APHIS BRS Stakeholder Meeting Transcript
December 8, 2022

Speaker 1: Welcome and thank you for joining today's BRS stakeholder meeting. Before we begin, please ensure you've opened the WebEx chat panel using the associated icon on the bottom right corner of your screen. Please note that all audio connections are muted. You are, however, welcome to submit questions throughout the presentation and these will be addressed during Q&A. To submit your questions in writing, select all panelists from the dropdown menu in the chat panel, enter your question in the box provided, and send. As a reminder, this conference is being recorded. If you require technical assistance, please send a chat to the event producer. With that, I'll turn the conference over to Jessica Mahalingappa, BRS Associate Deputy Administrator. Please go ahead. The microphone is muted, and we can't hear. One second.

Jessica Mahalingappa: Okay. Is that better?

Speaker 1: There. Got it.

Jessica Mahalingappa: Can you hear me?

Speaker 1: Yes, we can.

Jessica Mahalingappa: Okay, great. All right, to those in the room, yeah, please go ahead and get yourselves snacks and feel like at home to move around if you need to, to get yourself coffee. We do not, I had this question earlier, so I'll let everybody else know, we are going to take a couple of breaks, but we do not intend to break for lunch, so we encourage you to eat those snacks that are in the back. It's been great so far, even just seeing the folks who've come into the building for the first time in a couple of years, or maybe the first time ever, for some of you. So welcome. As the event producer mentioned, I'm Jessica Mahalingappa, the Associate Deputy Administrator for BRS. This is also my first in-person BRS stakeholder meeting since I joined during the pandemic, so I'm really excited to represent all the great BRS staff that are in the room and online who've made this event possible.

Those of you who are familiar with BRS may realize that we're missing a couple of key people here this morning. Bernadette Juarez, our deputy administrator, as well as Alan Pearson, our assistant deputy administrator, could not be here today. So, I actually have a quick note from Bernadette to read to welcome everybody because she and Alan both played a big role in setting the agenda and developing the presentations for this morning. So, from Bernadette, "We're excited to reestablish our in-person stakeholder meeting after a two-year hiatus. By continuing to offer a hybrid option, we're able to expand participation

and information sharing. With this year's meeting, reaching over 270 registrants after months of planning, we're glad to reconnect with you today. We have incorporated the agenda items you suggested and acted on feedback we received over the course of the year, in terms of information and updates of interest to you. Although I regret that personal matters have taken Alan and me away from the National Capital area, I know that you're in good hands with our well-prepared team. Enjoy the presentations, the opportunity to interact with our team, and refreshments at the back of the room."

So that's from Bernadette and I just want to close by saying that we're hoping that we have established a good setup to make both the in-person and the virtual meeting a really good one for everybody, but there are plenty of staff around both online and in the room here. We have a great team who can respond if you are having any issues with either hearing or seeing the presentations or if you have questions. So just wanted to let you know that we're open to feedback on that either now or after the meeting because we're breaking new ground here with this large number of people, trying to make it a really good meeting for both hybrid, for both virtual and in person.

Okay, now it's my pleasure to introduce our APHIS associate administrator, Mike Watson. Many of you recall that Mike was in leadership at BRS for many years, previously serving as the director of biotech risk analysis branch that Subray Hegde now holds. Since then, Dr. Watson has served as a senior leader in plant protection and quarantine at APHIS in marketing regulatory programs, human resources division. He's also championed APHIS Science Committee, and the science program, and the Office of Science, and has more recently been coordinating our efforts in the American Rescue Plan among many other things. Dr. Watson, welcome back to BRS. We're happy to have you here today.

Dr. Watson: Thank, Jessica, and good morning everyone. It's really great to see so many familiar faces. It's nice to rejoin the BRS stakeholder meeting. For me, it's really hard to believe, and Jessica mentioned my time at BRS, it's hard to believe it's been 12 years since I left BRS, but I'm really impressed with all the great things that BRS has accomplished during that time, and it's also really has been great to see the advancements in the technology during that time as well. So, I'm sure today will be a really great conversation about what we're doing these days and what we're going to see coming up at us in the future as well.

I'm pleased that the deputy undersecretary for USDA's marketing and regulatory programs, Katie Zenk is here with us today and Katie's going to talk to us about USDA's vision for the role that biotechnology can play in U.S. agriculture. So, it's really been a pleasure of mine to work with Katie over the past couple years and given that experience working with her, I can honestly say Katie truly knows agriculture from serving on the U.S. House Ag Committee as staff director of the subcommittee on Livestock and Foreign Agriculture, Economist for the full committee, and professional staff during consideration of 2018 Farm Bill to working with Land O'Lakes. Katie's seen firsthand the importance of taking care of our land, the people who farm, and all those

supporting American agriculture. Katie is a native of Danube, Minnesota, and holds a bachelor's degree from the University of Minnesota Twin Cities, a Master of Science in agricultural economics from Purdue University, and an MBA from Indiana University. Again, we are glad Katie can join us to kickoff this meeting and it's my pleasure to introduce the deputy undersecretary Katie Zenk. Good morning, Katie.

Katie Zenk: Thanks Mike, and thanks everyone. It's great to be with you even virtually, and I can sincerely say I would much rather be in the room with you all instead of as a giant head on your screen this morning, but I am in western Minnesota with family for a day handling some frigid temperatures, but I'm really glad to see so many developers, NGOs, state, federal, and international partners joining us today. Thank you so much for taking time out of your days to share your perspectives and insights with us. This is an energizing group to join this morning and it's a very exciting topic. As you all well know, biotechnology plays a key role in agriculture's global competitiveness and our ability to adapt to some of the biggest challenges of our day, including climate change. At USDA, we are committed to supporting this innovation while ensuring the safety and sustainability of these products through our regulatory approach.

This flexibility will be critical as we continue to address the new challenges going forward, especially related to climate change. USDA is fully committed to the president's whole of government efforts to reduce climate impacts and improve food and agriculture's resilience to climate and supply chain shocks. Agricultural biotechnology can be an important tool to help maintain and increase food production, which in turn reduces poverty, improves global food security, and lessens the environmental impacts from agriculture. That's why we know agricultural biotechnology is part of USDA's toolkit for a healthier planet in a sustainable future. For example, products developed with agricultural biotechnology can help reduce greenhouse gas emissions and can help us cut back on food waste. New cover crops can remove more carbon dioxide from the atmosphere, and they can also provide sustainable biofuels. And our friends across all of APHIS are also acutely aware that climate change has impacted the spread of some pests and diseases, and that means that making new tools to fight those concerns is more important than ever, and new traits that can help produce stay fresh longer will be vital.

As we look to continue to support access to fresh fruits and vegetables in every community across our country, innovation is key to driving continued progress in the biotechnology space and in helping us to create a more secure sustainable future. I'd like to give a couple recent examples of the work that APHIS has done in the last year to help move us forward in this regard. As you likely know, the agency reviewed a new purple tomato, which was modified to alter its color and nutritional value, as well as corn for animal feed that was altered to improve digestion, and also a non-browning potato and apple. These were the first products that were reviewed under our new regulatory status review process, which developers can use when they believe a modified plant is not subject to regulation. From our perspective, these new products are unlikely

to pose a plant risk, which brings them closer to commercialization and to broader use.

These are just a couple of examples of recent innovations that we are very excited about, and this administration continues to be focused on doing even more. Just in September, President Biden signed an executive order on advancing biotechnology and biomanufacturing innovation for a sustainable, safe, and secure American bioeconomy, and I see that we are lucky enough today to be joined by Anastasia Bodnar, USDA's biotechnology coordinator, who's been leading USDA's role in implementing this executive order. In the coming months, we will be assessing how to use biotechnology and biomanufacturing for further innovation in the food and agriculture sectors. USDA will do this through new and existing programs. We will use high quality, accessible and secure data sets to drive breakthroughs and to address the need gaps that we discover.

And we are supporting current and new grant programs to encourage climate smart production and uses for domestic bio-based products. In closing, thank you again for joining us today. I'm looking forward to working closely with you as we continue to advance innovation and transform the food and agricultural systems in this country, and to address the many challenges that we face together. Thank you again for your time and for your partnership, and I hope that today is a welcome and successful meeting. Thank you.

Janice Strachan: Thank you, Katie, for those wonderful words of welcome. My name is Janice Strachan. I'm a biotechnologist in the plant evaluation branch, and I will be your MC today. Let me get the PowerPoint up and running and then let me get... All right. The first thing I want to do is to give an overview of our agenda, so we all know where we're heading today.

The first item is a speech about the Biotechnology/Bioeconomy executive order, followed by a talk about Confirmation Request, and then another talk about Regulatory Status Reviews. We are going to hold questions for those speeches until our Q&A session at the end of those presentations. We will then have a short break where we can go across the hall for facilities or go back to the refreshment table and get additional drinks and snacks. Then we will come back and have a few more presentations. The first one, Permits Update, Microbes Update, Compliance and Inspections Update, and then our final presentation, International Engagement, and then we will have a second Q&A session. Thank you all for being here today. We're so excited to see all of you online and in the room. Let us begin with Anastasia Bodnar, the USDA Biotechnology Coordinator, speaking about the biotechnology and bioeconomy executive order. Anastasia?

Anastasia Bodnar: Okay, thank you so much. I'm very happy for the opportunity to talk about this important executive order and USDA'S efforts to grow the bioeconomy. I do apologize for not being there in person. I'm actually out here in the Midwest working with academics, meeting with industry on the bioeconomy. Next slide.

In September of this year, the White House published this executive order on advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy. Through this executive order, the administration aims to promote and protect the US Bioeconomy with biotechnology and bio-manufacturing innovation. Next slide.

I'd like to briefly go over some definitions in the executive order. The Bioeconomy is economic activity derived from the life sciences. And broadly, this means taking domestic, agricultural and forestry products, as well as waste, and transforming them with biological or chemical processes into intermediates and products that we need. Biotechnology in the EO is defined quite broadly as technology enabled by the life sciences, which is a little bit different than how we typically talk about biotechnology in the context of biotechnology regulatory services. Next.

USDA, excuse me. USDA is working to support the National Biotechnology and Biomanufacturing initiative that's established by this executive order, and it's really a whole of USDA effort with many agencies contributing, including Animal and Plant Health Inspection Service. USDA's role here is to help improve food security, strengthen supply chains, reduce impacts of climate change, and create jobs across America. It's also a whole of government effort with every federal department leading and contributing in different ways. Next slide.

So, I'll quickly go through some of the tasks that USDA is leading in this executive order. In section three of the executive order, we are asked to develop a report on biotechnology and biomanufacturing research and development for food and agriculture. We're tasked with looking at how to improve sustainability, food quality nutrition, protect against pests and diseases, and cultivating alternative food sources, and all of that using biotechnology and biomanufacturing. We're also supporting other agencies in their leadership of reports on health climate supply chains and cross-cutting research and development. Next slide.

In section five, USDA's tasked with developing a plan for U.S. biomass supply chains for domestic biomanufacturing, and bio-based product manufacturing. We're looking at programs to encourage climate smart production and use of domestic biomass, and while we're growing the supply chains, also advancing food security, sustainability, and the needs of underserved communities. Next slide.

In section six, we're leading and supporting federal efforts to increase domestic production of bio-based products, and that includes training federal purchasing staff on the value of bio-based products and where they can find them, publishing how much bio-based product procurement is done by federal agencies, identifying opportunities for new categories of bio-based products where there isn't already a readily available bio-based alternative, and generally, the administration is tasking agencies with striving to increase bio-based product procurement by 2025. Next slide.

In section eight, USDA, EPA, and FDA are co-leading efforts towards regulatory clarity and efficiency. Our tasks here are to identify areas of ambiguity, gaps, or uncertainties in the coordinated framework for regulation of biotechnology. We are tasked to provide plain language information on the roles, responsibilities, and processes of each regulatory agency. Of course, building on previous efforts under previous executive orders, and then we'll also be identifying regulations, guidance documents that can be created, updated, streamlined, or clarified to help create an enabling environment for biotechnology in our bioeconomy. Next slide.

There are many other activities that USDA is supporting and contributing to in this executive order, including data for the bioeconomy initiative to identify data types and sources that are needed to advance Bioeconomy related research. We're looking at a plan for training and education and how to expand career pathways into biotechnology and biomanufacturing.

There's a biosafety and biosecurity innovation initiative to encourage best practices for biosafety and biosecurity. A plan to measure the bioeconomy. We have to know how much the bioeconomy is producing, and to do that we need things such as a common bioeconomy lexicon so that we're measuring things effectively. There's also a plan for securing the bioeconomy, looking at vulnerabilities, and how to mitigate them. And finally, an international engagement plan where we're tasked with working with foreign partners, organizations, and non-governmental entities to grow the bioeconomy globally, not just domestically. Next.

So importantly, the government doesn't have all of the answers here, so we're seeking stakeholder insights. Already there have been five White House led industry listening sessions on food and... Climate supply chains and cross-cutting research that were extremely informative. We're also going to be releasing two requests for information that hopefully will come out shortly in December, and then there will be two virtual public stakeholder listening sessions in January.

We're also looking at specific requests that we're hoping to get input on from stakeholders, and those include short and long-term bold goals in food and agriculture that could be achieved with biotechnology and bio manufacturing. Where do you see the technology going in the future? How the federal government can work with both public and private sectors to achieve the goals. Successes, what's already working to accelerate the bioeconomy innovation? And then importantly, what are the challenges and the opportunities for resolving those challenges to encourage innovation? So, I definitely encourage everyone on this stakeholder meeting to take a look for those requests for information and provide input. We really need you in order to make sure that all of these plans and reports are effectively growing the U.S. bioeconomy. Thank you.

Janice Strachan: Thank you, Anastasia, for that excellent update. Our next presentation will be by Michael Stulberg. He is a senior biological scientist in the plants branch

biotechnology risk analysis programs, and his presentation is about confirmation request. Michael?

Michael Stulberg: Great. Thank you, Janice, and thank you everyone here today for giving me this opportunity to provide an update on our responses to requests for confirmation of exemption from 7 CFR part 340. Little delay. So, from August 2020 to November 7th, 2022, we received a total of 49 requests, and we have issued 24 confirmation letters. So, you can see the breakdown here. Received, this is 49, and we've confirmed and posted to our website 24 letters.

So, the large difference between the number received and confirmed is not because we have a large queue, but rather we are seeing a couple of issues that were common among some of those requests that gave us reason, that prompted us to update our CR guide, which I'll review those changes later in the presentation. One common issue was an understanding of what we meant by single modification for exemption 340.1(b)(1) where we mean a single target DNA break rather than a single deletion, that may have resulted from two DNA breaks. We've also received a good many requests that were not confirmed, required substantial revisions, and it was in the best interest of both the submitter and USDA to return those and receive entirely new ones.

This is a summary of the types of exemptions that have been confirmed. So, on the left are snippets of the regulation and they're grouped into two different categories. The B type exemptions or those equivalent to conventional breeding, which you can see have accounted for two thirds of our confirmation letters. And then the C type exemptions, or those that have the same plant trait mechanism of action combination that has previously undergone analysis, either through the petition or the RSR process and found not subject to the regulation. The PTMOA exemption, we've issued eight confirmation letters there, and these under the legacy regulations would've been petition extensions. We can also look at the types of submitters that have received confirmation letters, have been primarily small and medium size enterprises, though there have been a few academia and large companies. Also, we've seen a variety of plants that have been subject of those letters, right, so we've issued 24 confirmation letters, and it's been for 15 different types of plants.

Our regulations in 340.1(e), indicate that we'll provide confirmation letters within 120 days of receiving a sufficiently detailed request, and has taken us on average 34 days to review whether a request is sufficiently detailed and to notify the requester upon receiving a sufficiently detailed request. It has taken us 43 days on average to send the confirmation letter, and the back and forth has been roughly about 87 days on average. So, this has been meeting our 120 days, and again, as more first submissions are sufficiently detailed upon request, I anticipate that the average of 43 days will actually go up, but the 87 days may go down, although if we see a huge increase in submissions, who knows? So, future's hard to predict, but so far, we are meeting our regulatory goal.

In the hopes of receiving more sufficiently detailed requests on the initial submission, we updated our CR guide and published it to the website on September 1st of this year. We addressed kind of two major points. So, one, we reorganize the sections to better group them based on the equivalent to conventional breeding category and the same plant trait mechanism of action category. We hope that separating these two better clarifies issues related to molecular stacking, which is currently not part of the exemptions equivalent to conventional breeding, but could be exempt for same plant trait mechanism of action if there was a previously reviewed stack that was found not subject to the regulation.

And we also updated our definition of unintended modifications, so we added language to clarify that unintended modifications are the retention of exogenous DNA inserted as part of the modification process, or could be, and modifications to DNA that are highly similar to the target sequence and can be reasonably attributed to the editing process, that we call "Secondary targets". So, for example, we want developers discussing the specificity of their target and how they know, to the best they can with available genetic information, that they're targeting a single location in the genome. Thanks. And here are some resources, a link to the CR table with our confirmation letters and also to our guide.

Janice Strachan: Thank you, Michael, for that update. Very interesting information. Our next speaker is Suma Chakravarthy, sorry, branch chief of the plan evaluation branch biotechnology regulatory risk analysis program, and Subray will help her answer questions later, but I think she's going to do the presentation on her own. She's going to be talking about the regulatory status reviews. Suma?

Suma Chakravarthy: It's Okay. Okay. Good morning. Thank you, Janice for the introduction and welcome to all those attending in person and online. This presentation is about a regulatory status review, RSR, can everybody at the back hear me? Great. Okay. When APHIS receives an RSR request, we will conduct an initial review where we will determine if the GE plant or it's sexually compatible relatives will pose an increased plant pest risk relative to the comparator plant. For this, the following factors will be taken into consideration. The biology of the plant and its sexually compatible relatives, the introduced trait, and the mechanism of action, or MOA, by which the trait is conferred. We will develop documents, internal documents, that support our decision making. At the initial review step, problem formulation will be used to identify if there are any plausible pathways to increase plant pest risk.

Some more detail on our considerations have been provided in the revision to the draft RSR guide, which we expect will be published very soon. In the case when plausible pathways are identified, we will give the developer the option to pause or proceed to PPRA. During PPRA, APHIS will determine the likelihood and consequence of plausible pathways identified in the initial review.

During step one and two, the applicant may choose to apply for a permit to keep their activities ongoing or gather data to inform plausible pathways to plant pest risk. RSR letters will be posted on the website when our determination is complete. If an RSR proceeds to PPRA, that posting will happen when the entire process is completed. Many of you would be familiar with this overview of the RSR process. Receipt of a technically complete request will trigger the initial review process. I would like to describe the situations in which a request is declared incomplete, based on experience we've gained so far. The main reason a request is declared incomplete may be either too much information provided or not meeting minimal data requirements. We wish to receive publicly available information and not unique data which is not yet in the public domain.

Suma Chakravarthy: We welcome citations and references. We will use the literature you provide to conduct our own assessment.

In certain situations, we will allow for some extra information to be provided. For example, when there are novel and complex species, or if the MOA requires more than a few paragraphs of detail.

All this has been mentioned in the revised RSR guide, and this figure is also from the draft RSR guide.

After the initial review, if APHIS does not identify plausible pathways to plant pest risk, then the modified plant is not subject to the regulations.

If plausible pathways are identified and the applicant asks if it's to proceed for a PPRA, there may be two outcomes of that PPRA.

APHIS may determine that the plant is unlikely to pose increased plant pest risk, so not subject to regulations, or if it may be unable to reach that conclusion.

In this latter situation, the plant will be subject to the regulations, and its movement must be authorized under a permit.

There is possibility for that decision to change in the future via a re-review. If new scientific evidence becomes available that could inform the plausible pathways identified, then APHIS may redo the PPRA. APHIS will consult with the applicant before proceeding for re-review.

RSR focuses on a risk-based approach and eases regulatory burden for all developers. In this slide, we show the impact of RSR on innovation.

On the left-hand side, you will see that in the almost 30 years when APHIS accepted petitions, 101 of 135 petitions was submitted by major biotech companies.

A quarter of those petitions were submitted by small and medium enterprises and public developers.

In the two-and-a-half years since RSR was implemented, we already received 34 RSR requests. That number is slightly different as of last week. The slide was prepared prior to that.

27 of the 34, which is about 79%, was submitted by small and medium enterprises and public developers. We've already seen 20 types of crops in RSR, while 19 types were received in petitions.

This slide depicts in percentages the types of crops received in RSR and the nature of modifications they contain. 41% of the modified plants are annuals or row crops.

We've also received modified vegetables and fruits, trees, oilseed, and cover crops. There's a small number of ornamental plants and medicinal plants.

Most of the requests we received are for plants developed using transgenesis, while 28% were created using genome edits. Genome editing.

The deputy undersecretary referred to some of the RSRs which have completed step one, and this slide shows them in some detail.

These are the plants for which APHIS determined that the plant is not subject to the regulations. Norfolk Plant Sciences develop purple tomato with increased anthocyanin production.

Agrivida developed corn with increased enzyme production for improved digestion when used as feed. Toolgen developed potato with reduced enzymatic browning.

Simplot developed potato with altered tuber quality, reduced sugar in tubers, resistance to fungal and viral disease. Infinite enzymes produced corn with enzyme for potential detoxification.

Most of these plants also contain a marker gene or a gene for herbicide resistance. Within the coming days, we expect a determination on two more RSRs.

When you submit an RSR request, we would like to receive the name of the plant species, information on the introduced trait, the phenotype imparted, and the mechanism of action by which the trait is conferred.

The sequence of the insertion or the edit should be provided. In the case of genome edits, please provide an alignment of the edited region with the comparator sequence.

Reference numbers are requested when available, and the altered or inserted sequence must be annotated.

Just to clarify, because there's been some questions about this, when we say base pair location, it does not mean the region in the chromosome where it was inserted into because RSR is not event-based.

Finally, I'd like to reiterate that the revised RSR guide and response to public comments will be ready to be posted soon.

With that, thank you for your attention, and I turn it back to our wonderful MC, Janice.

Janice Strachan: [inaudible 00:36:56]. Thank you, Suma, for that great update. It's good to see that we have a lot going on in that area. We're now at time for our Q&A Session.

The first session, I'm going to ask Michael, Suma, Subray, and Jessica to come to the stage to fill these particular set of questions.

We're going to attempt to go between the room people that would have a microphone in the middle of the room and the online people. Tyler will be reading those questions in the chat.

If you're a little shy and you don't want to speak in public, there is a box on the side where you can write your question, put it in the box, and we will address it as we have time for that.

I was informed that we have extra time for this Q&A because we're a little ahead of the schedule, which is great. Are there any questions from those in the room for our panel of experts?

Oh, here's a person here. When you start talking, could you identify who you are and who you're representing?

David Heron: Good morning. My name is David Heron. I'm a former member of BRS until about two years ago, and now I'm an in independent consultant.

I have a question about the RSR procedure and the user's guide. I hope that this won't be too much.

The RSR user's guide says that it does not place any new obligations and its only guidance. But in actual practice, the things that are in the user's guide that are not in the regulation are being actually implemented that way.

I'm very interested to see that the short comment period that was over a year ago is going into a final version of the user's guide, and how that will affect RSRs.

That's maybe a more global issue. We just heard that it's taken over a year for APHIS to finish the initial reviews for these RSR requests.

The regulation says that APHIS will complete it in 180 days. What are the plans for APHIS getting to the point where it's completing the RSR initial reviews in the timeframe that's listed, described in the regulation?

Subray Hegde: I request Jessica to talk about why it got delayed, then I can talk over the future. Yeah.

Jessica Mahalingappa: Dave, can you just clarify, are you asking for the delay in reviewing the comments or the reviews of individual requests?

David Heron: Let me focus on an opportunity for you to describe how the program will complete its initial reviews for RSRs in 180 days, instead of more than 360 days. I think we saw 390 up to this point.

How will you get to the point of actually meeting the agency's obligation under the regulation? The public doesn't have an easy mechanism to find the agency for not meeting its regulatory obligation.

Jessica Mahalingappa: Okay. Yeah. You're looking more forward than acknowledging that some of the initial reviews took longer than 180 days. We had implemented...

David Heron: No. No, Jessica. All of them took more than 180 days. All of them took more than a year.

The staff is telling people who submit RSRs that it will take them 30 days even to say, if the RSR request is technically complete.

Now, I was with the program for over 30 years. We could determine technical completeness in less than eight hours if we were being slow.

It's not clear why the staff is telling applicants or requesters that it'll take 30 days for determining technical completeness, and about a year to get a response from the agency when the regulation says the agency will respond within basically six months instead of a year plus.

Jessica Mahalingappa: Okay. Yeah. I acknowledge that the first year while we are developing this process, the timelines were longer than what's in the regulation.

We have taken some steps to increase those or to reduce those timelines. I'll let Subray talk a little bit more about some of the changes that are underway.

You might notice that there's some staff in the room that you may not have met before. That's a big part of what we've done is to be able to bring on some new analysts into the staff.

It's not an easy process to identify good people and bring them on board, but we've been successful so far bringing five people on board.

That's a big step in the right direction and we're learning. Subray, do you want to talk about what's going on in the future?

Subray Hegde: Yeah. Thank you, Dave. I just wanted to correct. I know when the petition became larger and larger in the legacy regulation, we had 30 days to provide technical review. I know Dave could do it in eight hours, but we took more that time.

Coming back to what we are doing, as Jessica said, initially, we took more time for two reasons. We did not have enough staff initially. We added more. Probably, we added 10 more staff members in the last two years, and we are training them.

As you see, we have already provided five, and we are providing two more probably in a week or two. We put a timeline and we are training because it's a new process.

We have a lot of new biotechnologists. We are training them how to do it faster where we can really improve our processes.

For example, whenever we receive an RSR, there are two internal documents we have to prepare. One is called a plant reference document, some of the biology characters of the comparator.

Second one, in a mechanism of action in our development, how exactly you were introduced or modified. Gene would work. If ten people are submitting corn, we have to prepare only one part. We don't need to do that part again and again.

Second one, there are a lot of mechanism of action. If they are very similar, we can use the same document. This is the way. We really want to cut down the review process and we want to.

Our aim is, this year, to provide responses to at least maybe 15, 20 more so that we go back to providing our responses within 180 days. That is our plan. Yeah.

I think what we are doing is more training, how to prepare this document in a very short time. That's what we are trying.

David Heron: Have you set a date for the program to meet the 180 days?

Subray Hegde: Oh, yes. Definitely we want to do.

David Heron: When will BRS meet that?

Subray Hegde: It's very hard to predict when because we are so much backlogged now.

David Heron: So, you have not set a date for when you'll be meeting the 180 days?

Subray Hegde: Right now, I'm not in the position to tell when exactly.

Janice Strachan: Do we have any questions online, Tyler?

Tyler Reid: Yes. One of the questions online from Tracy is, "Has BRS considered a separate mechanism to review a PT-MOA combination for potential synergistic effects if a developer is interested in combining PT-MOAs that have already been approved, but appear separately in the PT-MOA table?"

Subray Hegde: [inaudible 00:45:34]. Okay. Tyler, can you repeat?

Tyler Reid: Yes. It's kind of long, so I'm going to slow down. Has BRS considered a separate mechanism to review a PT-MOA combination for potential synergistic effects if a developer is interested in combining PT-MOAs that have already been approved, but appear separately in the PT-MOA table?

Subray Hegde: Stacking? Yeah. If I understand the question, it looks like a deregulated earlier, the language. Different PT-MOAs.

Individually, they are eligible for exemption, but they want to combine it. How are we going to do it? That is the only thing we look.

If you combine, we just look at, are there any synergistic effect? Yeah. Yes. That's what we said in our guidance. Yeah.

Janice Strachan: All right. Let's take another question in the room. Is there anybody who has a question in the room? Please state your name and which company you represent.

Karen Carr: Sure thing. Karen Carr. I'm with ArentFox Schiff, a law firm here in Washington DC. Just wanted to have a question about the RSR step two process, the PPRA process.

We were glad to see some of the RSR step one's come out, but wanted to know if there was a timeline by which we could expect to see an RSR step two, so that there could be some more transparency about what the factors are that the agency's looking at with respect to those reviews.

Subray Hegde: Colleen, mic is here. It was not working.

Subray Hegde: Karen, can you just basically-

Karen Carr: Would you like me to ask again?

Subray Hegde: Oh, yeah. Yeah. That'll be great. Thank you, Karen.

Karen Carr: That's okay. I can lean down. Thanks. Thanks. I was asking a question about RSR step two in the PPRA process.

Are you able to share a timeline for when we may get to see PPRA step two and a little bit more information in detail about what the agency's going to be looking at in step two?

Since you didn't hear me the first time, I'm Karen Carr with ArentFox Schiff, a law firm in DC. We work with a lot of developers.

Subray Hegde: Okay. Thank you, Karen.

Karen Carr: Sure.

Subray Hegde: I believe you are asking about the timeline for step two and the mechanism, right?

Karen Carr: I'm asking about when the agency may complete its first step two so that we can see that process.

Subray Hegde: Oh, yeah. Our timeline, sorry, it's totally 15 months from the beginning for it completed, I want to make sure.

After the step one, if we find there is a plausible path, we contact the developer and we see exactly what are our questions, what is the particular question, what kind of data.

There are two way we do the step two. One is if the information is publicly available, we will prepare a plant pest risk assessment and an NFR notice for public review and comment, then make a determination.

We may not get any public information data to do plant pest risk assessment, then we would request the developer. This information is needed for us to conduct PPRA.

There are two possibilities for the developer. The data, it can be passed, until they submit the data. When they submit the data, we have to answer within... Let us say, six months, for the initially we felt taken.

We have to answer within nine months, that is the timeline. The PPRA will be a little bit different than what we did for petition, because in petition, we have set up data requirement irrespective of whether the data needed or not.

Here, it's very specific to the question we are asking. I believe we can provide a determination in step two within nine months.

Karen Carr: Just to follow up on that. Are there any in the queue that we can expect to see publicly anytime soon if there's a timeline where we may expect to see those?

Subray Hegde: Yes. We have few of them. We already communicated with the developer on one, and there are three or four more. We are going to communicate our decision regarding plausible pathway to plant pest risk. We have few of them. Yeah.

Karen Carr: Thank you.

Janice Strachan: All right. Let's take another question online, Tyler.

Tyler Reid: A question from Sharon is, "Are there any crops that would not be eligible for the RSR process?"

Subray Hegde: There is none. All crops are eligible for RSR. Certain modifications are not eligible right now. For example, PMPI. PMPI plants are really not eligible for RSR right now. But otherwise, there is no restriction on any plant species.

Janice Strachan: Any other question in the room? I saw somebody over here almost got up before. Give us your name and who you're representing today.

Patrick Henry: Yeah. I'm Patrick Henry... I'm... Can you hear me? I'm Patrick Henry pitching with Indigo Ag. I had a question about the impact on commercialization of the RSR outcome.

If a modified blend is considered to be a plant pest risk, therefore, it is subject to regulations.

Does that mean automatically that this outcome means the modified plant cannot be commercialized or are there scenarios under which commercialization will be possible?

Subray Hegde: I think even without RSR, someone can have a permit and things can be commercialized like PMPI right now. They're all in permits. They're all in commercial production.

This commercial production, it depends on the intent. For example, if there are food feed risk, if it's for the purpose of the food or feed, probably they go to FDA in a voluntary consultation. If it's a PIP, then they also have to go to Environmental Protection Agency because they also regulate PIPs.

When in RSR we say it is still subjected to regulation, it doesn't mean it cannot be commercialized. If you move, for USDA, an interstate movement importation or environmental release would be under permit.

Janice Strachan: Do we have another online question, Tyler?

Tyler Reid: This one I think partially was answered but I'm going to propose it again. Has any of the submitted RSRs already moved to the RSR step two process? Do you have processes in place to know how to process RSRs that move to step two?

Subray Hegde: Yeah. As we answered earlier for Karen, yes. Already, there is one RSR request has gone to step two, and we are expecting few more on incoming days. We know how to do it, yeah, the process.

Janice Strachan: All right. Back in the room. Is there another question? Come on over to the microphone and please state your name and who you're representing.

Cory Sanchez: Good morning. My name's... Is it morning? Almost noon. My name's Cory Sanchez. I'm with Suntory Flowers. General question. RS... RS... Thank you. I'm a little nervous.

Is there a priority... for example, are the applications received and approved are communicated in line or is there a priority over food, plants, ornamental, for example?

Subray Hegde: No, there is no priority. We are just looking into when it was submitted, and we are trying to go based on the sequence we received. We are trying to work on RSR which are already created. The products are already created.

Over theoretical, if somebody says, "I want to do this one," okay, because it is allowed, any theoretical products. If somebody has a theoretical product, someone has already created the product, our priority is on the one which is already created.

Second one. Some time, we can make a decision. Oh, yeah. We can. Probably, this will be the step one. Initial review only over the PPRA.

If there are species very common, for example, corn. We may look at bunch of them together just to get rid of what you call reduce our backlog in the initial.

Our priority is always, when it was submitted, in 180 days, which we are trying now, which we are not done so far. So That is the way we are looking at.

We want to improve the efficiency, but initially, we want to provide more responses to remove the backlog.

Janice Strachan: I understand we have time for one more question. Tyler, do you have another online question?

Tyler Reid: Yes. Another question from Tracy. When will a decision be made regarding the new exemptions proposed last year?

Subray Hegde: Jessica, do you want to answer?

Jessica Mahalingappa: Yeah. We don't have an exact timeline. We can't really predict. We're looking at the comments that we received and hope to be able to go public with our decision soon, but we don't have a specific timeline yet.

Janice Strachan: All right. Thank you to our panel for answering the questions that everyone has been thinking in their mind. We're now going to take a break. Are we coming back at 12:20? 12:15?

All right. We're going to come back at 12:15. Remember, there are refreshments in the back and the facilities are right across the hall from this room.

I'll be back up here in... What? 10 minutes? 15 minutes, yeah. All right. We'll see you at 12:15.

Janice Strachan: Hello? I'm not sure if you can hear me, but we're trying to get started again. If you could sit back down, that would be lovely. I have been told that our break is over. Hello? Hello?

Speaker 2: Okay. I just want to make sure I heard that right.

Janice Strachan: All right. For those people who are still getting a cup of coffee, please finish getting your refreshments and come sit down. Thank you for that. I'm trying to get them to come. All right. I hear a little lull in the conversation. Could everybody come back to their seats? We'd like to get started again. It's quieter now. That's good. If everybody could take their seats, we're going to get started again.

Yeah, I can't do that. If Ken would sit down, everybody around him would sit down. I know he is. All right. It says I'm sharing my PowerPoint. That's good. I didn't undo that. All right. Thank you all for taking your seats again. We have a few more presentations to do and we want to hear all of this wonderful information. Our next presenter is Deshui Zhang. He is the branch chief of the plants branch in the biotechnology risk analysis programs, and he will be updating us on the permits. Deshui.

Deshui Zhang: Okay. Thank you very much, Janice. Good afternoon, everyone. It's an honor for me to have this wonderful opportunity to provide you the update on the BRS permit. I would like to cover two major topic. First with the update on permit followed by the eFile outlook in FY 2023. First, I will start off by providing some context regarding the permit update. Our update cover three fiscal years. Oh Janice, we cannot see that.

Janice Strachan: Yes, I think I'm going to unshare and reshare.

Deshui Zhang: Okay.

Janice Strachan: Because something's not working right here. Let me find my little mouse under your papers. Okay. I'm going to stop sharing and reshare because it's not looking right to me.

Deshui Zhang: Oh, sorry about it.

Janice Strachan: Application. It's not you. All right. Is that better? There's something in our screen that's not showing the slides. And I am sharing them. We're getting some technical problem in there.

Deshui Zhang: Okay.

Janice Strachan: Sorry.

Speaker 3: Is there anything else available?

Janice Strachan: They're actually seeing it over here. Sorry, Deshui.

Deshui Zhang: No.

Oh, now it's back.

Janice Strachan: Now we can see it. All right. Sorry about that, Deshui.

Deshui Zhang: Okay. Pardon me? Oh yeah, how about over here?

Okay, sorry for the technical hiccup. I will continue. As I said earlier, I would like to cover two topic. Beginning with the update on permits followed by the eFile outlook in FY '23. I will start off by providing some context regarding the update. Our update will cover three fiscal years including FI 2020, '21 and '22. The reason for that, FY '20 was the year we review and process all the authorization under the legacy regulations. And we are using the ePermit system. Very few number for permit or notification were processed through the eFile. FY '21 was the year both the legacy regulation and the ePermit system on [inaudible 01:21:56] April 2022.

And lastly, FY '22 was the year we fully implemented the revised regulation and the eFile. With that, first I will give you an update on the total number for authorization. From this chart, you can see in FY 2020, we processed 794 authorizations that include 450 notifications and 340 permits. In FY 2021, we processed a similar number for total authorization. That's about 767. But compared to FY 2020, you can see the big difference. The notification number is reduced significantly. Instead, the permit number increased. And FY '22, there's another significant change. All the authorizations are permits. That's because, as I said earlier, FY '22, we fully implemented the revised regulation. There is no notification applications anymore.

And next, I would like to provide some other perspective of the authorization. First is the type of organism in the authorizations. So, we can break all the authorizations into three major categories that include the plants, arthropods and the microbes. That includes the bacteria, fungi and the plant virus. So, you can see in FY '20, out of nearly 800 authorizations, 686 are for the plants, 89 are for the microbe, 22 are for the arthropod. Actually, this trend is held in a very similar way. Oops. In FY '22, majority of the authorizations are still for the plants and microbe per permit is about the same percentage, like 8% or 9%. The plants is about 86%. And FY '22, we have the similar percentage of plant type authorization. That's about 88%. But it is worth noting in FY '22, we see the pickup of the number of permit for the microbe. That's 97 compared to 76 in FY '21.

Another perspective I want to show is the authorized construct number. As you know, the construct is a very critical component of the permit applications. From this graph, you can see in FY 2020, we authorized nearly 20,000 construct. In FY '21, we authorized above 17,000 construct. In FY '22, we authorized nearly 22,000 construct. A big increase in FY '22 compared to last year. It's about 24% increase. Another perspective of the authorization is the authorized release locations. From this chart, you can see FY '20, we authorized around the 3,000 release locations. In FY '21, we authorized nearly 2,700 or 2,800 release site. But you can see FY '22, there is a big jump. We authorized almost 4,500 different release locations.

It is about 60% increase compared to the year of FY 2021. So, all of these above updates demonstrates the complexity of authorizations is dramatically increased in FY '22 for two reasons. Number one reason is the release location and the construct number has increased compared to the previous years. The second major reason is the notification application was removed because of the new or revised regulation, so it was retired from the revised regulation. So, with this increased complexity of the authorization, that will demand more time, more resource to review. We want to evaluate our performance in terms whether we can process all these complex permit in a timely manner.

We just want to check the processing time by looking into the average application duration. The duration is defined as the time period for permit we receive until we issue the permit. We summarize the duration data based on two raw category. We want to make the distinction between the legacy and the revised regulation. Also, we try to distinguish between amount of different type of permits or notification because we are associated with different target timeframe. For example, for the importation or interstate movement permit, the target timeframe is 60 days under the legacy regulation. However, under the revised regulation, the target timeframe for this two type of permit are just 45 days. For the release or the combination of the release and the interstate movement permit, the target time frame is always 120 days regardless of revised or legacy regulations.

So, you can see for the import permit, we met the target timeframe under the legacy regulation of 60 days. Also, we met the target timeline under the reduced time of frame of 45 days. Similarly for the interstate movement, we also met target for both legacy and the revised regulation. For the release combined with the interstate movement, the days varies from year to year, but overall, we are well ahead of the target timeframe of 120 days. While we are pleased, we meet the target timeframe despite of the increased complexity of the permits, we anticipate the stakeholders expect us to process the permit even more quickly. Related to that, I would like to provide the eFile outlook for FY '23 for how to further improve our performance.

Starting in FY '23, we are making additional investment in approximately about $1 million in the APHIS eFile to make the bug fix and the functional enhancement to the BRS permitting process. There are three coordinated work stream that includes the operation and the maintenance process. The third is the data service and enterprise platform. More specifically, we are working towards three major category.

First is the help text to increase the support of application creation to clarify BRS expectations. The second category is about the BRS backlog and the reporting with the objective to fix the bug and improve the technical functionality. Also, to improve the reporting capacity in the APHIS eFile. With all of this, we expect to achieve the result to make the applicant can draft and submit the application with much less BS intervention, reduce the back and the fourth discussion during the internal BRS application processing. And finally, to improve the internal BRS processing time. And the third category is about the planting report. So, we intend to improve the submission success of the planting report, and we hope we can make the [inaudible 01:31:57] holder to independently submit and review the reports without BRS interventions. With that, I would like to wrap up my presentation. Thank you very much for your time and attention.

Janice Strachan: I certainly thank Deshui for his patience as we worked through the technical problems at the beginning of his speech. Our next presentation is by Martha Malapi. She is the branch chief for the plant, pest and protections branch in the biotechnology risk analysis programs. She will be giving us an update about microbes. Martha.

Martha Malapi: Thank you, Janice. Can you hear me well? Yes, in the back? Great. Well, good afternoon, everyone. I'm Martha Malapi and I am the branch chief of the plant, pest and protections branch. And today I'm going to be sharing with you the permit requirements.

Martha Malapi: And today I'm going to be sharing with you the permit requirements for modified microbes. And I'm very happy to see so many of our developers and stakeholders meeting today. So, thank you for coming.

So, let me start with what are the modified microbes that are regulated by BRS? First, if they meet the definition of a plant pest or a plant pathogen. Second, if

this modified microbe has received the DNA on the of a plant pest, and the DNA is able to produce an infectious agent or is going to encode a compound that is going to be able to cause disease. And the third group of microbes that are regulated by our group is that if these modified microbes are used to control plant pests, and they could pose a plant pest risk. So, with our revised regs, we also have a couple of exemptions from primary requirements for modified microbes.

So, what we have on the left-hand side is that the exemption for modified disarmed agrobacterium species. So, a permit for the importation or the interstate movement is not required for any of the disarmed agro. And there's an option, it is not mandatory, but it's an option for our developers. If you want to request a letter of no permit required like we were discussing yesterday, you're welcome to do that, and that will be for the importation of this disarmed agro species. And to highlight also that this letter does not has an expiration date.

So, what we have on the right-hand side is that also the second type of exemption for microbial pesticides for certain of them. And a permit is not required from BRS for the movement or environmental release of all the micro, of any modified microorganism product that one, has already been registered with EPA as a microbial pesticide, and it is not a plant pest. So then let me show you some of the trends that we have seen in the past few years on the permits that we have been issuing.

So, the graph that we have on the left are the total microbial permits for modified microbes that we have issued in BRS in the last three fiscal years. And that will include mainly modified viruses, fungi, and bacterial species. So, what we can see is that between fiscal year '20 and '21, we issued a very similar or consistent number of permits, around 70 per year. And in fiscal year '22, we issued over 90 permits for modified species, microbial species, for an increase of 34%. And we are anticipated that this trend of increase, we're going to also see it in this fiscal year.

But then I wanted to dig a little bit farther, and then divide between like modified bacteria, modified fungi and viruses, and see the trends, right? And what I want to show on the graph on the right is that it's really the modified bacterial species right now that they're in high demand. So, if we compare fiscal year 2021, we issued around 20 or 15 permits for modified bacterial strains. And in fiscal year '22 we issued over 60. So, we saw an increase of over 400% this fiscal year. So, we at BRS want to acknowledge the increased interest that we are seeing from our developers to work with modified microorganisms. And at the same time, these requests that you have for us to work on clarity on regulatory requirements to work with modified microbes.

So really, this calendar year in 2022, we received a request from the House Appropriations Committee for BRS to take measurable steps to establish a predictable and science-based regulatory pathway for modified microbes. We

also then received executive order from President Biden, and this is what Anastasia discussed during her presentation. And also, we attended, BRS, we all attended these two workshops this year to interact with you, with our developers, and hear your needs. First one was the future of the microbial biotechnology workshop that was virtual, that was organized by the Genomics Institute and the USDA, and the second one where we met a few months ago here in DC for the regulatory policy workshop.

So, I want then to move and show you what are the steps that we have taken in BRS to be able to help out with developers. First, in August of this year, we published the commonly asked question and answers for modified microbes. And basically, if you have not seen this document, I will strongly recommend you to do so. At the end of the slide, you can see where you can find, it's published on our website, and you can find different information of the type of microbes that are regulated by BRS. If you have a query, if you don't know if your modified microbes actually regulated by us or not. It also has information on where to submit this information and what type of information you need to submit for us to be able to do a review. We also put here examples of the modified microbes that are regulated by our groups, and also the not regulated, and modifications that also will not be regulated by our group.

Lastly, you will find some requirements for when you're applying for a permit, and some guidance on the type of information that you would need to submit, not only for movement and importation, but at the same time for releases.

And how we develop this document... Oh, no, it's happening again. I can see it here. But I can keep talking, because I only have two slides or three slides.

Janice Strachan: That's okay. Let me see if I can connect it.

Martha Malapi: Okay, while I do this. So how we developed this document was, we went through each one of the biotech queries that we received in the last three years. There were over 700 queries that we have received, and we had assigned this in my group going over it one by one, and divided for plants and then divided for the ones that are there for microbes. So, once we put all these queries together for microbes, then we divide them by group. And then what we did is that we look at what were the most frequently asked questions, and that's how we developed the document.

Just to give a few numbers, from the 700 queries that we received around 21% were specific for microbes. And also interesting, making sense that we are seeing the same trend, like what we for permit that we have issued, the fact that the majority of the queries that we have received were for modified bacterial species, and following for fungal species.

The next step, well, I'll just continue. The next step that we're taking in BRS is that we are developing this guide for submitting permit application for

microbes. And we have already developed this document, Bernadette is reviewing it, and we have some information about what are the microorganisms that are regulated by BRS, the type of permit applications that our developers can submit, what type of information, the SOPs, information about the diagnostic test, the monitoring. So, we are putting all this information, this guide document for you, for our developers to have better guidance on how to submit your applications.

The timelines that we have right now is currently it's under agency review. We have a target posted for the public for our developers to review it. It's getting worse, but I'll finish. I'll finish it for our developers to be able to give us comments. So, we're going to put it out in March, that's our timeline, and we are targeting to post the final version on our APHIS website in September, September 2023. And with that, I want to thank you again for your attention, for being here, and especially to my awesome staff members, they are really the ones who develop all the work that I presented today. Thank you.

Oh, my water.

Janice Strachan: All right, let me see if I can figure out how to get connected again. All right.

Janice Strachan: I see it here. I don't see it up here. I want to give the next presenters a good opportunity to go through their material. Is it online? Does the online look okay? Okay. The only thing we're missing is the front screen. I don't know why that is. I'm actually going to be able to see right there when it shuts off.

Speaker 5: Okay.

Janice Strachan: All right. I still see that up there. I'm still not seeing it over here.

Speaker 5: Yeah.

Speaker 4: The back screen, too.

Janice Strachan: Back screens? It's just the one screen in the front, and the people sitting in the front can't see unless they look kind of backwards. Okay.

Speaker 5: [inaudible 01:43:14] worry about it.

Janice Strachan: Yeah, good point.

I'm still plugged in, so I should still be on.

(Missing audio)

All right, we're going to try something here. Those of you that are sitting where you cannot see a screen, if you can move your chairs, the top screens at the top

of the ceiling are working. This is the only one. We've asked for some technical assistance, but we would like to continue with our presentations.

Speaker 5: Yes. [inaudible 01:46:15]

Janice Strachan: Oh.

Speaker 5: [inaudible 01:46:16] is not working.

Janice Strachan: Yeah, the only thing that's not working is this screen.

[inaudible 01:46:37]

Oh, that's a good idea... That's nice.

[inaudible 01:46:43].

I'm so sorry to get you out of your comfortable seats. And the screens up in the ceiling, we're able to see things if you can face one of the screens up in the ceiling. All right. I will let them settle a little bit first, so that they can hear. All right. Can everybody see a screen that wants to see a screen? Thank you so much for putting up with this. Our next presentation is by Doug Grant, the Director of the Regulatory Operations programs, and Nathaniel Yates, the Branch Chief of the Compliance Evaluation and Enforcement Branch from Regulatory Operations Programs. Today, they are talking about compliance and inspections updates. And we're going to start with Doug. Sorry.

Doug Grant: No problem. Thank you so much, Janice. And it wouldn't be an online meeting without some technical glitches, so we're just getting those out of the way for today and now we will have a perfect rest of the meeting, I'm sure. Thank you to everyone for being here in person that was able to make it, and thank you for everyone who's joining us online. We really appreciate you spending some time with us today, and it's been nice to see people and get to have some meetings face to face as we finally get out of the fully virtual world that we've been living in.

So, we will tell you a little bit about what we're going to tell you about today, which is we're going to talk a little bit about some planting and inspection data in person, in virtual inspection statistics. And then Nate's going to tell you about some compliance outcomes, some of the most common non-compliance issues, and some of the projects that we're working on in the coming year.

So here we have a map of the unique plantings across the United States in FY 22, and we had 833. You can see some concentrations in areas like the Midwest, Illinois, Iowa, Minnesota, Nebraska. And then also in the places where we have year-round trials, with the winter nursery locations in Hawaii and Puerto Rico,

we tend to have more plantings in those areas. And this is down from about a thousand last year in FY 22.

So, in terms of the inspection work, the concentration again is in those same geographical regions where we have a lot of plantings, so we can see higher numbers in the Midwest, and also in Hawaii and Puerto Rico. So, 663 inspections with 833 plantings, that's about 80% of the sites being inspected, whereas last year we had about a thousand sites planted and 700 inspections. So, we're actually up this year to about 80% from 70% that we had last year, keeping in mind that some of the sites will be inspected more than one time per year

As a lot of you know, we partner with other folks to get the inspections done. We have a lot of BRS internal inspectors that that's kind of their full-time job, and they are located throughout the country. But we also have a partnership with APHIS, plant protection in quarantine. And so PPQ does a good percentage of the inspections, and then state Departments of Agriculture in a handful of states who partner with us to conduct inspections on behalf of APHIS.

So, the last pre pandemic year, you can see in FY 19, BRS did about 70% of the inspections, PPQ, 25%, and states, 6%. Then when the pandemic hit, which was pretty early on in the fiscal year, we had 95% of the inspections done by BRS. And that's because we were doing all of our inspections virtually. So, in that year, we did have PPQ in states conduct some inspections before the COVID pandemic began in March of that year. And then we did almost all of them ourselves, because we were doing them in this virtual format, which we actually had piloted in FY 17 and 18. So it was good that we were already doing some virtual inspections before the pandemic hit.

But then in '21, we were able to get back out to the field more. We also were able to train PPQ to do some of the virtual inspections. So, we started to see the numbers climbing back up for PPQ in states. And then in this year, we had 83% of the inspections done by BRS, 13% by PPQ, and 4% by state departments of agriculture. So, we're starting to get back more to that even balance or more even balance, where PPQ and states are taking on a larger percentage of the inspection workload.

In terms of when the inspections occurred this year, it was a little bit of an anomaly with the late planting season this year, and maybe that's a trend that we'll see over time. But we had a really late spring. It was cold and wet for a number of months, and so things that often would be getting planted in April weren't planted until May or sometimes June. And so, we get those planting reports coming in later in the season, which pushes our inspection workload to later in the year. So, we had 41 inspections in the first quarter, 114 in the second, 120 in the third, and then 388 in the fourth quarter. So, it was very busy in that fourth quarter, and we've really tried to keep that momentum going. We've done a good number of inspections already, this fiscal year we've got

over a hundred completed. And basically, until the snow starts flying, we'll be out there trying to look at these sites. So, we have a total of 663 in FY 22.

Now, in terms of how many inspections we're doing in person, we really ramped it up this year. Last year we sort of started and stopped, thinking, okay, when are the travel restrictions going to ease? And they did ease a little bit. So, we were able to do 82 in-person inspections last year, but that was out of 700 inspections, so only about 11.5%. This year we did 420 out of the 663 inspections in person. So almost two thirds of the inspections were done in person, and that was really nice for us to get back out to the field, get to meet people, see their sites, and the majority of those were done by BRS, almost 80 by PPQ, and 28 by state Departments of Agriculture.

So, we anticipate this type of balance between in-person and virtual inspections continuing and FY 23, we like to get out there and see things in person when we can, but of course, we will continue to do virtual inspections to supplement our in-person inspections. And certain types of trials like the PMPIs, which are plant made pharmaceuticals or industrials, species with a higher likelihood of persistence, or other types of novel traits and absolutely trials with compliance issues, we inspect those with a higher frequency. So, it's not always just one inspection per trial, there are a lot of variables that go into that. So, we did then, of course, have the compliance outcomes from those inspections. And I will turn it over to Mr. Nate Yates to tell you a little bit more about that.

Nathaniel Yates: Thank you, Doug. As you see, we've talked about a number of transitions, whether it be regulatory in nature or whether it be from our compliance inspections, and obviously inspections yield results. So, over the last few years, you'll see that our compliance rates have pretty much stayed around 90% or higher. So, in 2020 it was 95%, in '21, 98%. And then we went down, and we saw about 90%. I want to speak to that briefly, because some of that has to do with the transitions from notifications to permits. Some of you have gone through this yourselves, where there were things that at one time you may have planted under notification, and they were not compliance issues that are under permit. So, in that transition space, we've seen that happen, but we've also been able to help educate and get people up to speed on what the new regulations or their authorizations require.

Of the notices sent, you'll see that we sent out 535 notices, which inform what the compliance outcomes were. Of those, 481 were compliant, 54 were non-compliant, with two that were considered other outcomes. When we talk about non-compliant and we say 54, it may raise some questions for you. Rest assured some of our notices that go out with non-compliance, if there was a situation or an inspection where there were multiple infractions that one site, we don't send you three different notices for the three infractions. You may get one notice that contains the three. So, when we consider the number of non-compliance, we know that there were three there, but the notices may not necessarily track one-to-one, because if there were multiple at one site, they'd go on one notice.

Some of the common challenges that we've faced and seen in the last year, especially now as we've made these transitions, are things that you see on your screen. Planting in unauthorized locations made up for about 27 of those infractions. That's things that were planted beyond where they should have been. Not following supplemental permit conditions. We had about a hundred of those, about 36 of them were identified during inspections, while the remainder were found during reporting or reviews by staff, many of whom are in my branch. Late plantings made up of about 28 of them. We have failures to submit planning reports. Those are some issues that come up, and they made up three. And then late volunteer monitoring reports made up about 13 of those things.

Now, amongst these compliance challenges that we've faced are the transition between legacy regs and the ones we have now, but also use and functionality or familiarity with e-file and its rollout as well. So, we have a number of things that we've been able to capitalize on as they've happened, but these pretty much make up what we've seen there.

As it relates to FY 23 ROP, or regulatory operations projects, among the projects that we have, one of them that we'd like to highlight is the sharing of the draft guide for submitting of reports. We've created a guide that's intended to help assist in these areas where we've seen these compliance challenges. Transitions, where do you go and how do you handle e-file? We want to help you to understand that. Those areas where reporting dates are now new, because maybe you've been reporting under notification, but now you're under a permit, and we want to make sure that you are aware of these things. We've made a guide that we intend to sometime this spring release for you to even comment on, and then let us know if this is helpful to you, so that we can get it finalized by fall. Sound good?

So, these are the things, this is one of the projects that's coming up. It's not the only one, but it is one that we think will be useful to address some of the concerns that we've had. And with that, I'll transition back over to continue on with the rest of the presentations.

Janice Strachan: All right. Very interesting information of how this change in our regulations has affected our stakeholders. Our next item on the agenda is international engagement, and the presenter for that is Jessica Mahalingappa. She is the BRS Associate Deputy Administrator. Jessica?

Jessica Mahalingappa: Thank you, Janice. Yes, I think everyone's heard from me a little bit, but now I'm going to talk and focus a little bit on our international collaboration that we've conducted over the past year, and what our plans are behind it.

Okay. So, this slide, which we call strategy, is basically the reason behind our international collaborations. So, we want to provide assurance in the credibility of our regulations, and we do that by explaining them, making sure that, especially with these new regulations, that there's awareness around the globe

about what they entail, and answer questions about those regulations. And then secondly, to build capacity in other countries for regulating organisms developed using genetic engineering, and how to do that using a risk-based approach. So, I'm going to elaborate a little bit more on some of the specific activities.

So, in fiscal year '22, we either hosted or participated in over 15 international engagements, not huge numbers when you think about some of the other things that BRS is doing. But we're talking about a very tiny staff, and all of the busy people that you've talked to, you've heard from today, who engage with international counterparts. And most of those collaborations were virtual, but as you can see on the screen, we were able to have two visitors, two groups visiting right here in Riverdale over the last year. And we're hoping to increase those in-person interactions, because there's a lot of comfort built when you can talk with people in person.

We also collaborated with international organizations, so the OECD, the Organization for Economic Cooperation and Development is our primary collaborator when it comes to multilateral engagement and setting norms and developing strong background documents to help with regulation globally. There's some other regional bodies such as IKA, or the Asia-Pacific Forum that we try to work with as well to address regional concerns. And of course, we collaborate with our trade agencies, so the Department of State, the Foreign Agricultural Service, those two bodies in particular and others, we have a really good established relationship to work with them on what priority engagements we can carry out, and to try to meet whatever needs they have when they hear that there's interest in a regulator talking to regulators.

And we also focused on advancing harmonization. So, a lot of that work through the OECD, but also talking bilaterally with individuals, other individual stakeholders and other foreign regulators that are working on their regulations so that we are in lockstep, we know what other regulators are doing, and we're not making decisions, or we're trying to avoid decisions that can cause some differences that would...

Jessica Mahalingappa: ... It'll cause some differences that would affect the ability to trade internationally. Looking forward in 2023, of course we're already a couple of months into fiscal year 2023, and we want to expand our engagement with international regulators. We're hoping to do more in person. In fact, already just last month I was able to attend a global regulators meeting for the Food and Drug Administration organized, and we were able to meet with 18 different regulators in their different economies and their regulators. We want to continue to provide that technical assistance to trade agencies to help both safeguard agriculture, but also minimize any trade disruptions. And particularly, I know Anastasia had in talking about the bioeconomy executive order there in the section 12 includes international outreach and they do specifically mention engagement among regulators. So, State Department's still working on their plan for that, but we will be supporting their work. And as far as international

harmonization, we have a number of ongoing projects with the organization for economic cooperation and development.

Closer to home our lateral technical working group with Mexico and Canada is a constant partner. So, we're very aware of the need for smooth regulations between Canada, Mexico and the U.S. And so, we're trying to engage consistently with them. And we have annual and quarterly meetings with them. And then we're anticipating additional work in Asia and with other trading partners. But of course, we've started to reach out more to some of the countries or economies that are in the process of developing their regulations. And we're very open to suggestions on what countries might be interested in hearing more about what we are doing as it might inform what they might do when developing their own regulations. Oh, that's my last slide. Back to you Janice.

Speaker 6: Right. You might as well go over that direction.

Janice Strachan: Sure. All right. It says here we're ready for another question and answer session. Again, those in the room can use the microphone in the middle of the room. Those online, I'll periodically go over and ask Tyler if there are questions online. For those who are shy, there is a box where you can write your question and if we have time during the session, we'll get to those. Otherwise, we'll address those questions after this session. So, I'm asking for Deshui and Martha and Doug and Nathaniel, Jessica and Subray. Subray please come up also. And now we get the screen back. Who knows? All right. There is a person in the room ready to ask a question when our panel is ready to listen to questions. All right. So please state your name and who you're representing.

Speaker 7: Sure. Hi, good afternoon, everyone. My name is Fan Lee Chow and I'm here representing the American Seed Trade Association. So, we represent close to 70 different companies from A to Z alfalfa to zucchini. So, any number of crops that you all may be seeing. So, Jessica, I have a question about your international engagement. I think the first is, is there priorities at regions or countries that you will be looking at and how do you set those priorities? And then also two follow up questions about your messaging. So, I think there are two different regulatory engagement. One is on these new products through plant breeding innovation that could have been done through conventional breeding.

And many of countries are developing policy around that. And to be fair, we are very much out of alignment with most of the countries. On the other side is the traditional transgenic products. And in that we are actually taking a quite, I always say, a progressive approach in our PTMOA approval. So away from the event by event. So, are there two different approaches here? Because in one place where we're very progressive compared to other countries and in the other side on alleging side we're not as progressive. Just want to hear your thoughts on that.

Jessica Mahalingappa: Okay, thanks Fan Lee. I'll start with the beginning. So as far as how we prioritize, I mean we're prioritizing with our biggest partners, so that's why we spend quite a bit of time talking with Canada, Mexico, that those engagements are ongoing. More recently and I would say a second priority level would be those countries that are currently in the process of making changes or developing their own regulations. And I think you hit the nail on the head Fan Lee, we are seeing some differences in how different countries are approaching some of the new technologies and what their concerns are. So, we're trying to answer questions about what we are seeing.

We're trying to avoid any issues with any trade or with companies being able to grow or in one place and have access to other markets, because of the different approaches that we have. Those differences are hard to avoid. We're working under different authorities. Some countries are developing new bio-safety regulations right now that kind of create a clean slate for them to develop regulations on top of. We're working under our existing authorities. So, we're certainly not advocating that other countries develop regulations the way that we have, but we're trying to make sure that there are not going to be unintended impacts of the differences among the approaches. As far as whether as our outlook in terms of being more conservative in some areas and maybe more progressive in others. Yeah, we're trying... Like I said, it's a case by case basis as to whether we can avoid any consequences of those different approaches or different outlooks with products. It remains to be seen if that will happen.

I don't know of any specific products right now where especially using some of the new technologies where the U.S. has approved something like all of our new approvals for RSR's for example. None of those companies are yet in other countries. We know a few countries have some products that we haven't seen yet. So, it'll remain to be seen, but we're trying to stay in contact with them, so we avoid any unnecessary disparities that cause trouble for trade or for movement of those products. Did I answer everything? I know you had a three part question. Anything.

Janice Strachan: All right. Let me see if there are any questions online. Tyler, are there?

Tyler Reid: Yes, there's a question from Josh. There's some background I have to get to before the question. He said UK parliament is in the middle of the genetic technology precision breeding bill currently in the House of Lords. It will be in the remaining stages of the bill for a few more months as they decide the details if they are going to proceed with the technology. His question is could their decision change our current deregulation direction?

Jessica Mahalingappa: The UK's decision? No, I don't believe that what the UK does will change our decisions in terms of what all the folks on the stage are doing here in our regulations. It may change how we communicate and what we communicate with the... Sorry, I'm looking at Tyler, but I guess I should be looking at the camera. How we communicate with the UK going forward. They have their own

concerns right now and they're trying to look at new breeding techniques. I'm aware of that. I had some conversations with our counterparts in the UK recently, so I know some of the things that they're considering. And they're trying to figure out a new path since Brexit and we're open to engaging with them. But I don't believe that it'll affect how we are approaching our risk assessment.

Janice Strachan: Thank you. Is there a question in the room? I see someone. Can you tap on the mic a little bit and make sure it's awake and then give us your name and who you're representing?

Speaker 8: Will do. Do you hear me? I am Eda Renot and I represent a developer company. Microbial Products Development Company, Indigo Ag. And my question is that, as we operate and develop products globally, we also do quite a bit of work in South America, more specifically in Brazil and Argentina. And Brazil has quite advanced in bioeconomy and biotechnologies in agriculture for agricultural uses. And that includes also microbial products for agricultural inputs and genetically engineered microbial products. And my thinking is and ask is that you also collaborate with Brazilian regulators with MATA for example and so forth. They have established quite a good regulatory scheme for such microbial products.

Jessica Mahalingappa: To be honest, we have not talked to Brazil very recently, but we want to. We were open to that. They were part of the regulators meeting that I referenced, that I attended last month. So, we were aware of what some of their advancements and we were very open to talking with them. It's kind of a bandwidth issue. I mean you've kind of heard what Martha here has been up to and the ability to reach out. But yes, we're very open to talking with Brazil.

Speaker 8: Thank you.

Janice Strachan: And we'd like to-

Speaker 8: Thank you very much.

Janice Strachan: Tyler, do we have another question online?

Tyler Reid: Yes, Susan asked, what about domestic regulatory engagement update IE. EPA, FDA. Any specific efforts going on there?

Jessica Mahalingappa: Yes, of course we've neglected our FDA and EPA colleagues all day and I think there's probably some on the line as well. Yes, I would say our communication and our interactions with FDA and EPA are constant. If a day goes by where I don't talk with someone from FDA or EPA, that's pretty rare. I think the same probably goes for Subray.

Subray Hegde: Yeah. We have a monthly engagement. A formal engagement with FDA and EPA. We update each other on the products, and we also have a regular meetings whenever we need any clarification. And they also call us if they need. I think as Jessica mentioned, we are constantly in contact with FDA and EPA.

Jessica Mahalingappa: And I will say on the international side too, we have very consistent engagement with FDA and EPA. They're often involved in the same discussions with foreign regulators. They're very engaged with OECD. So, both internationally and domestically we have really good relations.

Janice Strachan: Is there another question from someone in the room? I see someone coming to the mic. Make sure that it's awake and then give us your name and who you're representing. Thank you.

David Heron: I'm still David Heron. Still a private consultant. Just to follow up to the first question that came from online, they were asking if the UK approach would influence the direction of BRS, and I believe in the final rule when in 2020 BRS talked about broadening the exemptions, that part of the regulation that would be the exemption. So, I think that may be something that they were hinting at. That that's an opportunity and something that the agency has said in the rule. But my actual question has to do with a phrase that Jessica, you mentioned the risk-based regulation, and how this fits into the reviews in the RSR stage. And since you've said that some of the RSR requests, already you've decided that you've come to a conclusion that there's a scientifically plausible scenario whereby that genetically engineered plant would pose a greater plant past risk than the non-genetically engineered plant.

My concern is that if the agency is not describing which scientifically credible evidence it's using to reach that conclusion, that the risk-based approach will not be apparent and it'll become this kind of excuse to regulate that a number of countries have used around the world that if they say, well we're not sure therefore we're going to regulate. And that's a policy that the US government has argued against since 1986, internationally, strenuously, to say unless there's scientifically credible evidence of likely harm. And we do this under all of these international cooperations.

But my concern is that the agency in doing the RSR requests and putting that test that's in the regulation, that they, it's imperative that the scientifically credible evidence to support the agency conclusion of likely harm, plant pest harm, that it's there. Remembering too, that these crop plants are by definition not plant pests. And so, the only example that the agency gave in the proposed rule that's a plant could be posing a plant pest risk is if it is a reservoir of plant pests. So, pathogens, plant pests and thereby by being a reservoir that it poses a plant pest risk. So, I want to make sure that the program makes those scientifically based evidence to reach those conclusions that is clear in front of the public. Because otherwise it'll look like the excuses that a number of countries have used to just continue to regulate.

So maybe my question is, for those, Subray you had mentioned two or perhaps three. APHIS, will it make public the criteria, the evidence, the actual evidence that the public can see, how you reach that conclusion and not that you just don't have enough information? Will that actually be made public? Because I've heard comments from people in the program that will not be made public. So, if I could have clarification on that.

Subray Hegde: Yeah, that is a good question. Yeah. If you go the second step, what we say, plant pest risk, I understand that it's not just the real pathogen causing a disease. We also considered if there is an impact on non-target beneficial organism to the agriculture as a plant pest risk. Regarding how we arrived at the conclusion, yeah, it'll be published when we prepare our PPRA. It'll be clearly laid out in what questions we asked to say that there is a plausible pathway. We never saying that there is a plant pest risk. There is a reason to believe there is a plausible pathway. So that will be published in PPRA. So, people would come to know why we went to step two. What questions we asked. So, public have an option to review.

David Heron: But that's only if someone goes forward to a PPRA.

Subray Hegde: Correct.

David Heron: That would be. But if someone does not survive the initial review, you'll communicate that you've not survived the initial review. We've reached the conclusion that if there's a scientifically plausible scenario, will that be made... Will that be made publicly available so that people can see what evidence to see whether the agency's evidence for reaching that conclusion is well founded.

Subray Hegde: Currently we are not making that one public. It goes to the second step. Initially, if we say determination, it is not regulated. Yeah, it'll be on our website. If it goes to step two, that is there is a PPRA, we ask the developer, do you want us to continue? That will not be made public. If they say that yes, you know can prepare PPRA or they submit when we prepare PPRA, yeah then it'll become public because we are publishing an FR notice. If they say no, we are not interested, then we are not publishing that one that it went to step two. So, because of this reason, we are not going to publish that one.

David Heron: I understand that. Part of this goes to the issue of being risk-based and being transparent. Other countries, when they say you are going to be under this regulation, you're going to continue under that. Most of the countries in the U.S. government position has been transparently state the scientific grounds for doing that. And even under the SPS agreement, this is part of article two stating that there has to be scientifically sound evidence for making the conclusion. It doesn't sound like to reach that conclusion that something poses an increased plant pest risk or is likely to pose an increased plant pest risk. That you're going to make that clear to the public, either to your partners when you talk about international harmonization, developers or researchers. So, no one can tell what criteria are in play or even challenge the scientific validity of the evidence that's

being used to reach those conclusions. So, I encourage the program to think in terms of, first of all, relying on scientifically credible evidence in reaching those conclusions and not just saying, "Well we don't have enough information. There's an outside chance that this could cause a difference."

Subray Hegde: Dave, I agree. I really appreciate your input. But if you look at the history, what we have already published, we really followed science base. Why it doesn't require a regulation. We said, you know you can see. And second one, if you are going to the step two, we have to have a really a plausible, a reasonable. It is not that we don't have enough information, that's why it is going step two. No, I don't think that would be the criteria we will follow. We would really follow a science base based on the publicly available information to reach that conclusion. But yeah, I really appreciate that. Yes. We will not say, "Oh, we don't have much information. That's why it should be step two."

David Heron: I appreciate that you're going to focus on the publicly available scientifically credible information. I urge you, in implementing, to make it more transparent in, now you say you have two or three cases, so the public can see what you're actually doing. This is a big challenge that a number of regulatory systems face in biotech and other areas. And I think this is by not having the agency's rationale in individual cases clear. I think that puts the agency in a poor light.

Janice Strachan: Thank you for that conversation. Is there one more question online? And that will have to be our last question.

Tyler Reid: Yes, there's the last question from Vivian is how are advisory committees involved in the ongoing revisions of the regulatory process?

Jessica Mahalingappa: We don't have a dedicated advisory committee. But I'll have to check back on how they might have been involved in the past. And we'll answer that question in writing once we can look into it. I'm not aware of advisory committees. We don't have a dedicated one though for BRS.

Janice Strachan: All right. I'd like to thank the panel for answering those questions and I believe we have some closing remarks from Jessica Mahalingaba.

Jessica Mahalingappa: Okay. Thanks everybody. I know you've hung in there through the technical difficulties who knew that the people online would have a smoother experience than some of us in the room. But we really appreciate it. This is a good opportunity for us to learn how to have a hybrid engagement like this. But I want to say again, how much I really enjoyed being able to meet folks in person for the first time. I've seen a lot of you in blobs of heads on screens and it was great to see you in the flesh and invite you here. And so, I'll conclude by thanking you for your attendance here, for your active participation. And I will mention that we're going to collect all the questions. We're going to put the recording of this session online, so you'll have a chance to go back and review. If

you weren't scribbling down notes throughout the meeting, don't worry about it.

We're going to have all that information online in addition to any questions that we didn't get to that came through in the chat. So, we'll finalize that and have that available for everybody to see. I understood that there was a question about our organizational chart. I'm not sure, are we able to display our org chart here? We may have to put that into the recording as well, because I don't know. I don't think we have it available to display. But yes, I understand that some of the new faces and the new players might be confusing to folks who are not as familiar with how we're organized right now and some of the new people.

So, we'll have to get that into the recording that goes online as an after action. But again, thank you to everybody. Thanks especially to our BRS staff who are in the room. To all the folks who helped set up this meeting. The team involved in the audio visual, the team monitoring the chats and the questions coming in online. Everybody who helped develop this, who set up refreshments, et cetera. This is a real group effort and we're so appreciative of all the work that went into it. And I think some of us will be in the room here to chat as you exit if you're not rushing out to lunch or something. So, thanks again.

Speaker 9: That concludes our conference. Thank you for using Event Services. You may now disconnect.