: Thank you, Jessica. Finally, today we are going to hear from the USDA Biotechnology Coordinator, Anastasia Bodnar. Anastasia.

Anastasia Bodnar: Hello, and thank you so much everyone for those important updates about BRS activities. I'd like to provide some broader context and information about biotechnology activities happening across the Department. Next slide, please. So for that broader context, USDA is a large department, with about 100,000 employees across the United States and all over the world. We have eight mission areas with 29 agencies and offices addressing food, agriculture, forestry, world development, and more. Next slide. Our agencies are involved with biotechnology policy, research, regulation, commercialization, production, labeling, promotion, and trade. Altogether, many agencies are involved with agricultural biotechnology from innovation to table. Next slide. As Deputy Administrator Juarez mentioned, USDA's priorities in fiscal year '22 include addressing climate change, advancing racial justice and equity, creating market opportunities, and tackling food and nutrition insecurity. Along with other activities and innovations, USDA is committed to advancing biotechnology as an important tool towards meeting our goals. For example, we've recently launched major programs for addressing climate change, and biotechnology plays a role in all of them. Next slide.

The Sustainable Aviation Fuel Grand Challenge is a government-wide effort to reduce the cost, increase sustainability, and expand production and use of sustainable aviation fuel. The goal is to meet 100% of U.S. aviation fuel demand by 2050. That's an expected 36 billion gallons needed per year, but current production is just tens of millions of gallons per year. So USDA research will play a critical role, including in biomass feedstock genetic improvement. Next slide. The U.S. initiated the Coalition for Sustainable Productivity Growth at the United Nations Food Systems Summit in September to accelerate development of more efficient, productive, and sustainable agriculture and food systems. So far, there are 80 partners, including several organizations that conduct biotechnology research or capacity building. Sustainable productivity growth is critical for meeting the world's food needs, alleviating poverty, and combating climate change. Careful use of innovations like biotechnology can help us to meet those goals. Next slide.

AIM for Climate is a joint initiative by the United States and the United Arab Emirates. The goal is to accelerate climate-smart agricultural innovation. AIM for Climate will work to increase investment in innovation. At COP 26, the United Nations Climate Change Conference, AIM for Climate officially launched and announced $4 billion of increased investments over the next five years. It will also enable technical discussions to amplify those investments and establish

greater cooperation in shared research priorities between countries. AIM for Climate also has many partner organizations that conduct biotechnology research or capacity building. Next slide.

As you heard from Associate Deputy Administrator Mahalingappa, USDA does a variety of international activities, including technical collaboration with the Biotechnology Regulatory Service. USDA's Foreign Agricultural Service conducts a lot of international activities to facilitate trade in biotechnology products. There are too many activities to list so I'll focus on one big highlight. APEC, that's the Asia-Pacific Economic Cooperation, is a regional economic forum. For the APEC High Level Policy Dialogue on Agricultural Biotechnology, despite the pandemic and the 18 hour time difference between some of our economies, FAS led five virtual events in 2021, with participants from 19 economies. The participants identified three topics for collaboration in 2022 that I'm really looking forward to. Resource sharing on policy and regulatory approaches, including mentoring among economies and access to product approval information, joint communication efforts for increasing public confidence in agricultural biotechnology, and development and implementation of policy and regulatory frameworks so the leverage lesson's learned across all of our economies. Next slide.

In addition to all of those important climate-focused and international efforts, of course, there are many scientific activities across the department, including workshops and talks, panels and papers, on both plants and animals. For example, USDA held a Plant Breeding Stakeholder Meeting to help identify and direct research priorities. On animal biotechnology, USDA staff led development of an international workshop series and six regional workshops. USDA intramural and extramural research always has many interesting things happening, so I'll just mention one. Researchers at the USDA Agricultural Research Service are genetically engineering plants to flower continuously. This could enable astronauts to grow fruit on long space missions, and, perhaps more practically, could be used on Earth, in indoor farms, to help improve food security. Next slide.

Lastly, a topic I'm sure some of you are interested in, USDA announced the National Bioengineered Food Disclosure Standard in December 2018. The lead agency is the Agricultural Marketing Service. This is a national mandatory standard for disclosing foods that are or may be bioengineered, and the mandatory compliance date is January 1st, 2022. For the purposes of the standard, bioengineered foods are those that contain genetic material that has been modified through in vitro rDNA techniques, and for which the modification could not otherwise be developed with conventional breeding or found in nature. You can find more information about the standard and how to comply on the USDA website. Next slide. I hope that gives you a quick glimpse of the

Department's activities that relate to biotechnology. Thanks for the opportunity to provide this update.

Alan Pearson: Thank you, Anastasia. Okay, now we will move into our second question and answer session. There were a few questions remaining from the last session, as well as a couple of additional questions that have come up. I will start with a few questions from the chat, and then again, we'll open the mic up for that. I'll take the first couple of questions. There was a question about whether there is a guidance document for microbials. I assume that refers to microbes, and that is the guidance document Subray already referred to that his group is working on developing, and we'll be publishing a comment later in this fiscal year. There was also a question of whether there's a requirement for interstate movement of trichoderma. That's a very specific question, and I would encourage you to follow up with Martha Malapi-Wight who was listed on Subray's slides with that specific question.

Finally, there was a question, if a person uses the online tool to determine if a GE organism is subject to the regulation, will this be a substitute for the CR and/or RSR procedures? No, the online tool is not intended to be a substitute, and it's not going to tell you whether the organism is subject or not. It will tell you whether the organism may be eligible for a CR, that's maybe eligible for exemption, and provide you with information on how to submit a confirmation request if you want to obtain confirmation that it's eligible for exemption. Similarly, it will let you know if it may be eligible for an RSR and how to send an RSR request. So that's answers to three of those questions. We also had a question for Subray. What is the average or expected turnaround time on environmental release applications without any comments or requested changes by the APHIS BRS reviewer? Subray?

Subray Hegde: Okay. As I said, there were two permit platforms. We had ePermits and eFile. eFile is the new, new functionalities, and we are getting training to our biotechnologists. Why I'm mentioning this...they were taking some more time than the average. In ePermits, we met deadlines before 120 days, that is assigned to an environmental release permit. In eFile, initially we had some hiccups, but now, for all environmental release, we are giving authorization on permits within 120 days. Exact when I do not know how many days we really took, whether it is 80 days or 90 days, but yeah, we provided authorization within 120 days. When I said 120 days, that is for the comment for a completed application.

Alan Pearson: Thank you, Subray. The next question is for Bernadette. “In past stakeholder meetings, we've provided an update on BRS staffing. Is BRS expected to need or request additional staff to continue to implement the revised 340 regulations?”

Bernadette Juarez: Thanks for that question. So, it's not appropriate for me to talk about budget requests. What I will say is that BRS' budget has remained relatively static for the past decade, and we do anticipate an increased demand for services related to biotechnology, for all of the reasons that Anastasia discussed, and for all of the reasons we've discussed throughout this session, about the interest in using biotechnology to solve tough challenges and that sort of thing. So I hope that answers your question to the extent I'm able to. Thank you.

Alan Pearson: Okay. The next question is, “How is USDA working with the Nagoya Protocol requirements?" So I'll turn that over to Jessica, or perhaps Anastasia, for responses on that.

Jessica Mahalingappa: Thanks, Alan. We're not, as far as BRS goes, we're not working on that particular protocol, it's on sharing of genetic resources, that's part of the Convention on Biological Diversity. We're not really, we're not a party to it. I don't know if other parts of USDA might be, but it doesn't really enter into our regulatory role. Anastasia, do you have anything you want to add there?

Anastasia Bodnar: I can just add that USDA does engage in a variety of research partnerships with other countries and the ideas of fair and equitable sharing of genetic resources are important, but we aren't necessarily working through the Nagoya Protocol specifically. Thanks.

Alan Pearson: Okay let me see if there are any questions on the phone or through the webinar, verbal questions, oral questions.

Adam: All right and just reminder, ladies and gentlemen, you can raise your hand using the raise hand icon located in the top right hand corner of the WebEx chat window, or if you dialed in on the phone-only line, you can press #2 to enter the queue. And I do see, we have one question already. [crosstalk 01:18:41] Please go ahead.

Speaker 2: Thank you much. I think my question would go to Jessica. So, Europe has made a decision to still require permits, I believe, for what we are deregulating as far as stack traits. And it sounds like Mexico also has made a decision, too, to not allow deregulation. My question is, will they still take product from America regarding...is that going to influence their decision on, maybe, trade disputes or anything?

Jessica Mahalingappa: Yeah, well, any disruptions or trade disputes is what we hope does not happen as a result of our regulations. That's why we're talking with countries to make sure that they understand what we're doing, that they have a comfort level in there. But I haven't heard of any specific trade disputes as a result of the changes to our regulations. But that's something that we are interested in hearing about and trying to avoid any disruptions. Absolutely.

Speaker 2: Okay and then as a follow up to that, cause it is potential, is there any sort of outreach program to our farmers, or anything like that, that would ask for their opinion on the matter? Is there a comment period on that type of thought process?

Jessica Mahalingappa: Any producer, or really, any citizen, anybody who wants to, may comment on the guidance that we put out there, as far as any changes to our regulations or guidance or procedures. So yeah, those producers with concerns can absolutely make comments. Everybody's welcome.

Speaker 2: Do you plan for there to be a specific outreach or anything like, "Hey, this is what we're getting ready to engage in". Do you guys have...does the public, because I haven't ever heard any news on any of this stuff like in the media, so I'm just wondering, are you guys going to take an outreach effort to maybe put it...is there any options or is there any sort of game plan that you guys are going to do that makes it more public?

Bernadette Juarez: I'll go ahead and weigh in here on a couple of things. First, I know that Secretary Vilsack has met with counterparts in Mexico several times and at the forefront of the conversation is biotechnology and we're seeing some solid progress there. So do know that his eye is on the ball when it comes to international discussions, particularly with Mexico and as it relates to biotechnology. Second, within the Department of Agriculture, we have a Foreign Ag Service, Agriculture Service, who really takes the broad lead in engaging in bilateral discussions or just international discussions related to biotechnology and working closely with the Secretary's office in connection with those conversations. We have a small international program here in BRS that we use to support our Foreign Agriculture Service at the department level, and to engage in additional bilateral discussions, particularly with other regulators in other countries.

So we'll take your question back and make sure that FAS, our Foreign Ag Service, is aware that there is strong interest from members of the public in knowing how they're approaching engagement with respect to biotechnology. And also, I just wanted to point out that, I think maybe you asked about publicizing information regarding our program, and we did send out a tweet in connection with this message, or with this meeting, to try to use other avenues beyond our stakeholder registry and website to get information out regarding our program.

Speaker 2: Well, that's just fabulous. I appreciate the engagement.

Bernadette Juarez: It's our pleasure.

Alan Pearson: Are there any other questions over the phone or through the webinar oral questions?

Adam: I do not see any additional questions in the verbal queue at this time.

Alan Pearson: Okay then, we will take just a couple of more written questions and then wrap up so that we can take a break and go into our eFile. There was a question about MOUs because BRS has completed MOUs with other coordinated framework agencies over the years. The question was whether finalization of part 340 revisions has resulted in a need to update or revise those MOUs. I would say that the 340 revisions in and of themselves have not resulted in that need. We are looking at some of the MOUs simply because some of them are longstanding and do need to be revisited. That's a process that will play out over time. Doug, there's a question for you about whether BRS is considering exempting contained shipments from the requirement for permits, since the statement that such shipments are unlikely to pose a plant pest risk.

Doug Grant: Thank you, Alan. The answer to that question is not at this time. I think it's important to look at the language in the regulations and I would specifically encourage folks to look at the language under subsection 340.2 and 340.5. 340.2 starts with, "Except under a permit issued by the administrator in accordance with subsection 340.5, no person shall move any GE organism that, a) is a plant that has a Plant-Trait-Mechanism of Action combination that has not been evaluated by APHIS," et cetera. So I think the real mechanism for such exemptions would be on a case-by-case basis and would be dependent on the type of modifications that were made. I don't think that that's something that could be proposed through our current exemption process and it might actually require a change in regulations, but I do think that that is a good question. I appreciate the opportunity to respond.

Alan Pearson: Thank you. One more question for Subray. How many days does BRS need to process a permit for import or interstate movement?

Subray Hegde: The revised regulation, we said for importation and interstate movement, BRS will provide authorization within 45 days for all the completed applications.

Alan Pearson: Okay, thank you. And then I saw a comment. Well, thank you for that comment. A final question for Bernadette, referring actually back to Subray's presentation, the regulation says that we are regulating the movement organisms that have been modified by genetic engineering and the regulation defines the term genetic engineering.

Alan Pearson: . The slides that BRS uses the term modified organism when it's referring to organisms that are subject to the regulation is our new use of the term modified organism for organisms that fall into this regulation doesn't mean something other than the revised definition, [inaudible 01:27:22] more genetic engineering.

Bernadette Juarez: Okay. Thank you for that question. The regulatory definition defines genetic engineering, not genetically engineered. And although in some instances in the regulations, we've used GE to modify the word plant really from a regulatory definition perspective what we're focused on is, is the technique of genetic engineering. When a modified plant is subject to the regulations, it means it's a plant that's been developed using genetic engineering. In general, we seek to avoid using the label GE before plant or organism to avoid confusion as you've pointed out here.

Alan Pearson: Thank you. We had one other question around the definition of plant pest and what would be considered the plant pest. We addressed that question in some detail, in the preamble of the proposed rule. We're happy to provide an answer, but we will want to take some time to make sure that we can clearly articulate a very clear, straightforward answer to everybody that where there will be no, no ambiguity.

So we will answer that question in a Q and A document after this stakeholder meeting. Beyond that, I think that wraps up the Q and A unless we have any additional questions on the line.

Adam: We don't have any verbal questions in the queue at this time.

Alan Pearson: Okay. Well, I want to thank you all for attending the stakeholder meeting today and for all of your questions and remind you, we're going to have a five minute break now, and then we'll have an eFile breakout session. That's going to provide more detailed information on eFile developments for those of you who are interested.

Whether you're staying on for that breakout session or not, we were very glad you were able to join us today and we look forward to seeing you again next year hopefully in person. Wish you the very best in health for the upcoming holidays. Thank you for attending. We'll take a five minute break now and see those of you who want to stay on in five minutes.

(silence)

Speaker 5: Just reminder to everyone to re-mute yourself.

Alan Pearson: Welcome back to everyone who's decided to stay for our breakout session on a APHIS eFile. I'm pleased introduce again, Miranda Wanex who will lead us through this session, Miranda.

Adam: And Miranda you're on mute.

Miranda Wanex: Sorry. Welcome back everyone. So once again, my name is Miranda Wanex and I'm both a management analyst with BRS' communications group and BRS' lead for the APHIS eFile project. Earlier in the meeting, we shared a brief overview of the updates paid in 2021 and the enhancements to come in 22.

We'd like to share some more detailed information with interested stakeholders, primarily applicants who currently use or will use the APHIS eFile system. So thank you for your additional time this afternoon. I hope this leaves you just as excited as we are about the new features we have introduced to the system, as well as those to come.

Just a reminder, you'll find a summary of the same information in the handout available on BRS' website. So feel free to go grab a copy for yourself at the end of the meeting. For this breakout, we'll cover three topics. First we'll share a brief demo of our new tool called the BRS Permitting Assistant and show you where it can be accessed.

Next, we'll provide more detailed information about some upcoming system enhancement that will improve the applicant experience in the new system. And finally, we'd like to use this opportunity to cover some updates that are coming to required information for location records. So without further ado, let's get started. Bear with me just one moment while I switch my screen.

Okay. Hopefully everybody should be able to see my screen. It seems like somebody needs to mute their microphone. Okay. Thank you. Alright, so on my screen, you should see the APHIS eFile homepage.

This page is accessible to all users, regardless of whether you have an active account and is the first result in most search engines if you search for APHIS eFile. From this homepage, you can see an area to begin an application and an area underneath that includes several quick links for various APHIS processes.

BRS' Permitting Assistant may be accessed by clicking the link on the card with the microscope icon or by attempting to start a new application. The APHIS form 2000 web option in the start application dropdown.

On the following page, users will see some instructional help text outlining the steps for using the tool. Further down, you'll find an area with three steps. The first bit of info needed on step one is the name of the organism you're working with. I'll start with soybean as the organism I'm looking up. You can type the organism common name or scientific name into the box and select from the dropdown options.

You can also click the link here to see the full list of organisms and choose the organism name that way. New values are being added on a regular basis. So if

you can't find the organism you're working with, please reach out to our help desk to have it added.

To continue, you'll also need to provide the intended use. Some help text is provided to help guide your selection, but more likely than not the intended use for most applicants is traditional. So that's what I'll select.

Next is drop down to ask what you're applying for? All options available on the screen right now may not be present depending on the answer to the previous questions.

If I want to go straight to a permit application or see some onscreen guidance for submitting a confirmation request or regulatory status review, I can select either of these options. If I'm not sure whether my organism requires a permit or might be eligible for a confirmation request, I can select the “help me decide” option.

Lastly, I'll need to provide the movement type and then I'll hit Search to continue. Let's do interstate movement. When selecting the “help me decide” option applicants will see some additional questions posed in step two.

Applicants should answer each question one at a time from top to bottom, as later questions may not be applicable depending on the input provided. Here I'll say no, I'll say no here. And lastly, we'll answer no. You should continue providing the responses until a single outcome remains in step three.

That outcome will be a good indicator of whether a permit is needed based on the answers provided. Here we can see that based on my answers. I do need a permit for this movement. If you'd like to go straight to a permit application, you can always select the permit option from step one.

For most organisms that do not have exemptions listed in the regulations no additional questions will be asked in step two and you'll be able to quickly get started on a permit application. I'll clear my answers and select corn as my new organism.

I'll choose traditional once more. And then I'll select the permit option as well as interstate movement. As you can see, the outcome will show as needing a permit. I can add that outcome to my cart, and proceed with starting an application.

Past this point I'll need to log in with my e-Authentication account credentials. So we'll end the demo here and switch back to the presentation. I hope you found this overview helpful and feel comfortable using the BRS Permitting

Assistant next time you're unsure whether you need a permit. Give me just one moment to switch back to the presentation.

Okay. So next I'd like to share a bit more about the enhancements coming with BRS' deck system update. The development BRS is working on seeks to improve four key areas for all applicants.

One, submitting and processing large applications; two, generating PDFs; three, improving the XML-upload interface and data handling. Lastly, bringing both the application and review interfaces into a more streamlined and modernized look and feel.

The changes aim to make the amount of data that can be submitted on an application, much more flexible, and to make BRS' interface more user friendly for all developers who submit permit applications to BRS.

First, let's talk about the improvements to large application submission. In the last year, we learned that when thousands of records are entered on a single application, it causes some processing issues in APHIS eFile particularly when applicants try to submit the application.

With our upcoming solution, all applications will be moved into a queue when you submit allowing the system more time to work through all the data pieces, to turn an application into a submitted authorization. This queue will be first in, first out, and processing applications one at a time.

So you might see this take some time on days where there are large numbers of applications being submitted. As soon as all the data is processed, the submitter will get an email from the system that the application was submitted successfully. And you'll also see the application status change to submitted.

Next, we are working to improve the PDF generation functionality throughout the application process. As the system works now, the PDF's attempt to pull all the data throughout the different records into a PDF preview real time, which runs against a timeout limit in the case of larger applications.

After these updates are made, you won't need to watch a spinning circle icon waiting for the system to generate the preview copies. Instead, you'll click a button that will generate that document in the background, and it will become available for you in a downloadable format as soon as it is finished.

This will make it easier for applicants to see a preview of their submission, regardless of how much data is contained inside. Moving on to XML improvements, we'll be upgrading the XML user interface to a modernized look

and feel which lets us double the amount of data that can be uploaded into an XML or in an XML file from 10 megabytes to 20 megabytes.

XML applications will be able to hold approximately 20 million characters as a result, which is double the previous limits. Finally, these updates will let us sort the upload history backwards by default. So that the more recently uploaded file is on top, not at the back of the list.

The last set of changes in this update is to bring both the applicant interface and BRS' review interface into the more modernized UI that you might already be familiar with if you submit any PPQ or VS applications in the new system.

This update will preserve the existing functionality of BRS' applications, but also gives us an opportunity to make improvements. For example, these changes will enable BRS to make deletion functionality available in the SOP and attachment area to give applicants better control of their supplemental documents prior to submission plus each section of the application will include a save and next button so that the data is saved as you move between sections of the application.

Finally, this update will also streamline BRS' review interface so that large amounts of data can be processed with ease and application turnaround times can be improved.

The delivery date for this release is March 23rd of next year. BRS will be involving applicants in the testing of these new features. If you're interested in participating in testing, please shoot us an email at the help desk shown on screen.

As features are made ready for testing, we'll be reaching out to interested applicants with the scheduled dates and instructions for participation. A new interface means that BRS' existing resources will need to be updated and will need to give some fresh training to applicants as well.

Those training opportunities will be announced to users who have A) submitted applications and e-Permits, B) submitted applications in APHIS eFile, and lastly to BRS' stakeholder registry.

If you'd like to be kept in the loop on these training dates, look for the images below on the BRS website. These will help get you signed up for BRS' stakeholder registry so you won't miss these training notifications when they come out.

Finally, in order to align with the revised 7 CFR part 340, some additional information will be required on location for locations on permit applications. On

January 1st, 2022, the following fields will need to be filled out on most origin locations, all destination locations, all origin plus destination locations, plus all release sites.

We're going to need a street address for the location, a city name, and a zip code. Most applicants already provide this information, but following this update BRS will not be able to process your application without these details entered in the correct fields.

The exception to this role is origin locations on import permits. We recognize that a street address and zip code may not be available for foreign locations. So only city will be required for these origin locations. In the case that your location does not yet have a street address, please provide a GPS coordinate for the location in that field instead.

That'll help you get past the validation and will tell BRS where that site is located. Additionally, all locations must include at least one agent, AKA location contact, moving forward. You'll need to minimally provide the individual's job title, first name, last name, primary phone number, and email address in order to save the record and submit the application.

If you're an XML applicant and need some extra time to adjust your outputs to match this format, feel free to reach out and let us know. And we'll work with you to set a timeline that matches your organization's needs.

Just a reminder the APHIS eFile handouts provided on our website, help outline the information that's required for each location on each permit type. Feel free to use that as a reference to prepare for the location changes taking effect soon. And that's all I have for you today. Are there any questions about the information I've shared in this update?

Alan Pearson: No questions. Yeah, go ahead.

Adam: Just reminder to our audience that if you wish to ask a verbal question, you can use the raise hand icon located in the top-right of the chat window. If you're on the phone only line, you can press pound two on your telephone keypad. And I do not see any verbal questions at this time.

Miranda Wanex: Looks like we had a couple questions in the chat box. First was a request to demo a microbial application. I'm so sorry I couldn't see the chat during the demonstration. Ida, if you'd like to reach out to the eFile help desk, I can definitely work with you if you're having any trouble using the permitting assistant for microbial applications.

Alan Pearson: There's also a question. “Why is BRS requiring an agent for each location? What's the expectation for APHIS to reach out to the agent versus the permit holder?” Miranda do you want to take that or should I pass that over to Doug?

Miranda Wanex: I’d appreciate Doug's answer.

Doug Grant: Alan, can you ask the question one more time.

Alan Pearson: Yes. The question is “why is BRS requiring an agent for each location? What is the expectation for APHIS to reach out to the agent versus the permit holder?”

Doug Grant: Thank you. I see the question now in the chat, so there needs to be an agent affiliated with each location, and that can be one agent that is affiliated with more than one location. So that agent is then responsible for the activities that are occurring under that location that responsibility ultimately falls back to the permit applicant, which is also known as the responsible party in our previous vernacular. So, yeah that's important.

The second part, “What is the expectation for APHIS to reach out to the agent versus the permit holder?” When we're scheduling an inspection to conduct at a particular field trial site location, we will be in contact with the agent and you might have heard me use the term site cooperator previously and in my presentation, which is under the revised regulations, the equivalent to the term agent.

So yes, APHIS will reach out to that agent. That's why we need their contact information to schedule inspections. And if we're unable to reach that agent, then of course we would reach back out to the permit holder to make sure we can contact the correct individual when scheduling an inspection. Thank you.

Alan Pearson: Thank you. Doug would you like to take the next question also, which is asking “Why would a street address be needed for a location when GPS provided in the application?”

Doug Grant: So, we actually provide oversight of the entire movement, as well as the release into the environment. And we don't inspect every facility, that's receiving a shipment of regulated material, but we will often inspect facilities that are being used for storing or processing regulated material either before planting or after harvest.

And so we want to have the information for all of the locations that will be used. And that includes not just the locations for the field release, but also the locations involved the movement. And that's kind of part of saying that organisms, regulated organisms may be maintained only in areas and premises as specified in the permit.

Alan Pearson: I'm not seeing any other questions here. I'll give it one more moment. Before we wrap up, we're hitting three o'clock. Okay then, a final thank you to everyone for joining us today. We enjoyed having you here for both the stakeholder meeting and this breakout session after the meeting. And we look forward to seeing you again in the new year, both in video conferences, as well as in person. I hope you all have a great rest of your year. Thank you.

Adam: Ladies and gentlemen, and this concludes our webinar. Thank you for using Event Services and you may now disconnect.