BRS Stakeholder Meeting Full Transcript
February 26, 2026

Amanda Kenney:
Good afternoon. We are happy to be here with you today, both in person and online, for our annual USDA APHIS-BRS Stakeholder Meeting. My name is Amanda Kenney.

I'm a Senior Biological Scientist in BRS, and I will be our emcee for today. To kick off today's meeting, I will start with a few points of housekeeping. First, for the in-person attendees, restrooms.

There are two restrooms located on this floor. One is accessed just in this hallway here, right before you get to the opening before the BRS registration tables. The other restroom is located on the side of that large lobby that you enter through.

As you walk back towards the guard desk, it's on the far-right side of the lobby. Second, safety. If we need to evacuate the building for any reason, there are two exit options.

You can exit through the door right behind me, behind this podium right here. You'll cross a narrow hallway, and then there will be an exterior door immediately right there. You can also just exit back through the large hallway and go straight out the main entrance that you came in through.

Please mute your cell phones, and on a related technology note, the building is not equipped with guest Wi-Fi. We expect the meeting to run for approximately three hours. There will be a 20-minute break midway through the meeting.

During the meeting, we will have two 15-minute Q&A panels, with each panel focused on the preceding presentations. During each panel, we will take a limited number of questions in person and from our online participants. If your question remains open at the end of the session, please write your question down on one of the comment cards in front of you on the round table, and place it in the comment box that's over there by the read, sorry, by the BRS registration table.

And for virtual participants, we will enable the virtual Q&A feature during each panel session. After the meeting, BRS will endeavor to respond to all remaining questions in a timely manner. For your reference, we have provided a copy of the agenda, as well as a resources handout that contains our organization chart and some web links.

It's there on the tables, and it should be available to you virtually as well. Please help yourself to refreshments, which are set up on the side of the room by the windows. With that, let's dive into our planned agenda.

We have dynamic speakers who will share updates regarding changes in our program over the past year, recent successes, and our focus looking forward. We are honored to have Mr. Dudley Hoskins, Undersecretary for USDA Marketing and Regulatory Programs, and Ms. Kelly Moore, Acting APHIS Administrator, who will each now share some opening remarks.

Dudley Hoskins:
Well, thank you, Amanda. I see this nice note here, says please keep your remarks to over 45 minutes. Is that right?

Can do that. My name is Dudley Hoskins, MRP, Undersecretary. I was asked to say a few things about myself.

I'll spare you that, but I do want to share one thing. I'm a huge fan of what y'all do. The APHIS family at large, at BRS, the work y'all do is so important.

It matters. I know you do it under incredibly stressful time, pressure, and in sometimes complex requests from our industry partners, who are always understanding and forgiving, but what you all do matters, collectively, everybody in this room. I want to say a word about Kelly Moore here in a second, but when I think about APHIS and our BRS family, I think about, yes, the work matters, the program is incredible, the mission is challenging, but really, it's about the people, and when I think about people being policy, people being programs, people being partnerships, that is what APHIS does, and that's a credit to everybody in this room, and I just say that as an observer, as somebody that has a chance to work with APHIS in the past, that has a chance to get yelled at APHIS today on a regular basis, thanks, Kelly, but more importantly, as just somebody who's a fan of APHIS and BRS. That doesn't happen without folks like Donna and Michael and your leadership, thank you all for what you do and how you do it, I'm excited about the agenda you all have, I don't want to really spend any time talking about me, but I just wanted to come and say thank you, because it matters.

I guess it's, we were talking on the way over here, Kelly is week four now, but in dog years, you've been here like 20 years. It is, the work y'all do is impressive, it's challenging, and people outside the department don't sometimes understand how complex and intense the internal velocity of things can be, but you do it with grace, and you do it with character and integrity, and you've been doing that, and I know if Mike Watson were here, he'd be like, your time's up, stop talking, and now he's probably on a fishing boat somewhere, enjoying life. But Mike and the APHIS leadership that I've known have always cultivated that kind of ecosystem and that culture, and that was one of the reasons why I told the Secretary, we need Kelly to come and take the reins when Mike retires. So, I'm grateful, Kelly, for what you've done in the COO side of the role at APHIS, and what you're doing now in week four, but more than that, I'm just a fan of who you are and the values you have, the character and the integrity, and to know that that will continue at APHIS under your tenure.

So maybe that is five minutes now, but thank y'all for a few minutes at the top, thank y'all for being here, thank you for what you do. Thanks.

Kelly Moore:
I was told I would have to adjust to this a little bit, sorry. Thank you for the introduction, Undersecretary Hoskins, and thank you for having me here today. As Dudley mentioned, this is my fourth week on the job here, and I will tell you, it is so exciting to be able to work in this capacity, to understand more and more about the intricacies of the work that APHIS does every single day, and I just want to echo the sentiments from Undersecretary Hoskins about, it's incredible, the work that gets done, and it is wonderful to be a part of it, and I was thrilled to get the invite to come and be able to just spend a few minutes with you all today. I want to do take a minute and recognize Dr. Mike Watson, who obviously many of you have known for so many years, and his dedication to Federal service and to APHIS over several decades. He is definitely missed, but we are so happy that he is enjoying his life, enjoying what he has earned in retirement, and I do talk to him, usually I try to keep it to maybe once a week now, to ask him for advice, but he's really enjoying his time, and we just appreciate what he's brought to the agency over so many years.

You know, his contributions really strengthen the agency from the mission, driving the science-based policies, fostering collaboration across programs, and also empowering our dedicated staff. I really strive to do the same, using my operational leadership to support BRS, as well as the rest of APHIS, ensuring transparency and engaging stakeholders like you in meaningful dialogue. I am new to this role, but I've been at APHIS for two years, as Dudley mentioned, as the Chief Operating Officer, and then I've actually been at USDA for 18 years, so I've been in some other capacities around the department doing some things at the department level, running programs, and really my background is on the business side and program project management, and extensive work in contracting career field. So again, it's just an honor to be here and to be working in the APHIS administrative capacity. You know, I'm just so grateful for the opportunities that I've had and the skills that I'm able to bring to this particular job.

You know, APHIS as a whole is well-positioned for the challenges that we have, and I look forward to continuing to work with all of you. We've talked a lot, I think, about collaboration in a lot of different areas, and that's one of the reasons why we're here, right? We want all of you to come in and be able to have this collaborative opportunity with BRS and with APHIS to continue the work that we've started.

You know, we've tried to keep lines of communication open, regular updates, and revised guides for updated processes as well. I want to recognize that this was a reschedule of a meeting I think that we originally had back in November, so thank you all for your flexibility in being available and coming out today. It is wonderful to see such a large room filled, and I know we have a lot of participants that are online as well, so thank you all for being a part of that.

I want to talk a little bit about the blue moth orchid. This is really exciting, just to illustrate how well the new regulatory process has worked. This journey of the flower developed using genetic engineering, and the flower is a moth orchid genetically engineered to have blue flowers.

This was the first product review completed after we returned to original biotech regulations. Within 180 days, we received and reviewed the petition, completed a plant pest risk assessment, I'm still working on these, completed the regulatory analysis and development review, posted the first Federal Register notice, reviewed public comments, and published our determination. This is a lot of work that happened in a condensed timeline, and we're very proud of the fact that it has condensed it down to less than half of what prior timelines were for this.

I want to share that just because it emphasizes just how quickly we were able to adapt and adjust and move back from regulations that were in place and just be able to get those done quickly and really stick to the core mission of what BRS does. Our focus is still on delivering predictable and science-based regulatory services, and this is really to enable the innovation. Your engagement, your feedback, again, you all being here today is vital as we continue to move forward together.

We've come a long way in this process, and we're excited to be able to share other accomplishments, lessons learned, and the direction ahead. I do want to comment that I was really excited when I came in the room and saw all these plants on the tables with the scientific names. I have a lot of houseplants, and in my two moves I did in three years, I drove my houseplants in the back of my SUV from Colorado to Florida and Florida to the D.C. area. So, I know one of the staff members had these plants brought in from their personal collection, so I just want to say I very much appreciate the dedication to that as well. And so, with that, our BRS Deputy Administrator, Dr. Donna Lalli, will start walking through this journey. You'll later hear more about what these changes mean for the future.

I look forward to working with you as we better serve agricultural industries and communities that rely on us. Thank you so much for being here. Thank you for your partnership, and we appreciate the invitation today.

Thank you.

Amanda Kenney:
Thank you, Undersecretary Hoskins and Administrator Moore. We appreciate you both being here today to support BRS's work safeguarding American agriculture while enabling safe biotechnology innovation. I'm now pleased to introduce Dr. Donna Lalli, APHIS Deputy Administrator for BRS, who will present our Fiscal Year 25 highlights and an overview of BRS's goals for Fiscal Year 26.

Donna Lalli:
Thanks, Amanda, and thank you, Undersecretary Hoskins, and Administrator Moore. It truly is an honor to be with you all here today. I actually began my career with USDA.

I started at ARS as a postdoc researcher. I joined APHIS in 2010 or 2011. It's hard to remember at this point.

I feel like I've been around for a while now. I actually started as a biotech in BRS, issuing permits and notifications, as well as reviewing petitions for non-regulated status. So, in some ways, this really feels like coming home for me, and it's quite an honor to be able to serve in this capacity.

Before I begin, I just want to express my gratitude to the staff who worked so hard to make this meeting possible. Planning takes months of effort, on top of keeping the day-to-day operations going. Your dedication shows in every single detail we are experiencing in the room right now.

So, thank you so much. I also want to thank all of you for being here with us today. We really appreciate your flexibility with the rescheduling and thank goodness the weather cooperated for the most part today.

We might get some weather on Monday, maybe Tuesday. But speaking of flexibility and change, and here's the real challenge. They gave me a clicker, so we'll see how this goes.

Speaking of change, in 2025, BRS experienced a significant amount of change. We had been operating pretty much in a steady state and making substantial progress, approving efficiencies in nearly every aspect of our program. And in December of 2024, a court vacated our SECURE rule.

Overnight, we had to pivot back to our pre-2020 regulations, a framework that shifted us from exempting certain categories of organisms that could otherwise be achieved through conventional breeding, to an approach that focused on whether or not you are a plant pest or you contain plant pest sequences. In response, we had to move really quickly to reestablish some certainty for you all. We implemented both our regulatory and non-regulatory options that existed prior to SECURE.

So, we implemented our non-regulatory and Am I Regulated process, pretty popular, our authorizations process, as well as our petitions process. So, I'll start with the Am I Regulated process. We were able to get this up and running within 17 days of the vacatur.

We set a goal for ourselves to do this 35% faster than we've done before, and we really exceeded that target. We were able to turn these responses around 85% faster than we had done previously. Not only that, we did 69 responses this past year, and that's three times as many as we normally would receive in a year.

Next, we stood up our authorization process. We started with permits because that was a process that was already going throughout all of our regulatory changes. Oh, did I see?

This is my challenge, the clicker. Thanks, Sarah. So, these permits were stood up first and shortly after we were able to get the notification process in place.

We met our regulatory timeframes 95% of the time, and we did it 42% faster than we had ever done before. We are seeing some interesting trends, and many of you here today are probably

interested in this space as well, for modified microbes, and you're going to hear a lot more about that from Alan Pearson later in our talks. Once you receive an authorization, we know just how important timely communication is about your compliance feedback.

We know that's so essential for you to make sure that you bring your, if you have a compliance issue, that you bring that back into compliance as quickly as possible. We wanted to issue any notice of noncompliance within 14 days. We were able to do that 93% of the time, and on average, we were able to turn those around in 11 days.

So, we really appreciate the work that our compliance and inspection group has done on that. And then finally, I would like to talk about petitions. As Kelly mentioned, we did our first petition in the regulatory timeframe, 180 days, for the first time since the 1990s.

We really want to continue to try to meet these timeframes, and we're committed to tracking them very closely as we move forward. We know we have not historically been able to meet this timeframe, and study improvements and our continued experience have significantly reduced review times. Our petition review times have dramatically changed over time.

We went from pre-SECURE, averaging about 534 days to issue a determination of non-regulated status, to nearly cutting that in half with a SECURE rule, and we were able to bring these efficiencies and our experience over to our current regulations with the delivery of the first petition in 180 days. We're really striving hard to continue to meet those timeframes. Looking forward, we want to continue to build upon our experience, and we are working to introduce further efficiencies into our biotech regulations.

We've been developing a proposed rule intended to streamline our processes and provide targeted regulatory relief where appropriate. Some of the key elements that we're focusing on are moving away from event by event review to eliminate redundant product, redundant reviews of the same product. We also would like to look at providing regulatory relief for products that are already being regulated or registered with EPA, reducing rigid shipping requirements, and introducing added flexibilities, and finally, offering multi-year movement permits to streamline our authorization process.

We anticipate, we're really hopeful, that we'll be able to publish the proposed rule by the end of Fiscal Year 2026, and we really look forward to your feedback and your public comments. We always value the stakeholder meeting, and this dedicated time together. It's so great to see so many of you in the room in person, and we're grateful for the folks that are able to join us virtually.

If you need additional information throughout the year, please feel free to use these QR codes on this slide to help you stay connected. We have a great program ahead. I'm really excited for our folks to be able to share the work that they've been doing in more detail, and I just want to thank you for your time and attention and thank Undersecretary Hoskins and Administrator Moore again for sharing those opening remarks, and it's really meaningful for us and our staff.

Thank you for your time and attention, and I'll turn it back to you, Amanda.

Amanda Kenney:
Thank you, Donna. We appreciate your acknowledgement of BRS's hard work and your preview of what's to come later in the meeting. Next up, we have Dr. Michael Stulberg. Michael was the Acting Associate Deputy Administrator during our last stakeholder meeting, but soon after became BRS's permanent Associate Deputy Administrator. Michael will present an overview of recent organizational changes at BRS.

Michael Stulberg:
All right. Thanks, Amanda. Good day, everyone online.

Good afternoon, everyone in the room. Today, I'll be discussing some key staffing changes within our organization from the start of FY 2025 to now. First, the fun news is that in FY 2025, we had three new people join us.

Jennifer Nelson, the Branch Chief of Resource Management Services, who brings this positive, uplifting energy to BRS, which we really relied on this past year. Tina Furnkranz, Deputy Chief of Staff, who immediately strengthened our graphic presentations, crucial internal communications, and also the nice theming that you see behind all these slides and on the posters was all her work. Both Jen and Tina were instrumental in organizing today's meeting.

Thank you both very much, and thank you to everyone who helped set up. And last but certainly not least, Dr. Donna Lalli became our BRS Deputy Administrator in July 2025. She brings a wealth of experience, of leadership experience from roles at APHIS.

Previously, the APHIS Associate Administrator, partnering with agency leadership, including BRS's, to manage operations and represent APHIS in cross-agency initiatives. Prior to that, she served as the Associate Deputy Administrator for Wildlife Services. She's held positions as APHIS Science Advisor and Senior Policy Advisor at the White House Office of Science and Technology Policy.

I could go on, but I'm going to stop there. So, we're very fortunate to have her. It's been lovely working with her these last seven months.

Okay, so over the past 14 years, where we've had available data, yes, I did ask for 15 years and was told by 14 years of data. BRS staff numbers have remained steady, typically in the mid-70s to upper 80s. You'll note that the largest change over this period occurred in the last year, a 23% decrease in staffing, putting us below our normal, and where we currently sit is at 62.

With the decrease, we've consolidated staff supervision in every program. ROP branches were reduced from three to two now, BRAP from four to three, and ODA under Alan there absorbed a small branch, which kind of just streamlined our structure on that side. So, the reductions were felt across the program and under different programs.

So, ROP lost 29%, BRAP 24%, PPIC 25%, and the smaller programs, 13 and 14%, and that's also where we picked up Tina and Jenn. But again, this smaller BRS crew have really been hard at work to maintain and replicate the success that we had in FY 2024 for a year, a really big year for us, into 2025, which you'll see it's here today, and they've been carrying that momentum into FY 2026. And last, those of you in the room can tell we are not at Riverdale.

It's here today, so that's because we moved from the lease space inside the Beltway to this USDA-owned space outside the Beltway. The GWCC is just behind the NAL where we are here today by about half a mile. We're happy to meet you there or downtown.

So thanks so much.

Amanda Kenney:
Thank you, Michael, for sharing those updates about BRS's program. Our next speaker is Dr. Rebecca Fletcher, a Senior Biological Scientist in our Biotechnology Risk Analysis Programs. Rebecca will present highlights of the Am I Regulated process.

Oops, and there's her introduction slide. Sorry.

Rebecca Fletcher:
Thank you, Amanda, and thank you all for being here. I look forward to providing an update on the Am I Regulated process. But first off, what is the Am I Regulated process?

This process was initiated originally in 2011, and then as Donna pointed out, we restarted it recently in December 2024. It's a voluntary non-regulatory process that allows developers to submit a letter of inquiry to us describing their modified organism and asking us whether or not that organism meets the definition of a regulated article. And the outcome is that BRS issues a response letter confirming that the organism does meet or does not meet the definition of a regulated article.

And since we've restarted this process, we've gotten a lot of questions about whether or not we do a risk assessment under the Am I Regulated process. And we want to emphasize that we don't do any risk assessment through this process. The process is only used to confirm whether or not a modified organism meets the definition of a regulated article.

What is a regulated article? A regulated article is an organism that has been altered or produced using genetic engineering and that has one or more of its components derived from a plant pest or an organism or an unclassified or unknown organism or that APHIS determines is a plant pest or has reason to believe is a plant pest. And now I want to talk about some Am I Regulated trends over the past years.

But first, before I get into the actual numbers of this graph, let me walk you through the setup of the graph. First, on the x-axis, you'll see fiscal year starting in FY 2015 and ending in FY 2025. And on the left-hand side of the y-axis, you'll see the number of days to issue a response.

On the right-hand side of the y-axis, you'll see the number of responses. And the blue line represents our average number of days to complete a response per fiscal year. And the green bars show the number of responses that we've completed within a year.

The light green shows the number of responses to Am I Regulated. The dark green inside the dotted box shows the number of confirmation requests, response we completed. And the confirmation request process was a comparable process to the Am I Regulated process, but under the SECURE rule.

And as you'll see, the numbers for the Am I Regulated responses stayed relatively steady up until 2020, where we saw an explosion in the number of responses. And this marks the end of the AIR process and a transition into the confirmation request process. And then after that, we saw a steady increase in the number of responses we were completing every year.

But as you'll notice from the blue trend line, we completed our responses faster and faster with more efficiency every year. With FY25 being our most efficient year yet, we completed 69 response letters in an average of 28 days. There are a number of things that have contributed to our increase in efficiency in this process.

A couple examples. One is that we set some internal timelines that we've tried very hard to adhere to. And the other is in the last year, we formed a designated Am I Regulated team, which specializes in reviewing Am I Regulated inquiries.

And so, FY25, we saw a large variety of the types of organisms that came through the process and the types of traits that also came through the process. We responded to Am I Regulated for 20 individual plant species and nine microbes. By far, the most common species that came through the process was pennycress and tomato.

And here on the right side, you'll see examples of traits that we reviewed. Developers were targeting a lot of plant architecture traits, yield traits, disease and abiotic resistance traits and herbicide resistance among others. Now I want to talk about the types of modifications we were seeing in FY25 compared to previous years.

You'll see the pie chart on the right hand side for FY25 and notice that an overwhelming number of our responses were for genome edited organisms, 81%, which is different than what we saw in the previous Am I Regulated before SECURE where about 50% of the responses we issued were for genome edited products. And a far greater proportion back then were for transgenic and other. The other category includes things like epigenetic modifications that don't fall within the genome edited or transgenic categories.

You'll notice the large proportion of genome edited products in CRs and that's because confirmation requests was designed to assess specifically genome edited plants. And I want to talk about the types of organizations we've seen also come through the Am I Regulated process

in FY25 compared to the previous years. About three quarters of the submissions we received and responded to were from small and medium enterprises.

About 20% were from public institutions which include academic institutions, nonprofits, government research institutes. And about 50% in the Am I Regulated process prior to SECURE about half of the submissions were from small and medium enterprises and a far greater proportion were from public institutions and large biotech companies. 17% for the large biotech companies and 33% for the public institutions.

And 92% of the responses were issued to small and medium enterprises in the confirmation request process. So, we're seeing that these processes seem to be very popular with small and medium enterprises currently. And the last update I want to give before I hand it back over to Amanda is that recently in the last couple of months, we updated our Am I Regulated user guide posted on our website.

The updates were primarily to address questions, common questions that we received from developers. So, we add some clarifying language to the information requirements to submit an Am I Regulated inquiry. We also included a clarifying statement that we don't conduct a risk assessment through the Am I Regulated process.

And we made some minor administrative updates such as updating the address from the old Riverdale building to the GWCC. Here are some resources for those who might be interested in utilizing this process. And for those who want to scan while you're scanning, I'll say that we've genuinely enjoyed reviewing all of the products that have come through this process.

And we've enjoyed interacting with our stakeholders in the process and we hope to continue that interaction as we move through Fiscal Year 2026. Thank you. I'll let Amanda forward.

Amanda Kenney:
Thank you, Rebecca, for sharing those updates on the AIR process which is utilized by many of our stakeholders. Our next speakers are going to be Dr. Subray Hegde, Director of our Biotechnology Risk Analysis Programs. And also, myself, as I shared earlier, I'm a Senior Scientist in our Risk Analysis Group.

I'm really pleased today to be able to share some updates on the petition process with you all. First, for any stakeholders who are actually not familiar with this process, I thought I'd start by just giving you a brief overview of what it is. It is a regulatory process to seek deregulation of a genetically engineered or modified plant.

And in this case, it's for plants that APHIS determines do not pose a greater plant pest risk than the non-modified plant from which they were derived from. And there are four general steps. Developers submit a written petition that contains information to support that their modified plant does not pose a risk.

APHIS conducts a plant pest risk assessment or a PPRA. We publish the petition and our draft PPRA in the Federal Register for stakeholder comment. After that comment period, we then review the comments.

And then we publish our final PPRA as well as our determination. And if the modified plant is deregulated, it can be moved or planted without BRS oversight. So as Donna shared earlier, we reinstated the petition process in less than three months after the vacatur of SECURE.

We also made some updates to the process, which we're going to tell you about today. First, we revised our external petition user guide. Their prior guide had not been updated since 1996, if you can believe it.

As we all know, in that time, there's been a huge expansion of the tools available for genetic engineering. And so, there's a much greater diversity of traits that we see today. We also have a much clearer understanding of how to assess the risks of genetically engineered plants.

Therefore, we updated the guide to reflect the current state of knowledge, both on genetic engineering, but also how to assess the risk of GE plants. And our aim was to provide clarification regarding the data and information requirements for a petition under 7 CFR 340. We have also made some adjustments to bring our regulatory process into greater alignment with regulations, and we've shortened our review time.

Subray will share more updates about those topics later in the presentation. For the rest of my portion, I'm going to present an overview of our petition requirements and share some general tips for petitioners. So, these are the general categories of information required for a petition.

Broadly speaking, petitions for determination of non-regulated status need to include information about the non-modified plant and how the genetic modification alters the plant's genotype and phenotype in order for BRS to assess whether the modified plant is unlikely to pose a greater plant pest risk. This does include a description of the mechanism of action and both known and plausible phenotypic changes due to that MOA. We also need copies of the experimental data and analyses, as well as any publications or reports that are cited in the petition.

To fulfill the requirement for field test reports for authorized field trials, petitioners can just submit a list of the authorization numbers. And I would like to note that our risk assessment is comparative. We need to understand the baseline or non-modified plant, but our conclusion about risk is based on the analysis of the differences between the modified and the non-modified plant.

This is a list of characteristics and changes that are relevant to 7.340. I don't want you to try to read this list right now, but these are characteristics that are relevant to our PPRA and that APHIS needs to understand if and how these characteristics will change in a plant. A couple examples are disease and pest susceptibility or harm to non-target organisms beneficial to

agriculture. Please note that petition shall also include information known to the applicant that indicates the modified plant may pose a greater plant pest risk.

We use this information to conduct a plant pest risk assessment to evaluate whether the modified plant is unlikely to pose a greater plant pest risk. So, I know I just gave you what looks like a long list of information, but I really want to highlight here that sort of the type of data information that can be used to deliver that information can really vary depending on the plant and the trade. So, for example, regarding the biology of the non-modified plant, for a standard crop that we've evaluated many times like corn or soybean, we do not need a long extensive description of the ecology or reproduction of corn.

So, for like a standard crop, for that type of information, you can provide a brief synopsis and incorporate information just via published works, reference to published works. For other aspects of a petition, a synthesis of information from cited references may be sufficient. Similarly, in some cases, logical reasoning based on established scientific knowledge may be sufficient for particular components of a petition.

For other plants and cases or for other components of even the same petition, new experimental results may be necessary to understand whether and how a modified plant may pose plausible plant pest risks. So, it really depends on the combination of the plant and the treat. And this is a great segway to the concept of problem formulation.

Problem formulation is a fundamental approach in risk assessment that can be used to determine whether there are any plausible pathways to harm from a GE plant and what information would be needed to assess whether that harm may occur. So, for you can see I have this sort of graphic on the slide indicating we have a genetically modified plant and some arrows indicating plausible pathways to different endpoints. So, we can imagine maybe for, there could be a plausible pathway related to direct plant pest effects or perhaps harm to non-target organisms.

And we use problem formulation to identify these pathways based on the specific characteristics of the plant and identify information that we need to assess those pathways. We conduct a risk characterization to determine whether we can or cannot, sorry, can or cannot rule out those plausible pathways with the available information. This approach reflects the fact that not all genetically engineered plants are the same.

Using problem formulation, you know, we use it in a risk analysis, but also petitioners can use this to help determine what specific information would be important for you to gather and submit for your modified plant. I'll just close with a few general tips. If your plant has not been reviewed under a petition before, we would need some thorough information on the non-modified plant.

For example, its ecology, its reproduction, information on sexually compatible relatives, etc. As I said before, we evaluate both known and plausible phenotypic changes for pathways to greater

plant pest risk. Therefore, we need to understand your intended phenotype, but we also need to understand the mechanism of action well enough to understand the other plausible phenotypic changes.

And then also by definition or extension, what phenotypic categories are not expected to be different based on that mechanism of action. And so, petitions should explain this. So, we encourage you to think about plausible pathways to plant pest risk based on your plant, because that can help guide the type of specific information that would be relevant to a petition and relevant to our risk assessment.

And finally, we strongly encourage pre-submission consultation. As Rebecca shared earlier, we enjoy meeting with stakeholders and hearing about the products that you're working on. And also speaking with you to try to provide what guidance that we can.

I will now hand it over to my co-presenter, Subray Hegde.

Subray Hegde:
Yeah, thank you, Amanda, for clarifying petition process and the information requirement, not the... Sometimes when we say data, data doesn't mean experimental results. So, I will explain it later.

Oh, sorry. Okay. I want to highlight some of the major changes we brought to our petition process, because in the revised petition process, we understood certain things are not very clear, probably certain things are not needed.

So, this is some of the major changes I'm going to highlight. Earlier, before 2020, when you submit a petition, we review it. Within 30 days, we say whether petition is technically complete based on our regulation, what is requested.

If it's complete, that's fine. If it is not complete, we send a technically incompleteness letter. And we gave 30 days for our petitioner to respond to our review comments.

Assume that they resubmitted within 30 days, and we found that resubmission is still technically incomplete. We withdrew the petition saying that, you know, you have to start over again. That was earlier.

But here we have a change. What we do now is we do the same, that is review a petition for technical completeness. It is complete, clock starts the day you submitted.

If it's incomplete, we send you a letter. Now you have two options. Probably you have in all the data, you know, whatever we asked are the information.

You can resubmit within seven days. Let us say you want to collect more information or you need more time to really address our comments, you can pass. That is, it is not going to be withdrawn.

It can take your time to address our comments. Only time, you know, a petition is withdrawn is when a petitioner decides, because they don't want to continue. So, agency is not going to withdraw your petition.

That is the one change. Another is, I think another big change is earlier, you know, in the petition process, we always wrote an EA, Environmental Assessment, other than our Plant Pest Risk Assessment, or Environmental Impact Statement. Now, in the revised petition process, there is no NEPA analysis, means we are not writing EA and EISs.

Rather, we only prepare Plant Pest Risk Assessment and put it for public review. That is a major change we have done because that saves a lot of time for our agency. And there is a public announcement on our public-facing website, you know, why we did, you know, why there is no NEPA analysis and the reason behind it.

And the second change is, earlier we used to have three public, Federal Register notice on each petition. When it comes, the first one is we just put 60-day public review of a petition from the public. Second FR notice is we write a draft PPRA and a draft Environmental Assessment, and we put it for public comment.

The last one is our determination. There were three notices. The middle one is really, you know, removed now.

Here, what we are doing is, we put FR notice when your petition comes, a completed petition, and we also put draft PPRA for public comment simultaneously. There is no separate, you know, FR notice for PPRA. And the last FR notice, the second one is when we make a determination, whether it is, you know, there is no plant pest risk and not regulated, or, you know, that other decision that, you know, it is regulated.

So only two FR notices. So that way, you know, we have reduced regulatory timeline for 15 months earlier, we used to do, to six months. It is a significant change.

That is, within 180 days, we want to provide you a determination. And we did it anyway with one of the petitions so far. Okay, so this is just to highlight, you know, what did we do, how many petitions we received in the fiscal year 25.

We received 11 of them, and we finished one in 180 days. And we have seven, you know, if you look at, you know, it's FR notice, the Federal Register notice for the public comment along with our draft PPRA. And we have two of them still under review at the various stages.

And one of the petitions, you know, was withdrawn. And it was not resubmitted. And also, what we did with the type of crops we got.

Out of 11 petitions, we have six species out of 11 petitions. Out of that, we got four new species. That means we have never seen those species before.

I think this is a little, a comparison, you know, we can see, you know, what changes, that our petition process has brought. The first one, which is before 2020, and we have a large data set around 138 petitions in between 1990 to 2020. If you look, majority of the petitions were submitted by major biotech companies.

And very few from public universities and the academic institutions. And small and medium size in only 21%. If you move to the regulatory status review under the SECURE role, which was only four years, we have done 84.

Sample size is 84. And before we provide the responses out of that, we can see the trend. It was becoming more accessible to, you know, small and medium size enterprises.

You know, that means it was accessible to, you know, a lot of people, a lot of stakeholders. But you know, that 2024, you know, it was vacated. Now, coming back to now 2025, we learned some lessons.

Like, you know, how we can make our petition process easier to access for everyone. So, the trend remains. The sample size is too small to make any generalization.

It was only 10, sample size is too small, but the trend remains. It is still popular with small and medium size and also public institutions. That means something changed for them.

So my own analysis that the change is the clarification, clarification regarding information requirement that helped them, okay. And we said information, it is not experimental results all the time. And also, as Amanda mentioned, you know, we really want to use a problem formulation approach.

It's a different name, but the same concept, it has been there in science. Earlier, we used to say directed hypothesis testing. But what we are doing is though regulation says, you know, all the information we needed, but our focus is based on the crop, based on the trade, what exactly the agency needs to do, conduct their PPRA.

I think that changed. Here, you know, what we want to do further, that is we really want to further improve our petition process. These are the two main area based on our experience.

So, we want to improve. The first one is, so identify, you know, the internal petition process. We would like to know, we achieved great stride using a business process improvement on our permits.

Then, you know, we want to use the same type of concept, just map out entire petition process. See, where are the choke points? Why it is taking longer for certain steps?

How to address those, you know, choke points to improve the efficiency? So that's what we are planning to do this year. We have been doing it currently.

And the second is also equally important. See, this is what is happening. We wanted to reduce unnecessary data burden.

Under problem formulation, you only look at what is plausible pathway and where we need more information to write an effective plant pest risk assessment. For example, I can give you an example. Let us say I have an entirely new forestry species we never seen.

Then we need more information on the biology of the comparator plant probably. Let us use entirely new gene, which we have never seen. We would like to know if we have an intended phenotype.

Are there any associated significant change in the phenotype? Just like, you know, we want now, that is our problem formulation approach. What, where then the plausible pathway to harm exists.

So that really helps our stakeholders. What exactly agency needs? Because some of the petitions submitted by even the major companies we sent in, it is incomplete.

They have already, you know, 10 to 15 petitions deregulated. Then why they have the problem? Simply because they really don't know what agency needs.

It is not that they don't have data, but what data they really need to do a good effective PPRA. So that's, I think we would like to clarify during our consultation meeting based on problem formulation approach where we need more information. And these are the QR codes where you get the information.

And thank you for listening.

Amanda Kenney:
Thank you, Subray, for highlighting BRS's work to review petitions and provide a predictable science-based regulatory process. We will now have our first Q&A panel with the speakers and topics discussed so far today. We will take questions in the room using a microphone and online questions from a virtual Q&A.

We have now enabled the virtual Q&A feature for the online participants. So you can enter your questions online. I recommend for those using the browser-based version of Zoom that you refresh your browser to ensure access to that feature.

Tyler Reid, one of our BRS Biological Scientists will be your voice during the Q&A session for the online questions. For those in the room, please stand or raise your hand. We will bring the microphone to you.

And we do ask that all participants in the room and online provide your name and organization before asking your question. We will start with questions in the room and then take some

questions online. And I now invite the speakers to join me on stage for our first Q&A.

Who has the, yeah. Who has our floater microphone? I do.

Okay, there she is. That's Helana, she'll be our microphone taxi.

Emily Bass:
Hi, my name is Emily Bass. I'm with the Breakthrough Institute. I was wondering if y'all could elaborate more on the staff time and resources savings you're expecting from the change to no longer doing NEPA review for petitions.

Donna Lalli:
So, I think one of the, I guess, lucky timing of things, right? With the business process improvements that had been done with BRS over time, at the same time in 2025, we're at the lowest staffing level that we've ever been at.

So even though we're no longer conducting NEPA, we're kind of absorbing some of the other work that our staff would be doing. So, we went from 80, 75, 82 staff down to 62. We lost 25% of our staff this past year, along with all of these changes.

And so, at best, it's a wash, is the best way I could probably characterize it. I think that our staff is, even without NEPA and the staffing reduction, they're working full throttle right now. So, we just have really incredibly dedicated staff who care about meeting those regulatory timeframes and providing great customer service for you all.

So, I think that we're probably working right on the edge there, even without NEPA. Thanks.

Michael Stulberg:
Yeah, thanks, Emily. I'll just add in that it unfortunately is not very helpful for us in terms of the staffing time. We were not doing NEPA analyses under RSR. We didn't have a team dedicated really to doing NEPA analysis. And we actually had a different branch in APHIS that would help with our NEPA analyses. Now, we were anticipating and potentially going to try to get some resources there to help spur those along a bit. So, it may save our allocation of resources, but it was not a staff that had, where we had a NEPA group or anything like that. And then we're able to have a savings now for not doing it. So, it's just one less thing we have to be concerned about.

Subray Hegde:
Yeah, just one clarification. We are not going to do any NEPA for petitions, but there are NEPA questions we address for permits, but they are different. But there are standard questions that it doesn't take more time.

Ray Dobert:
Hi, Ray Dobert with Harambe Ag Consulting. I have a question with regard to the notice that you're going to be putting out an efficiencies rule in the not too distant future. So, one of the

questions is, is that expected to come out as a proposed rule or an interim final rule?

And can you make any comments on the expected timeline for when that is going to be released?

Donna Lalli:
So, the latest that we have is it will be a proposed rule. I think when it went into the regulatory agenda that you may have seen, it said interim final rule. It will be a proposed rule.

Timing-wise, we are really hoping that it will be out for public comment. We're optimistic about mid-summer. We're really hoping for before the end of the Fiscal Year.

Tyler Reid (speaking for Marie Faber):
Okay, we have a question online. From Marie Faber. She said, for modified plants, are you looking for petitions of only plants that will be moved across state borders from original locations where they were generated slash grown or all modified plants?

Does it matter if these modified plants are used for research contained in a lab and meeting NIH containment requirements?

Subray Hegde:
Can you repeat the question again?

Tyler Reid:
Yes. She said, are you looking for petitions of only plants that will be moved across state borders from their original location where they were generated slash grown or all modified plants? Does it matter if these modified plants are used for research or agriculture?

And for the research, she said, they're contained in a lab and meeting NIH containment requirements.

Donna Lalli:
So, Amanda, do you want to take it? They hate it when I try to talk technical stuff, so I'll let somebody correct me. But for petitions, you're petitioning for non-regulated status.

If you receive a non-regulated status, then you don't need an authorization, a permit, or a notification to move anything anywhere. Go forth. You're no longer regulated.

But if you have an organism that meets our definition of a regulated article and you haven't asked for a petition, you will need a permit or a notification if you want to import, move interstate, or release out into the field.

Fan-Li Chou:
Hi, everybody. I'm Fan-Li Chou from the American Seed Trade Association. First, I just want to thank you for hosting the stakeholder event because we were really excited to see you guys last

year.

It didn't happen. And then secondly, really, from ASTA and our members, we really want to thank you guys for stepping up and moving to Legacy 340 so quickly that I think our members really was so encouraged by that and was able to just keep moving with their own processes. So, thank you for that, especially since you guys did it with such little staff.

So, I appreciate that. Just moving from pre-SECURE and post-SECURE, there seems to be some process improvements. But we wanted to understand the notification process because that is something that did not occur under SECURE that's coming back online.

Just wondering if you have changed the way that you perceive what can qualify under notification because some of our members are noticing that insect-resistant plants are no longer permitted under notification.

Subray Hegde:
Yeah, Katie, right? This topic is going to be covered by one of our presenters. Yeah, so I don't want to take out the thunder.

Tyler Reid:
Yes, they [an online participant] said they would like to hear more about the USDA regulatory relief when a product is registered or permitted by the EPA, especially in terms of GE microbes.

Michael Stulberg:
Okay, so we had a provision right under the SECURE rule that if you are registered with the EPA with a microbe, then you would no longer require a permit from us here in BRS. That is something we are proposing in the efficiencies rule. Currently, we don't have that provision in the regulation.

Ray Dobert:
Again, Ray Dobert, in the past, when petitions were submitted, and especially when they went out for public comment, historically, BRS posted both their draft plant pest risk assessment as well as the petition on their website. Currently, it seems the orchid is posted, but none of the ones which are out for notice are being posted. Is that a shift in how you're going to operationalize sharing information with regard to petitions?

Michael Stulberg:
I'm looking here at Alan for cues. So, it's been like a work in progress. We mean to be updating the website as well.

We were trying to, you know, reduce the number of documents stored in various locations and centralized links and just refer everyone to regs.gov. It's been a work in progress. Alan, do you want to comment?

Alan Pearson:
So, the way, just to update, and as Michael says, it's a work in progress that we're ironing through, but the way that we're posting things now is at least post to the Federal Register notice through the regulations.gov site from which you can get access to all of the documents. So even if the documents, you don't see them on the website, you can get them that way. We're still working through with our webmasters exactly, you know, if we can get a little bit more direct links so that you're not having to go through multiple steps, but they should all be accessible.

And if anybody's having trouble finding one, you can just message us. You can send a message to me or to our petition. We have a petition's mailbox and we'll get that fixed.

Tyler Reid:
We have another question online. Okay, so many of their fee-for-service clients request that they produce gene-edited plants for them. If they use segregation to eliminate the transgenic editing machinery, what type of data is necessary to satisfy USDA APHIS?

That the, okay, what type of data is necessary to satisfy USDA APHIS that the plants are no longer transgenic?

Rebecca Fletcher:
All right, for the Am I Regulated process, we don't have specific data requirements. What we want to see is a description of your methods for how you screened for any exogenous DNA and plant pest sequences. We need like a pretty thorough description, whether you do PCR, you know, a good explanation of your primers.

If you do whole genome sequencing, some details there would be very helpful. But we don't have any specific molecular data requirements for the Am I Regulated process. Oh, yes, and please take a look at our guide on the APHIS-BRS website under the AIR section.

Has a lot more information about what you can include in your Am I Regulated inquiry to satisfy that requirement.

Amanda Kenney:
Okay, thank you very much for your questions. For our virtual participants, we're going to disable the virtual Q&A now, but we will re-enable it for the second panel session. We are now going to take our scheduled 20-minute break.

For those in the room, please feel free to help yourself to refreshments over on the side of the room. And just a reminder, there's two restrooms on this floor, just a single bathroom there in the hallway, and then a two-person, two sets of, a set of two-person bathrooms over in the main lobby. All right.

Amanda Kenney:

All right, we're going to go ahead and get started on our second portion while some of the guests are just gathering their final little refreshments.

Our next speakers are Ms. Janice Strachan, one of our Branch Chiefs in our Biotechnology Risk Analysis Programs, and Dr. Katharine Swoboda-Bhattarai, a Biological Scientist, also in our Risk Analysis Group. Janice and Katharine will present on process improvements for permits and notifications.

Katharine Swoboda-Bhattarai:
Right, thank you so much for the introduction, Amanda. Welcome back from the break, everyone. So BRS was selected at the APHIS level to undertake a two-year business process improvement or BPI project in Fiscal Years 24 and 25.

If I can get the clicker to work. All right. So today I'm excited to share an overview of what we accomplished this past year in regard to our main BPI objective, which was to reestablish a risk-based and familiarity or experience-based approach for reviewing crop-trait genotype combinations in permit applications.

So we undertook this BPI project to restore BRS's track record of issuing permits in a predictable and timely fashion and to rebuild confidence in our permitting process overall. And we set two measurable targets to help us track our progress. The first was to meet regulatory targets for average days to issue permits for import, interstate movement, and environmental release.

And the second was to issue 95% of BRS permits within our regulatory timeframes. So before I delve too deeply into what we accomplished in Fiscal Year 25, I'm going to give a short recap of what we accomplished during the first year of our project because this really set the stage for our continued success this year. So, we kick-started our BPI project by using a Gemba Kaizen walk-the-line analysis, which was pioneered by Toyota, as a way to make assembly lines, like this little tractor assembly line on the screen, more efficient at individual steps and as a whole.

So, we applied this approach to the BRS permitting process and identified several ways in which to streamline our permit reviews without compromising the quality of our reviews overall. For example, we streamlined the permit review workflow in APHIS-eFile by eliminating a duplicative supervisory review step and implementing soft enhancements that keep our internal workflow moving forward automatically. We also implemented new BRS import permits with multiple origins and multiple destinations that include reusable labels.

These replaced import permits that were limited to one origin and one destination, and significantly reduced the number of import and interstate movement permits submitted for the same material, basically. We increased consistency of permit reviews by ensuring that our permit reviewers have a consistent understanding of what information is required for an application to be deemed technically complete and revised the permit user's guide to make this information available to applicants. And finally, we developed standardized permit conditions for the environmental release of corn and soybean plants, which have helped us maintain

consistency across permit reviewers and across applicants.

So altogether, these process improvements had a significant impact on our permitting metrics in Fiscal Year 24. So, as you can see from this graph, from this slide, actually, we reduced three handoffs and shaved an average of five and a half days off the overall permit review timeline. So, this is a measurable improvement that positively impacts the bottom line of all of our permit types.

Also, compared to baseline data from Fiscal Year 23, we reduced the average number of days to process movement permits by nine days to 22 days on average, and held steady at 47 days for release permits. And as a result of these two efficiency gains, we increased the percentage of permits issued within regulatory timeframes by 9% for movement permits, so from 87 to 98%, and by 1% for release permits to 99%. So overall, this meant that we exceeded our BPA goal of issuing 95% of permit applications within the regulatory timeframe.

And as you can see from this data, we were on really strong footing at the end of Fiscal Year 24 and started Fiscal Year 24 with a lot of momentum. However, as you all know, we soon faced a major challenge, which was the vacatur of our revised regulations in December of 2024. So, our team had to quickly pivot and refocus on realigning BRS permits and notification authorizations with our original regulations.

And we did so in three main ways. The first, unfortunately, we had to walk back some of our previous process improvements following the vacatur. One of these was a multi-year permitting flexibility for import permits and interstate movement permits, which are now limited to a one-year duration.

We also had to resume accepting permit applications in APHIS-eFile as soon as possible to prevent service delays for our stakeholders. And finally, we had to reestablish the notification process for crops and traits that BRS has extensive experience with and that allows for more streamlined reviews for lower-risk activities.

So, getting permits back up and running quickly required an all-hands-on-deck approach. So, we partnered with other teams in BRS and were able to leverage the BPI framework that we established in Fiscal Year 24 to quickly realign to our original regulations following the vacatur. Our eFile team worked quickly to realign required information fields in APHIS-eFile permit applications with our original regulations. We also worked to ensure that both our standard permit conditions, which are codified in our regulations, and our supplemental permit conditions were realigned with our original regulations.

We revised the permit user's guide and the additional regulatory requirements for BRS authorizations document and made these available to applicants on our website. And finally, as a result of all this hard work, we were able to start accepting permit applications in APHIS-eFile on December 19th, 2024, which, as Donna mentioned earlier, was only 17 days after the vacatur. So, if you ask me, this was a pretty monumental effort that yielded great results both

for BRS and our stakeholders.

After we got permits up and running, we turned our attention to reestablishing the notification process. So, our eFile team created a temporary notification application pathway in APHIS-eFile that made it possible to effectively turn permit applications into de facto notification applications by clicking one box. So, this was a really clever approach that allowed us to get notifications up and running in APHIS-eFile as quickly as possible.

And we published a revised version of the notification guide on our website, which contains important information and updates related to our reestablished notification process. And once these two pieces were in place, we were able to begin accepting notification applications in APHIS-eFile on February 7th, 2025. So not long after the vacatur either.

So, to ensure that we got off to a good start with our reestablished notification process, we established a small team of experienced biotechs to restart notification reviews in a consistent and timely manner. This team was able to adjust our internal notification review processes in real time as needed, and they worked hard to document decisions made during notification reviews to increase consistency for reviewers and for applicants alike. So, if you remember, BRS adopted the permitting process as our only method for authorizing regulated activities under our revised regulations.

And we undertook this BPI project in part to reestablish some of the benefits of what was then our legacy notification process. So now, following the vacatur, we are in an era of being able to offer both our improved and more efficient permitting process, as well as our streamlined notification process to applicants, I think which is kind of an amazing place to be right now.

Okay, so because some of you may not be familiar or as familiar with the notification process, I'm going to give a very quick overview. But please remember that you can always refer to our notification guide for more information. So, notifications, let me just change this slide. I'm going the wrong way?

Yes, here I am. Thank you. All right, so notifications for the introduction of certain regulated articles are codified at 7 CFR 340.3. So, to qualify for the notification process, plants must meet six eligibility criteria. And they must be introduced in accordance with the six performance standards that are outlined in the regulations. So, as you can see on this graph, notifications have reduced regulatory timeframes compared to permits. So BRS has 10 days to acknowledge interstate movement notifications after the receipt of a complete application, and 30 days to acknowledge both import and environmental release notifications after the receipt of a complete application.

Under our revised regulations, BRS had 45 days to issue interstate movement and import permits after the receipt of a complete application. But now that we are under our original regulations again, we have 60 days. Our longest regulatory timeframe, 120 days, is for issuance of environmental release permits.

So, I want to point out that based on our Fiscal Year 24 metrics, we have reduced average permit processing times. So, they are within, let's say, throwing distance of our regulatory timeframes for notifications. So, we were at 22 days on average for interstate movement and import permits in Fiscal Year 24, and 47 days for environmental release permits.

So, in general, I think this is just great news for applicants, right? We're getting better across the board.

So, the temporary notification pathway in APHIS e-file was replaced by a standalone notification application on June 13th, 2025. It was released alongside the new pre-application questionnaire in APHIS e-file, which walks applicants through a series of questions to determine if their application qualifies for a notification or if a permit is required. So, these are little schematics of our notification and permit workflows. And what you can see is that notification and permit, what you can see is that notification and permit workflows are different.

Because notifications rely on performance standards outlined in the regulations, they do not have the conditions collaboration stage where permit conditions are reviewed by BRS managers and applicants on permit applications. And on rare occasions, when a notification application is submitted that does not meet the qualifications for the notification process, BRS has the ability to convert the notification application into a permit application. So, this flexibility was not available in e-permits, which was our online permitting system before we switched to APHIS e-file in 2021. But I think this will be a useful tool for our permitting staff going forward.

So, despite the backdrop of the vacatur and the hard work that was required to stand up our regulatory processes under our original regulations, the BPI team continued to make progress on other BPI objectives in 2025, Fiscal Year 25. So, we aligned authorization review processes with our original regulations, including updating procedures for amending permits that were issued under our vacated regulations.

We expanded our growing suite of standardized permit conditions with new SPC sets for cotton and tomato. So hopefully some of you have been able to take advantage of these new SPCs. And in Fiscal Year 25, we started to examine PMPI, which are plant-made pharmaceuticals and industrial products, and invertebrate permit review processes for potential efficiency gains.

So, although these complex permits make up a small portion of our issued permits each year, they represent two areas of our permitting process that are ripe for improvement.

All right. And our micro-permitting team has also been working very hard over the last few years to improve the predictability and timeliness of our micro-permitting process.

So, in FY25, this team developed standardized permit conditions for import and interstate movement permits. So, under these SPCs, all greenhouse use requests require an APHIS inspection either by BRS or by PPQ. And for PPQ inspections, they must have been completed

within the past three years.

And the inspection must apply to the organism listed on the permit. So, if you look at the graph, on the right, you can see that imports and interstate movements accounted for close to 90% of micro-permits issued in Fiscal Year 25. As a result, these standardized permit conditions have had a big impact on our microbe for our micro-permit applicants this year.

And although microbe, excuse me, and although environmental releases make up a smaller, but still very important portion of our micro-permit pie chart, this team started to address or started to standardize conditions for environmental release permits for microbes in Fiscal Year 25. And Alan Pearson is going to talk a little bit more about these efforts in his talk, which is the next one.

Our microbe team also developed a uniform set of permit conditions and regulatory requirements for developers who may want to move large numbers of microbial species between multiple contained facilities.

So, these kingdom-level high-throughput permits authorize interstate movement only, do not authorize greenhouse use, require applicants to list each microorganism, require applicants to list at least one construct, and have specific reporting requirements that are outlined in the permit conditions. So, for example, although applicants only have to include one construct on the application, they are required to submit a report that contains detailed information about all microorganisms, constructs, and locations where specific constructs will be moved no later than six months after the permit's effective date. So, there are some reporting requirements with these permits that are a little bit different.

The permit conditions and reporting requirements for these permits are clearly described in the revised permit user's guide, along with step-by-step instructions for entering construct data into APHIS e-file. So please see these resources if you're interested in applying for one of these permits. So, it has been a pleasure to provide an update on our BPI project accomplishments.

I'm going to turn it over to Janice to tell you about how we did in Fiscal Year 25 and what we're planning to do next. Thank you.

Janice Strachan:
I get the fun of telling you what we accomplished and what we're planning for the rest of 2026. In 2025, we issued 879 permits. That's four more permits than what we issued in Fiscal Year 2024.

On this bar graph, you can see that we issued 450 interstate movements. That was 51% of our issued permits. We also issued 14% of import permits and 35% of environmental release permits.

On this pie chart, you can see that the majority of our permits are for plants. That's 81% of our

permits that are issued go to plants. The next biggest group are the microbes at 148, which is 17% of our permits, and invertebrates are gaining traction. They're at 2% of our permits. For the permits in 2025 or 2024, the microbes had 123 permits, and in Fiscal 25, they had 148 permits. That is an increase of 17% from one year to the next.

For invertebrate permits, in Fiscal Year 2024, we had eight invertebrate permits, and in Fiscal Year 25, we had 18, which is an increase of 56%, which is why Katie indicated that invertebrate work will be done this year to deal with that increase and standardize some of that review process. We excelled in 2025 for how we met our goals. The first measurable target that we set for ourselves was to meet regulatory targets for the average days to issuance, and that would go from technical completeness to issuance.

As you can see, the number of days that it took us in 2024 is in the dark blue, and the light blue is for Fiscal Year 25. And you can see red lines on the graph. This shows what our regulatory timeframes are for each of these processes.

In 2025, it took us two days less to process both movement and release permits. You can see that it was 22 days for interstate movements and imports, and this year it was 20. For releases and interstate movement releases, it went from 47 days to 45 days. This shows that we are making improvements in our efficiency.

The bar graphs on the right show the percentage of permits issued within regulatory timeframes. During Fiscal Year 24, represented by the light green bars, and 25 is represented by the dark green bars.

And again, this is measured from technical completeness to issuance. In 2025, we were able to issue 95% of import and interstate movements permits within 45 days, and 96% of release permits within 120 days. Although these percentages decreased slightly from Fiscal Year 24, in Fiscal Year 25, we were able to exceed our BPI goal of issuing 95% of permit applications within regulatory timeframes.

This is a testament to all of the process improvements we made to the permitting process over the past two years.

Let's talk about notifications. BRS acknowledged 43 notifications in Fiscal Year 25 since the regulatory process was reestablished in February. Of these, seven were for imports, that's 16%, 44 were for interstate movements, that's 33%, and 22, or 51%, were for environmental release. We applied the same two measurable targets to notifications as we did for permits, and this graph shows the average number of days that it took us in Fiscal Year 25 to process interstate movement and import release notifications from technical completeness to issuance or acknowledgement. On average, it took us five days to acknowledge interstate movement notifications, and 10 days to acknowledge import and environmental release notifications.

As you can see, we were well below the regulatory timeframes that are represented by the red

bars on the graph, which is good news. The next graph shows the percentage of notifications acknowledged within regulatory timeframes during Fiscal Year 25, which is measured from when an application is deemed technically complete to when BRS acknowledges the notifications. We were able to acknowledge 91% of interstate movement notifications within 10 days, and 100% of import and release notifications within 30 days in Fiscal Year 25.

Overall, we exceeded our BPI goal of acknowledging 95% of notification applications within the regulatory timeframe, which really stand up, which really shows the hard work that was done by the BPI team and BRS more broadly to stand up the notification process. This past year, in summary, we were able to make appreciable changes to the BRS permitting process over the past two years and get the notification process off to a great restart, but there is still more work to be done. In Fiscal 26, we are planning to finish documenting the BPI process improvements and accomplishments.

We will complete our records about the techniques used to identify potential efficiencies and specific changes that were implemented, so there is a historical record about this project. We will build on efficiency gains going forward. For example, many BPI documents were saved in different locations on our SharePoint site.

We intend to pull these documents together so they are easier for staff to find and use. We will measure and monitor impacts of implemented initiatives and course correct as needed. Several reports and dashboards are available to monitor current processing metrics.

This allows for fast assessments of productivity and identification of potential slowdowns. We will continue to implement process improvements that increase efficiency and consistency. Such improvements may come from changes in technology or lessons learned from a performing current work.

Our overall objectives in Fiscal 26 are to ensure more interstate movement notification applications are acknowledged on time. For example, we have noticed that we need to pay attention to deadlines that may fall on a weekend or holiday to ensure that work is completed prior to the deadline.

Streamline review processes for PMPI and invertebrate authorizations. Those two teams started their assessment of processes in Fiscal 25 and have a good start on completing their work in Fiscal 26.

We will update PMPI and invertebrate information in external guidance documents by providing better guidance to the public. Submissions arrive with the needed information and that leads to more efficient reviews of those authorizations.

We will continue to improve communication with applicants and stakeholders. By keeping the lines of communication open, we intend to provide timely and accurate information to assist with submitting and reviewing your authorizations. Here are some QR codes to reach us should

you need to ask us questions or ask about the processing of your permits.

Thank you for your attention.

Amanda Kenney:
Thank you, Katharine and Janice, for highlighting our process improvements to our authorization processes that support customer service for our stakeholders. Our next presentation will be from Dr. Alan Pearson, BRS Assistant Deputy Administrator, and also Mr. John Sagle, Assistant Deputy Administrator in Plant Protection and Quarantine for their Pest Exclusion and Import Programs. Alan and John will share updates regarding APHIS's regulatory framework for microbes.

Alan Pearson:
It's a pleasure to be here today to address you on our work on regulating microbes. John Sagle, I'm also really pleased to be joined by John. He's not able to be here in person due to other PPQ business, but he is joining us online, so you will hear him come through the speakers in the ceiling a little bit, but I wanted to give you a picture of John so that you can associate a face with the voice that you will hear soon.

So, recent years have seen a big expansion in the development of new microbial biotechnologies propelled by advances in genomics and in genome editing, automation, and AI, which have really driven new discovery and new product development. Additionally, biotechnology as a whole, and particularly microbial biotechnologies, become really a US strategic national priority, and that's also driving work in this area. So, we're seeing a lot of different microbial biotechnologies developed.

For this, for our meeting today, of course, people are most interested in the agricultural uses, whether it be pesticides or be fertilizers, biostimulants, and so on. There's technologies being developed in foods, and of course, fuels, chemicals, other biomanufacturing applications. The result of this, the explosion for APHIS has been that we've seen a great increase in the number of permits coming to us, both in both of BRS and PPQ.

So, I'll show you here our data from BRS just in the last five years in terms of the numbers of permitted microorganisms that we've gotten, and you can really see the increase that we're experiencing from just over about 60 permitted microorganisms five years ago to over 2,400 last year. This includes both movements, just moving microorganisms, either importing them or moving them from one facility to another, but also now we're also seeing increases in field releases and field trials of microbes. Let me turn it over to John to give some data from PPQ.

John.

John Sagle:
Yeah, thank you, Alan. Just a quick sound check. Make sure you can hear me.

Alan Pearson:
Yep, we hear you.

John Sagle:
Excellent. Well, greetings from PPQ from South Texas, down here in McAllen. Sorry, I couldn't be with you all there today in person.

Yeah, to say the least, the growth in microorganism permitting applications is going up significantly, and this graph here I think gives a good illustration of the magnitude and volume. This is all situations, imports, state to states, things like that. This is a gross total.

Pay not too much attention to the FY22 line. That was some data reconciling challenges there. But I think from 23 on, you get a sense of the growth and magnitude here of what we're dealing with in PPQ in terms of permit organisms and applications that are coming in.

And we're certainly on track and paced this year in 26 to continue in that same trajectory. And really give a lot of kudos to our staff. This is not a large group of staff individuals processing all these permits, but they do a really good job of trying to keep pace and provide the level of rigor and evaluation that's needed to make sure we're managing the risks as well.

You can go to the next slide, Alan, thanks.

Alan Pearson:
Yep, so over the last few years, we've issued, either BRS has issued on its own or in coordination with our coordinated frameworks, partners in EPA and FDA, some requests for information on biotechnology regulation. The one that we issued ourselves was focused on microbial biotechnology. And we've heard some consistent concerns in the comments that we've received in response to those RFIs.

And I'm outlining the three major concerns we've heard here. First, that BRS and PPQ should really develop a harmonized approach to microbe regulation for plant health. And that this harmonized approach is really very important to ensure alignment between our programs when determining whether microbes are subject to regulation.

And providing greater clarity and predictability to researchers and developers. Second, that BRS itself should develop a clear, predictable pathway or pathways for commercialization of regulated microbes. That those pathways should include risk-based review processes and exemptions or fast-track reviews for microbes that are well understood or pose minimal risk.

And then third, really, that BRS permits should have fit-for-purpose risk-based permit conditions when it comes to field releases of modified microbes. And that there should be a clear pathway for scaling up the size of these releases. So, permit conditions should be tailored to plausible or actual risk based on the organism, the modifications made to the organism, and the intended use of that organism.

They should be aligned with agricultural practices rather than getting in the way of standard agricultural practices. And should enable data collection that can help developers both develop their products and get through the regulatory process. And then thirdly, they should be aligned with PPQ conditions for field trials if the modification itself doesn't increase plant pest risk.

So, recognizing the importance of taking a consistent approach to microbe regulation, in August of last year, BRS and PPQ leaders established a joint team to develop a harmonized framework that includes a common understanding of regulatory jurisdiction for plant pests and a common understanding of the level and nature of evidence that's needed to make a jurisdictional determination. This team's been very actively engaged, meeting regularly, and has now established a core principle for this framework and the foundation of the framework. And BRS and PPQ, they've briefed BRS and PPQ leadership and our leaderships have agreed on this core principle and foundation.

And for more details on this, I'm going to turn back over to John.

John Sagle:
Yeah, thank you, Alan, I appreciate that. And yeah, this has been quite the endeavor and really kudos to staffs from both BRS and PPQ for the work that they've made so far, the advancements. I stressed before, the staff that were processing those tens of thousands of permits are the same folks also working on this endeavor of harmonization.

So, it's certainly trying to hit that kind of optimization level of really making sure we have a good path paved forward here for this, but not losing any pace or speed with what's currently being processed and coming in as we speak. So, they've done a really great job of doing this. And so, yes, they've come together and between BRS and PPQ, we've agreed at a very core principle level how we want to define this from a regulatory sense.

And that's simply what's on the slide here. For an organism to be regulated as a plant pest, there must be demonstrated evidence or a plausible hypothesis that the organism can cause direct or indirect harm to plants. I really want to focus on that plausible piece of the hypothesis.

This is not simply an element we've thrown in here to just give us quick, easy regulatory stance. We're really going to make sure we're using good application and process here to determine what we're reading and finding at a hypothesis level is credible. It gives merit to caution and to regulation, but it's certainly not a default standard that we'll just quickly gravitate to.

And then certainly past the core principle, this is kind of an illustration of the foundational kind of framework that the teams have put together. When you really look at kind of such a wide spectrum of microorganism permits and applications coming in, particularly ones that clearly have focus and purview, both in BRS and PPQ, we can really put those into kind of three distinct categories here, which you see plant pathogens, insecticidal microbes, and antimicrobial microbes. And so, the team really took time at each of these kind of categorical levels to kind of determine how we need to determine risk and cause and determination of regulation.

So, for plant pathogens, a microbe is regulated if there's evidence demonstrating the microbes ability to infect and cause disease in a plant, or even if there is a single credible report indicating pathogenic potential that could meet the threshold. Again, similar to the plausible hypothesis, the single credible report is more of a disclaimer. It could be a single report could provide us to be in a position that we feel we need to regulate it, but it is not a default standard.

There will be certainly a lot of evaluation to that in terms of, is this what we're seeing, finding and reading about credible? Is it something we need to take seriously or not? It is not a default standard there.

And then certainly onto insecticidal microbes, a microbe is regulated if there's evidence that it harms or could plausibly harm a beneficial insect and cause plant harm and could lead to plant harm. Same process there for the plausibility side of this. That's always the teams get together and really evaluate this at an objective level and determine is there sufficient information that makes us think that there is a potential risk here that we need to manage.

And then lastly, the antimicrobial microbes, it's regulated when evidence indicates there's the antimicrobial properties could plausibly lead to indirect plant harm, but do note that the mere production of antimicrobial compounds in and of itself does not meet the threshold.

Alan Pearson:
So how will this framework apply then to modified microbes regulated by BRS? Pretty simply, if either the donor microbe or the recipient microbe, or I should say the donor organism, or the recipient microbe are known to or could plausibly harm plants, then the modified microbe would be subject to regulation under the Part 340 regulations. I want to stress that the harmonized framework itself is not going to be used to assess the risk of the modified microbe.

It's going to be used simply only to determine jurisdictional status of the donor and the recipient microbes, and thus of the modified microbe. Risk assessment itself then becomes a separate part of the process that I'll turn to in a minute. But first, I want to turn back to John to give you sort of a final slide on what is coming next from the team, which continues to work.

John Sagle:
Yeah, thanks, Alan. So where are we now? We're in that finalizing the scientific criteria process. So, it's truly the nuts and bolts at the level of, we've given the framework, the foundation, the core principle. So, then we get into some more of the specifics here of how we harmonize the criteria as close as you can go at a granular level. You know, we're never going to cover every scenario, everything in one fell swoop, but I think we're trying to get as close to that as we can.

And the teams are doing a great job. They're keeping us briefed, updated. This is not an easy task, in what they're really trying to tackle here.

You get a lot of highly capable, strong scientists in the room to get to consensus on criteria. It's

not always, and I say that with fuel and endearment, is do you get to that, it's not easy, but their heads are in the right places and they're really making some good progress. With that, when we get to that point, and I'm hesitant to give you firm timelines as to exactly when this will launch and be ready for implementation, but that's a very key point of implementation.

That last bullet is pretty much a subset or is an equal part of implementation. And that's certainly making sure that we're engaging with you, all the stakeholders, providing advanced awareness of when this is going to go live, how it would impact you and what you're applying for and what the process will look like, along with other stakeholders, even our intergovernmental partners at Customs and Border Protection, making sure import level microbes come in with minimal hiccup or any confusion about whether this is still something that they need to validate, things like that. So, implementation is going to be big, but what we can certainly promise and assure you of is this will be an inclusive implementation with stakeholders so that we're all on the same sheet of music here when we're moving ahead.

Alan, I really appreciate the opportunity to come and join you at least virtually here. This will be my last kind of slide here. However, I will be hiding up in the speakers of the room there for you for a while for the Q&A session later.

So similar to what Dr. Lalli mentioned before, I'm not the technical expert. I tend to get myself in trouble, but I will be around and do my best. But I'll turn back to you, Alan.

Thank you.

Alan Pearson:
Great, thanks, John. And we really, really appreciate you being able to join us today virtually so that we can really speak to you from both programs at the same time on this because that's so important that we take this aligned approach. As I mentioned a moment ago, this aligned approach is really about what comes in, what is subject to regulation.

That's incredibly important, obviously, to everyone. But then there's a lot more that happens after some things come in. And what I'm going to do now is turn from the work that the BRS PPQ team is doing to work that right now isn't going on entirely within BRS, although we will continue to, we are and will continue to consult with PPQ as we undertake some of this work and as it proceeds.

So, we know that once we've got a microbe that's subject to regulation, that microbe can exist anywhere along a spectrum of risk from low risk to high risk. And we are currently establishing a team within BRS to develop what we might call microbial permitting scale-up and commercialization pathway. This team, among its goals, will be defining distinct risk profiles or categories for modified microbes to guide regulatory oversight.

These will be based on the characteristics of the non-modified microbe, including its occurrence and prevalence in the environment, as well as the effects of the modifications on the microbe

and on those characteristics and on the intended use of the microbe. The team will also be working on further refining our permit requirements to align with the risk profiles so they're clear, risk-based, and predictable. And the team's going to be working on developing regulatory pathways from the lab to commercialization, including options for reduced regulatory burden and regulatory off-ramps where the risk is minimal.

So, for those organisms that are clearly low risk from the start, we're looking at whether we can implement streamlined review processes. For those that are higher risk or where we have high uncertainty, it may be necessary to start more in a lab environment and or a small-scale field trial environment where data to inform risk evaluation can be gathered that could then enable scale-up and ultimately, if the product proves viable to the developer, ultimately enable commercialization. One of the first things that we're looking at doing is to establish an approach for issuing commercial permits under our existing regulations while we're exploring other potential pathways to commercialization that might require regulatory revisions.

When we think about what these other pathways are, that is also part of what the team is doing and determining what pathways we might be able to work under our current regulations, what pathways might need regulatory revisions. So, all that is under consideration at this time. And in all of these efforts, whether it's permit conditions, commercial permits, LONPRs, which stands for a letter of no permit required, we are or will be consulting with PPQ to better understand their approaches to these issues and when and how, based on risk, we might adapt aspects of their approach as appropriate to modified microbes so that we can continue to ensure a coordinated and seamless customer experience between our two APHIS programs. Turning to permit conditions themselves, you've already heard from Katie about some of the work that we are doing on permit conditions for microbes. We've been making revisions; we continue to make revisions to our permit conditions for release permits so that they're more risk and performance based considering the organism and the intent and context of the use.

As a sort of a general principle, we start with more stringent conditions for new microbes, microbes that are new to us or the developer or for new companies. And then as the company collects data and both the company and we gain experience with the product, we can often relax some of these conditions moving forward. So, I'll give a few examples here and the first has to do with isolation zones.

If there's greenhouse or field data or there's scientifically reliable references showing that a microbe doesn't move and isn't going to move from an inoculation site and then based on how the microbe is applied, for example, is it applied as a seed treatment or is it applied as a spray, we could reduce or even eliminate isolation zones. So, the second example, we're looking at possible changes to our approach to post-trial monitoring of a field site based on risk and data collected in the greenhouse or in the field. For instance, if greenhouse data on persistence of a modified microbe may be able to support a reduction in the length of persistence monitoring during a field trial.

And then third, we're looking at our devitalization requirements and whether we can change

some approaches there based on documented trends in persistence. For example, if you have three consecutive sets of negative test results in the field environment in the areas where you have inoculated the microbe within the field site, that may be sufficient to consider the microbe devitalized and the field trial concluded.

In addition to continuing to evaluate and adjust our permit conditions, we're doing a few other things. BRAP and ROP are updating the permit authorization workflows, particularly vis-a-vis pre-authorization inspections so as to ensure timely permit issuance. ROP is also updating its pre-authorization inspection checklists and training additional inspectors to inspect facilities and microbe release sites so that inspector availability doesn't become a roadblock to issuing permits. We're updating our permit user guide to incorporate updated microbe guidance.

And as I've mentioned, we're developing a transparent and predictable process for obtaining commercial permits. With all of these activities, we look forward to continuing to engage all our stakeholders in order to improve the risk-based regulation of modified microbes and enable the development of new microbial biotechnologies while continuing to protect plant health in the years ahead. And with that, I'll finish and I'll welcome questions that you have during the Q&A session.

Thanks.

Amanda Kenney:
Thank you, Alan and John. It's exciting to hear about BRS and PPQ's collaboration on a risk-based regulatory framework for microbes. Our next speaker is Dr. Doug Grant, our Director of BRS Regulatory Operations Programs. Doug will provide updates regarding compliance activities and trends for Fiscal Year 25.

Doug Grant:
Thank you so much, Amanda. And we've had some really technically dense talks here today. And it just really reminds me of what a great group of intelligent and thoughtful folks that I have the pleasure of working with.

And also, what a really great set of stakeholders that we have here that we get to partner with. So, thank you for being here. I was looking at the Brazilian prickly pear on my desk before I came up.

And as Alan was talking, I was thinking, I sure hope Colin had the proper PPQ import to bring that in today. So, I'll tell you a little bit about our regulatory operations. We basically deal with everything downstream of permit and notification issuance.

I'll start off with sharing a little bit more about staffing changes. Michael already provided some of that. Then I'll share some inspection data as well as compliance outcomes.

And finally, an overview of noncompliance in FY25. So, we lost over a quarter of our staff in the

last year in ROP. Dr. Phil Mason, who some of you may have known as the Branch Chief of Western Compliance Assurance Branch out in Fort Collins. He took the DRP, the Deferred Retirement Program, in April. And Mr. Nate Yates, he actually just retired in January of this year. So, we have Ms. Heather Brown as the Acting Branch Chief for the Western Compliance Branch as of earlier this month. And she's one of our Senior Compliance Specialists, very knowledgeable about all of our processes. And we also have Laura Andrako as the Branch Chief of the Eastern Compliance Branch there in Raleigh. So, it's nice to have some semblance of stability as we navigate a lot of changes.

So, one of the things that we decided to do after losing a significant portion of our staff was to really kind of streamline and restructure ROP. So, we took the folks from the Compliance Evaluation and Enforcement Branches, and we folded them into the Eastern and Western Compliance Branches. So now we just have the two branches.

But what we found was this actually provided a lot of efficiency gains. We have a more direct line of communication from inspectors to our compliance team if they identify a potential non-compliance when they're out on an inspection. And we also have really good feedback coming from our compliance folks back to the inspectors to help kind of increase that understanding of what ends up being compliant or non-compliant.

So, you know, we're lean and mean right now. Not necessarily mean, but we're lean. So, when you look at the compliance inspection goals, we, you know, had to really take a pause with the vacatur that occurred in December of last year and go, all right, the regulations have changed back to what they used to be before.

We have, you know, some new people who are not here pre-SECURE. But also, we have to really look at our worksheets and update those questions and our compliance evaluations to make sure that they align with the very specific language in 7 CFR 340. So, we took that pause to bridge that gap and then we got back to work.

And fortunately, we were able to meet our targets. We had a target of completing 500 inspections in FY25 and we were able to complete 505 and we were able to issue 93% of notices of non-compliance that were resulting from inspection within 14 days, as Donna mentioned earlier. And that actually resulted in an average of 11 days, which is an 89% improvement over kind of the historic average.

Now, I want to talk a little bit about permitting statistics, mostly focused on FY25, but you can see if you go back to FY21, when we last had both permits and notification, the number of permits issued and number of release sites authorized per year, we average about 810 permits issued a year and about 4,200 release sites. So FY25 was a little bit higher than that with 879 permits issued in the 43 notifications and the 4,300 release sites. But what you'll be able to see here from the next slide is only about 20% of those release sites end up being planted.

And so here you can see that we have high densities of field trials in the Midwest and along the

coasts and then also in the winter nursery locations in Hawaii and Puerto Rico. And hopefully you'll be able to see that our number of inspections per state is really correlated with where we have the high concentrations of field trials. We make sure to inspect each permit that's released in the environment at least once.

There are some permit types such as the PMPIs that Katie mentioned that do get multiple inspections. And the vast majority of our inspection, over 95%, are for field releases, but we do some of those containment facility inspections for modified insects and microbes. So, I'll just give you a second to take this in.

Maybe you want to look at the state where you're from or the state where you had field trials last year. And of course, we have some states that didn't have any inspections because they didn't have any trials.

Now, when you look at the inspections by quarter, we had 160 inspections through Q2 of last year. And this year, we're pretty much on track for about the same numbers. We've already completed over 130 inspections this year and we have another month to go before the end of Q2. Now things start to really ramp up for us in the Continental U.S. coming up here in Q3 when the planting reports start flowing in heavily. And then through Q4, through the end of the Fiscal Year, we're really busy out in the field making sure to take a look at all those trials.

Now, looking at our compliance statistics for FY25, we have various sources of information that feed into our compliance evaluation, right? There's the inspections. There's also self-reports that are required under the regulations if there's a loss of confinement or some other potential issues such as you notice that you sent something to a location that wasn't actually listed in your permit. And then we also do records reviews and reviews of incoming reports to evaluate compliance. So out of those 244, 128 notices of non-compliance were sent and 45 of those were resulting from inspections.

So, we were out in the field very heavily last year with 92% of our inspections conducted in person and we plan to keep up that pace again this year. Of course, we do conduct a small number of inspections as sort of virtual or hybrid types of inspections and those are often sort of post-harvest, off-season types of inspections. But of those, 460 were found to be compliant and 45 were found to be non-compliant.

So, we have really high compliance percentages with field trials which we're happy to see resulting in 91% compliance. And this is just for FY25. Now, just kind of looking at some summary statistics for FY25, 91% of the inspections were found compliant and we already talked about the averages.

With the 93% issued within 14 days, that's actually an improvement over last year where we had 85% of them issued within 14 days. And we work to really try to get them out quickly regardless if it's a result of an inspection or a self-report or another area. If you've been inspected and you haven't gotten a response back quickly, that doesn't necessarily mean that

the end determination will be that it's non-compliant.

You're always welcome to reach out to us. We also initiated 18 compliance agreements and a lot of times these are to try to make sure people are brought back into compliance as quickly as possible. For instance, if you had a permit that expired and your material was still on the ground, we would enter into a compliance agreement to make sure you were complying with all of the conditions of your permit until you were able to get a new one.

And then we completed 13 proactive compliance assessments, and these are educational opportunities that we engage with stakeholders, often new applicants or people who have had compliance issues in the past or are seeming to have repeated compliance issues. And sometimes that just comes from a lack of understanding of all the kind of details that you see in a permit and the supplemental permit conditions. And so, we really want to work with those folks to help prevent future instances of non-compliance, which is also, as Donna had mentioned, a reason why we try to get those notices of non-compliance out quickly to help prevent recurrence.

So, looking at the most common non-compliance issues, these are sort of similar trends to what we've seen in years past. So, one of the big things is late or missing reports. 70 instances of that with 20 of those being related to late planting or as we might call them in e-File, environmental release reports, of course, because not everything is a plant, right?

We have microbes and insects as well. So, if you're getting ready to do a trial for the first time or you've had this issue come up in the past, please make sure to mark your calendars. Those planting or environmental release reports are due 30 days after the planting is done.

And that's actually a change in years past. We had it as the 15th of the month following the month of planting. We also saw 25 instances of incomplete records.

Nine of those were related to incomplete equipment cleaning records. Eight from lack or incomplete in-season monitoring and seven related to incomplete volunteer monitoring records. We had 24 unauthorized movements and releases.

11 of those were for areas not authorized and six were for unauthorized movement. A lot of times people just aren't paying super close attention. Please double check those GPS coordinates of that authorized area before you put your material on the ground.

And if you're sending something, you know, to a shipping destination, make sure that it's covered by your authorization. And we had 22 missing records or reports, including seven missing equipment cleaning records. So, one of the things that you can do that's, you know, helpful when you're starting your trial is make sure that you kind of have templates of what records you need to keep.

Those forms that you make sure are filled out every time that you do something like equipment

cleaning or volunteer monitoring. So, one final thing that I want to mention that we accomplished in FY25 was the updated guide for submitting data and reports and notices in APHIS-eFile. This is a really nice resource and I hope you folks will take advantage of it if you have an authorization and you're trying to figure out how to navigate some of the challenges that we have in our electronic permitting system just in terms of what data needs to be submitted and how you go through that process to make sure that it is submitted.

We did update it post vacatur to incorporate the requirements for notification and we got the final updated guide published in March of last year. So, with that, I want to thank my team for really doing a great job over the past year and continuing to and I also want to thank you all for attending today.

Amanda Kenney:
Thank you, Doug, for sharing about BRS's work to help our stakeholders maintain compliance. Our next speaker is Dr. Suma Chakravarthy, one of our Science Advisors here in BRS. Suma will provide an update about BRS's international engagement.

Suma Chakravarthy:
We're almost there. Thank you for coming all the way to attend our stakeholder meeting. Let me see, does this?

No, I was looking for the red, yeah. One of the key components of BRS operations is interacting with international regulators and organizations either bilaterally or multilaterally during meetings and conferences. There's extensive coordination with other US Government colleagues which happens in the background as we prepare for these meetings so that we can present a united front while presenting our regulations.

Our engagements were somewhat fewer this past year compared to previous years, but they were very significant given the vacatur of SECURE and how we moved on. This is a bit of a busy slide, but I'll walk you through it. We always emphasize the importance of science-based and risk proportional assessments for products of biotechnology while speaking to international audiences but this year we also messaged the flexibility of our regulations and continuity of operations after vacatur of SECURE.

We conveyed that we still complete our assessments under the same legal authority but using different regulations and with lessons learned from the efficiency gains we had under SECURE, some of which you heard earlier today. In addition to sound science, we've spoken about the important aspects of any regulatory system which is efficiency, stakeholder engagement, timeliness, transparency. A question we get often and one that we sort of learn to put upfront in our presentations is how we consider products of genome editing under the current regulations and we also include always significantly for an international audience is how certain transgenic organisms do not meet our definition of a regulated article.

These are photographs of presentations we did for Korea and Japan in the middle of last year.

As I mentioned earlier, we work a lot with our interagency partners to prepare for these meetings and often tailor our talking points to the needs of the audience or questions we receive ahead of the meeting. I want to take a minute here to pause and thank our colleagues from other government agencies, some of whom are there in the audience today, EPA, FDA, State Department, Foreign Agricultural Service, USDA and USDA APHIS International Services who help us plan and we coordinate together for these meetings.

BRS delivered presentations on our regulations to audiences from over 17 countries this year and I don't have a photograph because it's an online presentation but we have an ongoing trilateral technical working group with Canada and Mexico. We meet at least twice a year. We share regulatory updates and we also talk about topics of mutual interest.

The United States is a member of the working party for Harmonization of Regulatory Oversight in Biotechnology, HROB, and a major output of this working party is to produce technical documents to support the assessment of products of ag biotech. BRS leads the U.S. delegation to the HROB meeting and this year we participated in seven ongoing projects and these include biology documents for two mosquito species, we have a revision of a maize biology document, we have a microalgae document and I'm hoping that at least two of these will be declassified or published this year. Last year we successfully proposed and have since initiated the development of a citrus biology document in partnership with Brazil and we are very proud to have eminent experts of citrus biology on the team and we're excited to see how this will progress.

We coordinated a U.S. government response to a questionnaire to explore the need and scope for a unique identifier system for transgenic animals similar to the one we have for plants. And finally, we participated in the development of a safer innovation approach, SIA approach, guidance document for developers.

BRS served on the scientific program committee for the 17th symposium of ISBR, International Society for Biosafety Research held in Belgium this year.

We were invited to speak at a plenary session and a parallel session but unfortunately, we couldn't attend because the meeting was in November and we were on furlough status. Oh, something, a nice crosstalk between these two platforms. The OECD presented a poster at ISBR showcasing 40 years of its work on biosafety so that was a nice opportunity to bring the crosstalk between organizations.

We attended the high-level policy dialogue on agricultural biotechnology which we summarized to call HLPDAB at Asia Pacific Economic Cooperation Meeting in Korea. At this meeting and generally our engagements with APEC, our USDA biotechnology coordinator and FAS, Foreign Ag Service, play more of an onstage role at HLPDAB but BRS's presence provides value while discussing more technical and regulatory topics. Yeah, we supported the US delegation at the COP-MOP meeting by drafting talking points and a position paper for negotiations under risk assessment.

You know, all these multilateral fora give us the opportunity to underscore the importance of science-based and risk proportionate regulations and their role in enabling innovation.

In addition to our presence at meetings, we also provide technical comments on draft trade agreements which come to us via USTR, our US Trade Representative and our International Services Branch at APHIS. Our comments are usually related to how we use science and how we evaluate products of agricultural biotechnology.

We have a very small international collaborations team but we work very hard to bring the impact of what we do to a global audience. And with that, I thank you for your attention and attendance at this meeting.

Amanda Kenney:
Thank you, Suma. It's great to be reminded of BRS's work to promote global harmonization and adoption of science-based regulatory frameworks. We will now have our second Q&A panel with the speakers on topics that were discussed after the break.

We will again begin questions in the room using our mobile microphone and Helana's assistance and then we will then take some questions from the virtual Q&A, which we have re-enabled. As another reminder to the online participants, if you're using the browser-based version of Zoom, go ahead and refresh your browser to ensure you can access the Q&A. And as a reminder, we ask that participants provide your name and organization with your question.

I will now invite the speakers to the stage.

Anastasia Bodnar:
Great. Hi, I'm Anastasia Bodnar with Corteva. My question is for Alan and John.

I appreciated hearing about the work between BRS and PPQ to establish more consistent permit conditions and also the cooperation with CBP. I was wondering how you're working with EPA on field trials that might also be regulated by EPA, the handoffs, consistency, things like that.

Alan Pearson:
So, what we're doing with EPA, we've had conversations in the past with EPA about this, and I think Donna already sort of previewed for you some of our thinking about that when she talked a little bit about what we're proposing in the efficiencies rule. Without going into great detail about that, because that's not out yet, you'll be able to see it when it comes out, but that would essentially create a smooth handoff process there so that we're not having duplicative regulation.

Karen Carr:
Hi there. This is Karen Carr with Arentfox Schiff. On the microbe harmonization topic that I really appreciate being a part of the agenda this year, just a comment and then a quick question.

First on comment, thank you so much to both you, Alan, John, and to the BRS and PPQ teams for coming together. A number of developers have been asking for that kind of coordination, as you noted, for a long time, and it's really, really great to see. We know it's labor and time intensive for you all, and greatly appreciate all of the effort and work that's gone into that.

I'm also really excited to see the harmonization principle and the framework. I just have a question about cadence in terms of stakeholder engagement. So just wanted to understand a little bit about how much will stakeholders know and have transparency to before implementation and kind of what that cadence might look like?

Alan Pearson:
Thanks. So, we're really committed to providing that kind of transparency to stakeholders and to providing additional opportunities as we continue to flesh out the final details of this and begin to provide guidance to stakeholders. I think it's probably going to be a bit of a rolling implementation, but I think we're still figuring out the implementation, more specific implementation aspects of this.

Karen Carr:
And just one small follow-up question about any rough timelines for when we could expect to see even the beginnings of the rollout?

Alan Pearson:
I can't give you timelines right now, no.

John Sagle:
Yeah, I can add on. I think I don't want to give hard dates, but I do know this is a focus priority for our leadership team in APHIS this Fiscal Year. I don't want to say we'll have it done by this date or that date, but this is something that we're prioritizing, and we want to see some outputs on sooner than later.

I know that's broad, but it's something that we're actively focusing and prioritizing for this Fiscal Year to get through, whether it be a partial rollout execution, as Alan said, or full, but to start having some deliverables for you all soon. Every time I give a hard date, it comes back to bite me. So, I'm really careful not to do that yet.

Tyler Reid:
So, we have a question online. Someone said they need to send and receive disarmed agrobacterium strains. The revision to the previous regulations that require full permits to transfer represents a large increase in burden for them and others.

Is this issue known to you and will you be working to mitigate this issue so that labs can more easily work with one another?

Alan Pearson:
Could you repeat the last part of the question?

Tyler Reid:
Yes, is this issue known to you and will you be working to mitigate this issue so that labs can more easily work with one another?

Alan Pearson:
Yeah, we're aware of that issue and yes, we'll be working on that issue as well. I don't know if anybody here wants to say any more.

John Torres:
Hi, John Torres with the Bockorny Group. I also want to echo a few of the others in congratulating the BRS and PPQ teams in working toward harmonization. So, I think that's great progress.

You might not be able to answer this right now, but I think the post, you know, going back to the Legacy Part 340, the Am I Regulated process, I think has been tremendously successful. It's been very helpful. This might be more for John.

Could we see a similar process and a similar Am I Regulated process over on the PPQ side? I think that would be helpful for stakeholders on that side.

John Sagle:
Certainly, great suggestion. I'm happy to, I'm more than willing to take it back and run it to the team. I know it's served BRS well. If you feel like that's something that would serve you well and certainly as we're in the middle of transitioning our process here, it could be a timely thing to do as well. So absolutely, I won't commit to you that it'll be there tomorrow, but I think it's a great idea and happy to support it.

John Torres:
Thank you.

June Yao:
I'm June Yao with NuFarm. My question is more for Suma regarding international engagement. So again, I also appreciate lots of effort US government have been doing with other trade partners.

I don't know whether you can comment on some highlights regarding what has a positive impact being, you know, coming out from those engagement and in terms of like improving approval efficiency or regulatory process, you know, if there's some positive outcomes you can highlight and what will be your priorities for international engagement this year?

Suma Chakravarthy:
I would say some of the workshops we attend, especially at HLPDAB and APEC, some of the, we

break out into little groups and then we meet with a smaller group of economies from a smaller group of attendees from different economies who often have a lot of questions on our methods. And so, what we do is we tell them about how we've used familiarity or how we have evolved some of our processes to improve efficiency. And that is something that the other economies and other regulators go home with.

And I think also through our comments to trade agreements, we often provide suggestions which hopefully are useful for other countries as they finalize their frameworks or make changes to their frameworks. Very often with some countries, we get a list of questions ahead of the meeting because the delegation is interested to know about certain aspects. And those questions are not just for USDA, they're also for EPA and FDA.

So, we work ahead of time to either provide them answers during the meeting or have discussions. So, in terms of direct tangible impact, I can't say, oh, we met with such and such country this year and then they went and wrote new regulations. It's not such a direct effect.

It's more indirect. It's more intangible, but it's definitely there. I think our presence in the room is always valued and people do have questions for us.

Yeah, and more than the meetings, I think also our involvement at OECD, we are able to drive discussions towards more risk proportionate and science-based safety assessments. So even the development of those documents is important because it's used globally. Those are free for anyone to use.

They're publicly available.

Fan-Li Chou:
So, I jumped the gun last time. So, I'm going to repeat my question on notification and to the right parties here. I'm just curious to know whether there's been changes in the interpretation of the criteria under notification because I'm hearing from some of my members that where they were able to do notification pre-SECURE, they're unable to do so now.

Katharine Swoboda-Bhattarai:
Right, so I'm going to tackle your question. So, I think I heard you ask whether there have been changes to the criteria themselves. There have not been, right?

We're still using the same criteria that were put into place all of those years ago under our legacy regulations, which are our current regulations again. So, when the notification team was re-establishing the notification process, we did take a hard look and gathered information on how we were processing notification applications right before we switched over to SECURE. And then when we established our new re-established notification procedure just this past year, we took another look at all of those criteria sort of based on the new landscape that we find ourselves in now with newer technologies, some newer types of IR traits coming in.

And so the criteria that she's specifically referring to is there's one of the six criteria's that a plant that qualifies for notification cannot encode a substance that is known or is likely to be toxic to non-targets. So, considering that we're in a sort of a new landscape now, we made the decision to not allow notifications for plants with IR traits when we re-established. And I know this is different than what we did before.

The criteria are not different, but I think it was a decision that was made to sort of re-establish things on a different footing. I know that this is a question of interest, not just to your group and the group that you represent. I think this is something that if you have a particular product, we're always open to pre-consultations with applicants who might have questions about how we re-establish a notification procedure.

And so, I just encourage you to come in and talk to us about a specific product. And we'd be happy to talk about this further.

Ray Dobert:
Hi, Ray Dobert. I noted that there was a comment with regard to some of the specific provisions on modified microbes and the fact that one particular activity listing out all of the different microbes, and I presume that's for import into contained use facilities. And then it basically said it does not allow for greenhouse work to be conducted.

If it's a contained greenhouse, underneath what authority does BRS have authority to regulate what activities are taking place inside of a contained greenhouse?

Alan Pearson:
What the slide, what the point was being made there was that it was in relation to the kingdom-level permits. So, I believe that kingdom-level permits were not going to be issued for working contained, excuse me, greenhouses that for the kingdom-level permits that would be restricted to sort of laboratories and contained laboratories. So, it's not so much regulating the activity that's going on in the contained greenhouse, but rather sort of the scope of that kingdom-level permit.

That's something that we have heard some concerns about and that we are certainly welcome to further consider and engage our stakeholders in talking about that and seeing whether there are other options available in some circumstances.

Tyler Reid:
The [online] question is, their questioning is the ability to ship strains that have been disarmed and contain no binary plasmids. It would include other knockouts to the agrobacterium genome made through CRISPR-Cas. They would not have DNA from other species.

Is there any chance of getting these exempted? Would a petition for deregulation need to be submitted?

Alan Pearson:
Right now, those strains are regulated because they meet the definition of a regulated article. An applicant is welcome to submit a petition for that purpose if they wish. That would obviously be something new for us.

Most of our petitions, well, all of our petitions right now, as you know, are for plants and not for non-plant organisms. And that's these pathways to finding that organisms aren't subject to regulation. Microbes are not subject to regulation.

It's something we have a team actively working on right now. So, it may take a little while as we work through that process. But if somebody wants to do that, they're welcome to do that.

Amanda Kenney:
Oops, sorry. I didn't mean to blind my fellow co-presenters there. Thank you very much for your questions.

And again, if anyone has some remaining questions in the room or a comment, you can enter it on that comment card and put it on the comment box near the registration table. And thanks to our online participants for your questions as well. And this concludes our meeting.

Thank you everyone for participating in our annual stakeholder meeting. BRS appreciates our collaborative relationship with our stakeholders. We look forward to working with you throughout the year for learning from each other.

For those in the room, the library building closes today at 4:30pm. You are welcome to sort of stay and chat until then. Please have a good night and travel safely. And for those online, thank you and have a good night.