APHIS BRS Stakeholder Meeting Transcript
November 15, 2023

Speaker 1 00:00:00 Good afternoon, ladies and gentlemen. We're so happy to have you all here with us today for our annual USDA APHIS, BRS stakeholders meeting. For those of you who don't know me, I'm Doug Grant. I'm the director of Regulatory Operations Programs here at BRS, and we're so excited to have you here in the room and also online joining us. We've got a great game plan and agenda to share with you today. And I want to start with a few points of housekeeping. We'll have another number of presentations, and then a 10-minute break around 2:20 PM Eastern. If you have a question today, we ask that you please write it down and save it. We'll have a Q&A session at the, towards the end of the meeting with a microphone set up. And we also have a microphone that we can pass around here in the room for questions.

Speaker 1 00:01:00 And we have a great team monitoring online. If you have a question online, please submit that in the using that chat box. In WebEx, you'll find refreshments and snacks in the back of the room, and restrooms are directly across the hall by the elevators. There's also another set of restrooms if you go down the hall, past the guard's desk by the other, bank of elevators. If we need to evacuate the building for any reason. What you're going to want to do is go out these doors, turn left, and then turn right past the guard's desk out that set of doors, and exit to the building parking lot. For those in the room, if you could please mute your cell phones. We'd appreciate that. We don't have a guest Wi-Fi, password to use in the conference room today. So hopefully you have good cell reception. If you need to use your phones, though, we hope the amazing content that we've crafted holds your undivided attention today. And with that, I'm honored and very pleased to introduce to you our first speaker today, USDA, Under Secretary of Agriculture for Marketing and Regulatory Programs, Jenny Moffitt.

Speaker 2 00:02:39 Thank you, Grant. And it is a pleasure to be here today with you virtually. I'm sorry, I, can't see all the folks in the room. I am able to see who's, who's online, but can't see the folks in the room. And so, I, you know, sorry that I'm not able to be there in person with you. I just want to thank the biotechnology and regulatory services, or BRS staff for, inviting me here to join, and to speak about USDA's priorities and really want to thank all of you. Reiterate what Grant you just said. thank you all for participating. I'm glad to see virtually and to know that in the room there are so many developers, NGOs, public interest groups, and many state and federal work, workers and stakeholders with us today. while we have many different perspectives, we all have a common interest in agricultural biotechnology, and the many challenges to confront together, we're battling things like nutrition security, we're battling things like climate change.

Speaker 2 00:03:43 We're battling all these other different aspects. And, and, and those are shared challenges that we all have. To tackle nutrition insecurity, we're investing heavily in the department's core nutrition programs to ensure that all Americans have access to healthy, safe, affordable food. We're also working across the department on making sure that that producers have opportunities for more new and better markets. Biotechnology is a critical tool to help us address these important issues. Harnessing the power of biotechnology, and improving the quality of our lives, our economy and the environment are central to Executive Order. 1, 4 0 8 1, which President Biden signed last week, well, sorry, last year. BRS will share more about USDA's efforts to comply with the Executive Order. But for now, I want to assure you that our primary goals are to incentivize and to enhance biosafety and biosecurity practices to reduce risk and to improve the clarity and the efficiencies of the regulatory process.

Speaker 2 00:04:50 We'll continue to collaborate with our federal partners and stakeholders to maintain a rigorous science-based regulatory framework that ensures safety is an unduly burdensome for developers and developers from all, of all sizes. So, to that end, we've seen already a huge impact in BRS' 2020 overhaul of the regulatory exemption system has had on innovation in this space, the system created two categories for regulatory exemptions. One for GE plants with traits that could be achieved through conventional breeding methods. And then another for plants with certain traits that were previously already evaluated. Since 2020, we've seen small to medium-sized developers, rather than large, well-funded entities dominate in the area of critical biotechnology advancements. A similar level of engagement has also emerged in the regulatory status review process, which is another regulatory pathway for GE plants. We'll continue forward movement and progress thanks to engagements such as the ones we're having today. Each sector represented here plays a key role in what lies ahead. I look forward to working with you to better serve agricultural industries and communities that rely on us. Thank you. Now it is my pleasure to join me, and to introduce our, deputy administrator for Biotechnology and Regulatory Services, Bernadette Juarez. She is just certainly a champion and, and has been working really hard with, along with the team at BRS to make sure that we continue to advance many USDA priorities. Thank you.

Speaker 3 00:06:35 Thank you. Under Secretary Moffitt, it's wonderful for you to be able to join us today. All right. It's fabulous and it's fabulous to see so many of you in the room. Our room is completely filled, and I thank you for joining us. I also wanted to thank my team. Every single BRS work unit has contributed immensely to making this meeting special today, and I, really appreciate all of their effort. In particular, our comms team. This is their anchor project for the year, and they've done a remarkable job. If you, entered through this door over here, you saw a nice handout that had some one-page accomplishments. I hope you were able to pick that up. We'll touch on those during our presentation, but it's nice to have some others available to you as well. I also want to thank Alan Pearson, my assistant deputy administrator, who has been also serving as the supervisor for the comms team.

Speaker 3 00:07:28 He's been wearing multiple hats and has done a marvelous job organizing this meeting. David Richardson has also been, a huge help to us. He usually has other folks supporting, and he did it all himself this year. So, I want to make sure that, he knows how important his help was to us. So, thank you, David. And then also, all of the presenters have worked very, very diligently on their presentations. They developed content, they refined their content, they practiced their content, and we really worked to address the questions that we received in response to our, invitation to submit agenda items. I hope that you see that your questions are answered as we work through our presentations. If we have missed one of the questions that you submitted, please let us know at our question and answers session, and we'd be happy to, to do that, to answer those questions.

Speaker 3 00:08:17 With that, I want to share some good news. My presentation is going to focus mostly on good news that occurred in fiscal year 2023, but we've had some relatively good news this week, so I want to make sure that your attention has been drawn to that as well. On Monday, we posted two documents to the Unified Website, and these documents include a plain language description of the regulatory agencies that oversee products of biotechnology. This was a commitment under the Executive Order that the Under Secretary mentioned, and we're pleased to share it with you. We're also pleased to share with you a summary of the feedback that you provided to us in response to the request for information that we issued last December, We compiled and analyzed and categorized your feedback, and developed a summary report so that you have a sense of what stakeholders across the spectrum, provided to us in, in response to that request for information. On Tuesday

Speaker 3 00:09:15 And we, we became public facing on the public inspection page, with respect to a notice that proposes five additional modifications a plant can contain and qualify for exemption. We welcome your, your feedback and your review of those proposals and it was published officially today in the Federal Register. So, you can also find it there. We look forward to, all types of feedback, especially any type of scientific literature that we may be able to rely on to, to further build our record with regard to those exemptions. Please take a look at the resources that, that we have cited, and if you have others, let us know. Yesterday we also announced the release of 12 additional regulatory status review responses. Those have been posted to our website. We're happy to start the fiscal year strong and we'll continue to, to do that as we move through the year, and you'll hear about some of the process improvements we're making in that regard. And then just this morning, my team issued nine confirmation requests, as well. So, this will have a nice strong start to fiscal year 2023. We issued 40 of those last year. So, starting this month with, with nine is a good start for us. This goes to show exactly what the Under Secretary said. That is, that there is strong interest in our regulatory status review process and our confirmation process, and we're excited to tell you more about that as we move on with our presentations. Yep, that covers that part.

Speaker 3 00:10:51 So I thought it would be fun to do like a David Letterman style slash BRS top five so that you have a sense of what we felt were our best accomplishments in fiscal year 2023. And we'd add a little bit of a lighthearted start to this meeting. So, the first one we'll start with is 80% in, in person. Last year, or I guess it was in January of 2023, the Secretary lifted the travel restrictions with respect to Covid related activities or the Covid pandemic. As a result, we were able to resume in-person inspections. 80% of the inspections that BRS conducted were in person. We were also able to resume more in-person time together here in the office with my team. I have many team members with me here today in the room. If you have a chance, reach out and meet us.

Speaker 3 00:11:44 It's wonderful to see you in person. We've seen you in person here for meetings, and we've also seen you around the country and internationally during meetings this year. So, we are excited to be back in person and gathering with you safely, as we work through new projects together. Number four, 100% consensus. BRS has long supported the organization of Economic Cooperation and Development in terms of their working party on biotechnology. And after 19 years of negotiation, the group has completed its environmental considerations document, and it's now available on the OECD website. We really are excited about reaching closure on the issuance of this document and are even more excited to see it in practice. So, we are working to amplify the use of this document to help ensure that products of biotechnology are evaluating use, are evaluated using scientifically sound methods. So that's number four.

Speaker 3 00:12:45 And number three, we've had a threefold increase in the responses that we've issued under the confirmation request process and the regulatory status review process. As I mentioned, last year, we issued 40 confirmation requests. The year before that we issued nine. This year we completed 15 regulatory status reviews at the step one phase. We, we completed others that progressed, in, in another direction on to step two. I mentioned this particularly because we completed three the year before. So, we're certainly moving in the right direction. And as I mentioned, we just issued our first tranche of regulatory status reviews for fiscal year 2024, and that was 12. So, we, we are happy with the direction that we're moving. We know that we have increased demands for regulatory services in this way, and we'll continue to refine our processes to meet those workloads

Speaker 3 00:13:37 and you'll hear more about that throughout the presentations today. Number two. We have a 78% cost savings, as part of the work this year and because we have completed a, a solid number of regulatory status reviews, we were able to undertake a cost assessment for completing a

regulatory status review assessment. We compared that with the cost of completing the most common type of petition under the legacy rules and we use the regulatory impact analysis cost estimate and adjusted it for 2020 dollars and determined that we have achieved a 78% cost savings, through the regulatory status review process for each of the products that we have reviewed. We are excited to be able to share the government's savings with you. We believe that this will continue to improve as we become more efficient in reviewing our products and we look forward to working with the industry to begin to develop a cost assessment to see what it, the, the regulatory expenses for you under our revised rules compared to our legacy rules.

Speaker 3 00:14:45 So that's number two and number one. We are also very excited to be able to demonstrate for the first time this year the impact of our, revised regulations. As the Under Secretary mentioned, more than 75% of the submissions that we receive under both the confirmation request process and the regulatory status review process are submitted by small and medium sized developers. We've been able to foster innovation, in a way that we have not been able to do in the past, and we're very excited to, to bring this experience forward and share it with others beyond equity of access to the regulatory processes. What we're seeing are a larger portion of products that are now geared towards addressing environmental and social goals and we're excited to see those, emerging as well. So, for us, these were the top five achievements that we delivered over the past fiscal year, and I am excited to share them with you and more about what we've been up to over the past year as I pass it on to our next speaker. Thank you.

Speaker 1 00:15:58 Alright. And our next speaker is Alia Shabazz, and she's going to give us a BRS workforce update.

Speaker 4 00:16:11 Thank you, Doug. Good afternoon. My name is Alia Shabazz and I'm the branch chief for Resource Management Services.

Speaker 4 00:16:20 Part of our, my presentation will be to give you an overview of our workforce and also introduce you to our new staff members who have joined us since we've started since the last, stakeholders meeting, as well as some exciting new promotions of internal staff. At the start of this fiscal year, our bench strength was 83 employees, and we have two occupations that make up our mission critical occupations, and that is our biological scientists. And we have 52 staff members on board and also our administration and program management, job series. And we have 13 staff members on board. Now, of course, we can't do our jobs without having our mission support occupations, and that includes eight occupations, which have 18 staff members on board. We're also pleased to have veterans as part of our staff, and we have 7.22% of our staff that are veterans. As far as retirement eligibility, just like all other federal agencies, we have a lot of the people who are be eligible to retire. But also, it makes sense too, because we are so a highly educated workforce and we currently have 17 employees who are currently eligible to retire, and then 30 employees who will be eligible to retire within the next five years.

Speaker 4 00:17:52 One of the things we like to do is make sure that we have a sense of areas that we want to strengthen over the next several years, and this is where we want to focus on our workforce forecast. As far as our Biotechnology Risk Analysis Programs, we know we need to recruit individuals with advanced knowledge of microbes and trees. As far as our Regulatory Operations Program, we want to recruit employees with advanced technical skills and experience using GIS and satellite imagery. Lastly, our Policy, Program International Collaboration Branch would like to have more staff who have knowledge of international, topics and an ability to review and interpret regulations and statutes. Our organizational chart. One of the takeaways from last stakeholders meeting was that we really wanted to be able to post on our website based on your feedback, our organizational chart and our chart will include

also leadership contact information. One of the things also that we've done since the last stakeholders meeting to better serve you is we've added an additional branch to the Biotechnology Risk Analysis Programs. We've added the Plants and Insects Branch now to some exciting information. As I mentioned, we have some really new staff members to our team. And as far as our Biotechnology, our Risk Analysis Program, we have Alina Davis. She's a biological scientist, and she's part of our Plant Evaluation Branch. We also have Zach Schultzhaus. He's a biological scientist as well. He's part of our Plants and Microbes Branch.

Speaker 4 00:20:02 Also, part of the BRAP program is Ariel Heminger, and she's a biological scientist and she's a member of our Plants and Microbes Branch. New members to our Regulatory Operations Program include and Ann Gobei-Bacaylan, and she is an intern. We always love to have our interns, and she's a student at the University of California. Next, we have Phuong Le, part of our Western Compliance Assurance Branch. Last, we have Jolene Prochazka. She's a biological scientist with our Eastern Compliance Assurance Branch. Also new to our ROP staff is Cindy Stouffer Powell. She's a biological scientist, part of our Western Compliance Assurance Branch. And Moises Vega, he's a biological scientist, a member of our Eastern Compliance Assurance Branch. And lastly, we have Ashley Fehn. She's a biological scientist and a member of the Compliance Evaluation and Enforcement Branch. The newest members of our Policy, Program and International Collaboration Branch include Lak Ramamoorthi, and he is a science advisor and has been with USDA for many years. And lastly, we have Joseph Tangredi. He's a program specialist and has been with APHIS for a number of years. A new member of my staff is David Richardson, and he's a program assistant.

Speaker 4 00:22:11 Next, our exciting promotions, one of the things we like to do as a program is to try our best to recruit within as part of our succession strategy. And we're happy to have Laura Andrako serve as a branch chief for our Eastern Compliance Assurance Branch, as part as our Regulatory Operations Program. And she's been with our program since 2015. Next, it's exciting to have Suma Chakravarthy serve as a senior scientific advisor in the Office of the Deputy Administrator. She's our newest senior leader, and she actually had served many years ago as an AAAS fellow and came back to BRS because she loves us so much to be a branch chief for Biotechnology Risk Analysis Programs. Next, we have Samantha Greer. She's a biological scientist in our Eastern Compliance Assurance Branch, and she's been with BRS since 2011. And last but not least, we have Michael Stulberg, who's now a branch chief for Plants and Insects Branch within the Biotechnology Risk Analysis Programs. And he's been with our organization since 2020. Thank you for your time, and I look forward to any question you may have about our workforce during the question-and-answer period.

Speaker 1 00:23:49 Thank you so much, Alia. It's really nice to see all those smiling faces of the, new employees and changes that we've had. Next up, we've got Alan Pearson, and he is going to be giving us an update on the EO 14 0 81.

Speaker 5 00:24:12 Thank you all. I'm glad to be here today to see, a bunch of familiar faces from the past. I'm glad I was not able to make the first, in return to in-person stakeholder meeting last year. so, I'm glad to be here today. I'm going to give you an update on the Executive Order, 1 4 0 8 1, Advancing Biotechnology and, and Biomanufacturing Innovation and the activities that we've been doing along with our regulatory partners in EPA and FDA.

Speaker 5 00:24:43 The Executive Order starts with a section, Section One on a statement of policy. And within that statement of policy, there's a specific statement of policy regarding regulation of biotechnology products and stating that it's the policy of this administration to clarify and streamline regulations in the service of science and risk-based, predictable, efficient, and transparent regulation, and

use of biotechnology products. The Executive Order also has a section devoted specifically to biotechnology regulation, and that is Section Eight of the Executive Order. And within Section Eight, there are, the regulatory agencies are directed to undertake five specific tasks. The first is to identify ambiguities gaps and uncertainties in the coordinated framework. The second is to provide plain language information regarding the roles and responsibilities of the regulatory agencies, as well as the processes that they use. The third is to develop and provide a plan with processes and timelines to implement regulatory reform.

Speaker 5 00:25:54 The fourth, to enable developers to submit inquiries about a particular product and promptly receive a single coordinated response. And then lastly, to provide an annual update on our progress under undertaking the first four items. Most of my talk today is going to focus on the first item on this list. As I review, give a high level overview of the comments that we received on our request for information published last late last year on ambiguities gaps and uncertainties in the coordinated framework. And as is, as has already been mentioned throughout the course of the rest of the meeting today, you'll be hearing from various presenters about actions we're taking to address some of the feedback that we've received. Additionally, as was already pointed out, we just published on Monday a report on the stakeholder comments that we received on the RFI as well as plain language information that we, have developed, among all the regulatory agencies. And we're currently working on enhancing our ability via the Unified Website for developers to submit inquiries and request meetings with the regulatory agencies. We're also working to complete a regulatory reform plan, which we anticipate posting on the Unified Website in the coming months.

Speaker 5 00:27:16 So turning to the feedback we received on the request for information, which was published in December of 2022, we received 88 distinct public comments, including a sign-on letter with over 6,000 signatory signatories. We also organized a listening session in January of this year that was attended by 281 people and 16 commenters offered comments during that listening session. The Biotechnology Innovation Organization, the American Seed Trade Association, the Biological Products Industry Alliance, also organized their own listening sessions, which they invited to us to attend. And we received a number of additional comments via those listening sessions. The comments that we received on the, on the RFI really fell into four overlapping themes, a theme on regulatory clarity, a theme on regulatory coordination, one on regulatory reform. And then finally, on regulatory resources. And I'll step through each of these four areas in turn. In the area of regulatory clarity, all of the agencies were asked to increase the clarity of, of their regulations and to provide increased assistance.

Speaker 5 00:28:35 And we've begun to do that through the plain language information that I, mentioned, as well as our own individual agency publications that we've been, providing over the last year. Specifically with regard to BRS, we were asked to provide additional clarity on the regulatory status review process, including information needed to meet technical completeness for an initial submission, and the criteria for determining when a plant pest risk assessment will be required. And we were asked to provide additional clarity regarding regulation of modified microbes, including which modified microbes require BRS permits, particularly when it comes to, biocontrol organisms. In the area of regulatory coordination, we, there were four different, groups of comments that we received. First, the agencies were asked to wherever possible align their definitions, their exemptions, and their data and information requirements, and review timelines for biotechnology products. Secondly, to clarify the jurisdiction and harmonize their approach for, regulatory approaches for microbes. And in that area, particularly, there were requests that we clarify jurisdiction, both between APHIS and EPA, and then additionally within APHIS, how BRS and PPQ are regulating microbes. There's also a request that we harmonize our

approach to determining which microbes would warrant pre-market oversight, as well as harmonize our field trial requirements where possible and our product review requirements and processes.

Speaker 5 00:30:19 Third, there were a number of comments that asked us to reduce, duplicative oversight. And fourth, we received comments asking us to establish, greater interagency coordination mechanisms. And in that regard, and again, harking back to microbes, I just want to let, everyone know here that we have started to undertake regular meetings with our EPA counterparts on microbes this year, and have also stood up a working group with our PPQ, colleagues on microbes that meets regularly as we can, as we undertake efforts to address these various, comments and, and feedback that we received. We'll continue to work with e with both FDA and EPA to harmonize the implementation of our regulations and reduce duplicative oversight wherever possible. We do meet as, as a group regularly to discuss products that we're reviewing and will continue to take steps to enhance our coordination. In the area of regulatory reform,

Speaker 5 00:31:22 an overriding theme was that commenters asked for risk proportionate regulation, although there were differences of opinion among the commenters on what that would look like. Most commenters ask that the agencies update their regulatory frameworks to account for genome editing and minimize the regulation of genome edited products and to streamline their regulations and regulatory processes and reduce regulatory burdens and duplicative regulation. Additionally, some commenters asked the reg, the regulatory agencies to provide more, reg more oversight and more thorough and continuing oversight of biotechnology products based on the entire life cycle of the production process, including developing specific regulations to assess human and environmental health effects and of, biotechnologies. More specifically to APHIS, we received a number of comments along the lines of regulatory reform, including a request to expand our exemptions for plants, including polypoid plants and plants containing multiple edits, and to establish exemptions for modified microbes, comments requesting us to meet our regulatory status review and permit issuance timeframes, and to reduce the regulatory burdens for lower risk activities, including restoring our legacy, notification process for plants request to streamline the procedures and information requirements required for interstate movement permits, both for plants and microbes, and to establish a clear, efficient and predictable pathway for field testing and commercialization of modified microbes, including regulatory off-ramp for modified microbes.

Speaker 5 00:33:04 Finally, we also received requests to include the noxious weeded provisions of the Plant Protection Act within the USDA biotechnology regulations at seven CFR Part three 40. In the area of regulatory resources, commenters requested that the regulatory agencies be appropriately funded, staffed, and trained, and employees trained so as to ensure timely and consistent reviews. And specifically, for APHIS BRS, there were requests to develop streamlined consistent science-based permit templates and review processes so that we can ensure that all the reviewers are treating similar requests in a similar manner and really maintain consistency, in our, both our communications with, applicants as well as our responses and our permit requirements and so on. Finally, I just want to close by sharing some positive feedback. It wasn't all, just requests and, and telling us what we could do better, but also, we were very appreciative of the, of the positive feedback we got, including that our revised regulations were considered by commenters to be a major advance and a positive step towards risk proportionate regulations for which we should be commended.

Speaker 5 00:34:21 And really that all the regulatory agencies are doing positive things and that one of our strengths is the quality of our scientific reviews and reviewers, and the fact that we encourage informal pre-submission consultations and discussions with researchers and developers so that they know how they can, what they need to do to proceed through the regulatory system. So, with that, I'll close and just say again that you'll be hearing from the rest of our speakers today about ways in which we will be

addressing some of the comments and feedback we got on the request for information. And I'll turn it back to Doug. Thank you.

Speaker 1 00:35:03 Thank you so much, Alan. Really, really good presentation. Next up, we have Neil Hoffman, and he is going to be telling us about a proposal to add modifications that qualify for exemptions for regulation under seven CFR three 40. Take it away, Neil.

Speaker 6 00:35:24 Thanks, Doug. So, as many of you know, the regulations revised regulations have a provision to exempt plants with additional modifications based on what can be achieved by conventional breeding. In July of 2021, we proposed three such exemptions, largely to clarify what we had intended in the codified exemptions. We received helpful comments and supporting literature. Among the comments that resonated with us was a comment that the proposed exemptions were piecemeal and could be replaced by an overarching exemption that the pre-empting exemptions should be extended to polyploids because these types of modifications have been successfully introduced into polyploids by conventional breeding. And similarly, that multiple modifications can routinely be introduced into plans through conventional breeding. Based on the supporting literature that was provided to us plus our own research, we largely agreed with those comments, and we are now proposing five exemptions. We will no longer be following through with the three exemptions that were proposed in 2021 as they have been entirely incorporated into these five new proposed exemptions. By the way, these exemptions were published today, this morning in the Federal Register, and we hope you will review them and send us your comments by December 15th, which is when the common period closes.

Speaker 6 00:37:09 So as I mentioned, there's a provision in the regulations at 340.1(b)(4) where it provides a way to expand the exemptions with additional modifications based on what could be achieved through conventional breeding. This process involves double notice. So first we propose the exemptions, and we allow the public to comment. Did I mention we want you to comment by December 15th <laugh>, and then notify a second time finalizing the exemptions? The proposals, and they could be submitted by you through the Agency or by the Agency to exempt plans with additional modifications will be based on scientific evidence demonstrating that the proposed modifications can be achieved through conventional breeding. I'd like to review the current exemptions because they will come up later in this presentation. So, the first, and these are the exemptions that are found at 340.1(b). So, we call these the B exemptions. (b)(1) says, oh, I'm sorry, I'm getting a little ahead of myself.

Speaker 6 00:38:29 The, what we're talking about here is the scientific rationale for the exemptions. The scientific rationale was that genetic engineering in and of itself does not introduce plant pest risk. That conventional breeding has a history of safe use related to plant pest risk. And that we, based on that basis, we can exempt plants with certain modifications that are achievable through conventional breeding. Okay, here we are. And now what I'm talking about the current exemptions, the current exemptions at (b)(1) says, a change resulting from cellular repair of a targeted DNA break in the absence of an externally provided repair template. And then (b)(2) is a targeted single base pair substitution. And (b)(3) is the introduction of a gene known to occur in the plant's gene pool, or a change in a targeted sequence to correspond to a known allele of such a gene or to a known structural variation present in the gene pool.

Speaker 6 00:39:36 So as I mentioned, we had a new notice in July 21, 21, maybe that's not so new that tried to clarify what was the meaning of a signal modification. It also allowed the use of an external template to be made during a deletion. It allowed multiple cuts to be made in a single gene. So, all of that functionality has been included in these five new exemptions. In addition, we've proposed new kinds of modifications and there are new concepts in the proposed regulations for proposed exemptions. We have this overarching loss of function modification. We have a mod, an exemption that covers polyploid plants,

another one that covers multiple edits, and another that deals with how to make successive edits and qualify for exemption. So, let's start with the very first one, AM1 stands for additional modification one, and this is the overarching exemption for loss of function.

Speaker 6 00:40:43 So what this would include would be it would exempt certain plants with loss of function mutations in the same gene across all chromosomes regardless of how the mutation is generated. Another aspect of this, exemption is that it would apply the modifications differently in diploids and auto, autopolyploids versus alloys in diploids and autopolyploids. A plant with any combination with loss of function modifications could have happened to one or all alleles of a single genetic locus in the allopolyploid, we are being more restrictive. We are limiting the number to four pairs of homologous chromosomes. We know this is a lot of words. In the next couple slides, I will be diagramming to give you a little bit better understanding of what we mean. So, this slide is trying to emphasize two concepts. One, that this loss of function modification is not prescriptive.

Speaker 6 00:41:56 So the, the exemption applies to a single genetic locus, and it really doesn't matter how you modify that single genetic locus provided the outcome is a loss of function. That's number one. And number two, in terms of counting modifications, this is a question that has come up. What happens if the modifications that create a loss of function are not exactly the same? And we are emphasizing that they do not need to be the same. A loss of function is a loss of function. So shown here are two pairs, a pair of alleles with a gene in red, marked 9, 10, 11, 12, representing different spaces on that allele. And suppose you use CRISPR editing to knock out the gene and region, 12 on one allele is knocked out or made a deletion, and you delete regions 11 12 on the second. Both of those lead to a loss of function. They're counted as a single modification.

Speaker 6 00:43:06 This slide, it's got a lot of information in it, but it's trying to give you an understanding of what we meant by the scope of this exemption. It shows three kinds of plants, a diploid such as corn, an allo, an autotetraploid such as potato and an allopolyploid, such as could be weed, could be in this case it's strawberry. Note that in corn has two copies of each chromosome, it's a diploid. Potato has four copies of each chromosome, but it only has one genome. And basically, the diploid was chromosome number was doubled. So now you have four copies of each chromosome. In the allopolyploid you have a different situation. You have, in this case, with a strawberry, which is an octaploid. You have four distinct genomes. The genome is represented by, there's a pink chromosome, a purple chromosome, and a yellow chromosome.

Speaker 6 00:44:12 And again, this is just for illustration purposes. They don't have that number of chromosomes. They have more than three. But illustrating that you have one genome in corn, one genome in potato, four genomes in this allopolyploid of strawberry. And these chromosomes behave differently in meiosis. So, there are going to be different possibilities in terms of how these, how much genetic combination you're going to get during, meiosis and how much you can change in conventional breeding. And this underlies some of the basis for why we're having different rules for allopolyploids versus autopolyploids. So going into what the scope is, let's say a loss of function is representing by a black asterisk. And if we look, start with the corn, and we look at the pink chromosome, you see two black asterisks we're saying, yeah, you can knock out that represents a knockout in a single allele, and you can knock out both alleles of a single genetic locus.

Speaker 6 00:45:22 So two in corn, there are four of those such alleles in potato, you can knock out all four that would count as one modification. If you look at what happens in the allopolyploid, you have eight of those pink chromosomes. You could knock out each one of those that would count as four separate modifications. We're allowing up to four homoeologous modifications to occur in the

allopolyploid. So, for emphasis, I should mention that there are plants that have more than four genomes. And as we've proposed, we are setting the limit to four. And if this is the sort of thing where if you have examples where conventional breeding can make homozygous mutations in more than four homoeologous genes, we'd like to know about that. We're not, we don't think we've exhaustively perused literature. Okay? So that was AM1 that's probably the most confusing one. AM2 is a little simpler.

Speaker 6 00:46:32 AM2 refers to a single contiguous deletion. So, we're allowing on homologous chromosomes to have a single continuous deletion of any size that would apply to diploids and autopolyploids. You know, this, this exemption was getting to the fact that that exact same deletion could be made over and over again on the same, on the corresponding regions on the various chromosomes. And we didn't think that you could apply that across all the chromosomes in allopolyploids. And that's why that's not represented there. But we're talking about a single modification, a modification on a single continuous deletion of any size resulting from cellular repair of one or two targeted DNM breaks on a single chromosome at the same location on two homologous or more homologous chromosomes without the insertion of DNA. And in the absence of a repair template, what does that look like? Whoops, it is not advancing it. Okay, there we go. I must have, I must have pressed the wrong button.

Speaker 6 00:47:59 So deletions of any size achieved by two breaks. So, this illustration, if we look at the pink chromosome on the left, and you see there's a red portion, suppose you have a guide RNA that causes a break on either side of that portion of DNA. And then you see on the next pink slide, that piece of red has been broken and it excises, and you get a deletion. We're saying that deletion could be any size and it, the exact same deletion could be made on the two sets of chromosome in the diploid and the four sets of chrome in the auto polyploid. Okay, what about exemption AM3? AM3 is intended to apply the codified exemptions at 340.1(b)(2) and (b)(3) to autopolyploids. (b)(2) was that single targeted base per substitution. (b)(3) was where you can insert, or you can change a gene to one that is, already in the gene, correspond to one that's in the gene pool.

Speaker 6 00:49:09 So what that looks like, suppose we, I'm not sure how well you can see this. Suppose in one allele there's a cytosine and you want to change that base to a thymine. So, you have that C to T transition in diploids, you could make two of those, in autopolyploids, you would be able to make all four of those substitutions. So that's the single nucleotide substitution and the analogous situation, supposedly there's an allele in the gene pool. You want to convert the one allele to that allele in the gene pool, and that corresponds to that blue region. And you could make that change that across all four chromosomes in the autotetraploid.

Speaker 6 00:50:01 Let's go now into AM4. AM4 is where we're talking about being able to make multiple modifications to the plant. What would qualify for an exemption? It would apply to, diploids and autopolypoid plants and to autopolyploids with some limitation. So, the modifications could be made simultaneously or sequentially. Each modification must qualify individually for an exemption. Each modification must be made at a different genetic locus. So, we're not saying that you could make two or three changes into a single gene. No, this is talking about a modification that would you otherwise qualify for, and it has to be in different genetic loci. Now, autopolyploids were allowing that loss of function to be made in a homo, an homologous alleles. But for the (b)(2)and the (b)(3), we're saying, only for proposing only a single allele. When I show you the picture, we'll get into that in a moment.

Speaker 6 00:51:15 So let's talk about four separate modifications and let's, I'm representing those four with different colored asterisk. And let's say we have a loss of function that's represented by the green asterisk, and you could make that across homologous chromosomes. So, the yellow chromosomes, you make that loss of function modification on both homologous alleles. Now, let's suppose you have a

second loss of function, the black asterisk, and that's made in a different part of the genome that's made on the pink chromosome. And now let's suppose you want to do a nucleotide substitution, the (b)(2) exemption, well, that it would be, say, represented in red and let's say as allele replacement, that would be represented in orange. So, you could combine all of those sorts and the numbers that you could get are represented in this diagram in the diploid, you're seeing your getting eight alleles that are modified altogether in the autotetraploid, you're modifying all 16 because we're proposing that you can allow all the homologous chromosomes to be modified in the allopolyploid.

Speaker 6 00:52:30 We're saying it's going to be slightly different. We're allowing the loss of function because the loss of function, it happens at a much higher frequency. because those changes do not need to be identical. But the nucleotide substitution and the little replacement we were proposing to be as heterozygotes. And you know, this is going to be something that's up for, further discussion. If you, we have, we proposed it this way because we did not identify any examples from the literature, which found four modifications being made in allopolyploid with homozygous mutations across all the modifications. We came across examples where say there were four genes that were stacked for disease resistance and, but each one of those was dominant and they were only as heterozygotes. So, we welcome you to identify additional information and we would consider that. And when you submit your comments, please submit additional information that might make us reconsider what we mean.

Speaker 6 00:53:41 Okay? Let me now move on to the last proposed exemption. AM5 which would be for successive modifications. This would apply to plants that have completed the voluntary confirmation process. So, the plant that is subject to the confirmation response, if it is produced, grown, and then observed very much like what you would do in conventional breeding, that kind of gets a reset. So those plants then could then be eligible for any of these exemptions that we discussed. Anything under 341.1(b), including any additional modifications that may be finalized through the ongoing notice process. So, let's go back to the example I showed in the last slide, which is the maximum that we're proposing to allow. Four modifications in those three kinds of cases, the diploid, the autotetraploid, and the allopolyploid. If you make four modifications that qualify exemptions under 340.1(b), and then you do a confirmation request and that confirmation exempt, that confirmation request is acknowledged, now you plant, grow and observe those plants, you can now make another four modifications ad infinitum. Okay? Thank you. That's, that's all I'd be happy to take questions. I'm sure you have questions in the question and answer period.

Speaker 1 00:55:27 Alright, thank you so much, Neil. That was a intellectually stimulating presentation, gives everybody something to wrap their brain around a little bit here while we take a break. So, we are scheduled for a break, and we are actually, ahead of schedule, ladies and gentlemen. So please enjoy some time speaking with your, your friends and colleagues. We've got refreshments in the back. for everyone who's in the room and online, please be back in your seats promptly at 2:30 PM so you don't miss the second half kickoff. Thank you very much.

Speaker 1 00:56:15 What a wonderful group that you all actually are organized enough to get back in your seat. Thank you so much. Hope everyone got some Gatorade or a snack. I know we have a nice spread of pastries back there. Thanks to, Bernadette and Jessica for providing all the refreshments for everybody. And we have a very compelling second half of our afternoon for everyone today. So, without further ado, our next speaker is Subray Hegde, and he will be giving us an update on the permitting process. Take away Subray.

Speaker 7 00:56:59 Thank you. Thank you. Okay. So you, you heard from Alan and also from Neil , my program have to implement, program has to implement or whatever they're talking about. So, if it is

delayed, you know, I don't complain. <laugh>. Okay. Yeah. my name is Subray. I'm the director Biotechnology Analysis Program. We provide, we authorize permits and, review RSR and also write the confirmation request, you know, responses to confirmation request. Today, I'm going to talk about a couple of issues regarding permitting, what we have done last year and, what are some of the flexibilities we would like to bring based on the feedback from the stakeholders. And also, some of the tips I would like to share, you know, to, to improve, timeline for our applicants and also the improvement we would want to bring to permitting process through the business improvement process.

Speaker 7 00:58:16 So we have been our stakeholders all the time. Okay. What we did last year, in fiscal year 2023, we authorized the 784 applicant permits. We get more, but we authorized 784. You get that the graph on the left side. So those are the number that is both environmental release, importation and interstate movement. A majority are for the importation and interstate movement, almost 62%, yeah, around 38% for an environmental release. And the pie chart, it shows, you know, that this is not surprising, a majority of our permit authorizations to modified plants from 87% last year, followed by microbes. Microbes are getting more attention. For example, from 22 to 23, there's almost, 60% more, application for, for movement and release. And very little for insects, modified insects. Okay, how did we do with the timeline, for example?

Speaker 7 00:59:44 These are in days, and if you look at it, in our regulation, we say for a completed application, if your application is complete, we provide authorization within 45 days for importation and interstate movement and 120 days for release. If you look at the second column from technical completeness, there are two baseline. I'm showing our data. One is when your application is complete with all the information required by our biotech reviewers to, you know, review and authorize, the second column. And the last column is when you submit it in how many days it took for us to provide authorization. The second column, if you see importation and interstate movement permits, we did it in 31 days from the technical completeness, that means we have 45 days, we did it in 31 days. And the, the last row if you look at the release, we have 120 days.

Speaker 7 01:00:54 We did it in 47 day on average. But if you go to the last column here from submission, how did we do? We took 50 days to provide on average authorization. That means we took more days than required, that 45 days and, and for the interstate movement and the importation and 87 days for release, we met that one. So, there's some gap, you know, from the day you submitted. But overall, 90% of our authorizations were processed within the targeted timeframe from the technically completed date. That means over 784, 90% is around 702, that the rest of them we could not provide authorization in time. It's not just because of, you know, we did not work on it. There are other factors like whether we got the response on time from the applicants and we needed more information. And it's also that there are more microbe permits are not authorized on time because most of them are new.

Speaker 7 01:02:02 Okay? So, what flexibilities are we already, you know, bringing to our permitting process so that it really helps the stakeholder. One is so far in all these 33 years, whatever since 1987, and even the old legacy regulation and in the current regulation, we only provided in a movement permit whether importation or interstate just one year, it's valid only for one year. Every year they have to, you know, you have to submit application for the movement. So, what we have done is recently we would like to provide a multi-year movement permit/import importation in movement. So now after three years, you, it's valid. And we just did a couple of months ago, I think, we published a stakeholder notice that, you know, applicants can ask for multi-year movement permit. And it will save time for BRS also for the applicants. And second one is completely updated instructional and help text in the eFile. In the eFile, you know, we are providing more and more clarification to what we have written already, so that you know, based on our experience, what applicants ask us. So, thinking that it would help our applicants to

understand the requirements in eFile. Okay, in place that is what other things we have done. Updated job aid for permit application means sometime, you know, let us say you applies 10 permits and you do not know how long it's taking BRS, you have to count manually. <Inaudible>

Speaker 7 01:03:53 Now you can see yourself how long it has been with BRS that is being improved, this functionality. And also, we created a template SOP, that is a standard operating procedure. This is voluntary, but it would help what critical information we are looking for when we review a permit application. So, it helps if you provide those information. So, we would like to know whether the, the regular shipment or release there, there is a possibility of an unanticipated escape and spread of,. a microbe <inaudible> we want to make sure that there is no unanticipated escape or accidental escape. So, we can authorize, your permit on time.

Speaker 7 01:04:46 And also you know, we published a revised draft guide for submitting permit application for microbe. Microbe is something new. As you saw, you know, majority of the permit applications are only for the, you know, plants not for the microbes. Even microbes earlier it was only for the movement, hardly there were any releases, one or two. Except currently we are seeing more releases for microbes. So, people, you know, most of them are new to microbes, modified microbes. So that's why we developed the guide. We got the, you know, comment from <inaudible> and also the developers and you know, we provide a second draft. You know, we published, I think it's the 13th of October, a second draft. So here, as I said earlier, microbes can get, you know, multi-year movement permit. They don't need to apply every year. And another thing we wanted to do is earlier all our application, majority of our plants and also microbes for only one species, unless, you know, it is similar you can similarly ship.

Speaker 7 01:05:54 Now we would like to provide flexibility that, you know, any number of species within, know, a fungi or bacteria you can move. So that is another flexibility. You don't need to have, you know, a hundred different permits per hundred species within a particular genus. And finally, we want to, you know, the third one in the legacy regulation, that is 1987 to 2020, we had a plant pest list. So that our, our stakeholders knew what is in and what is out of regulation, but we found out that the old list was outdated. It would only list organisms under kingdom, for example, virus it says. Or it says a class or Order ,very high taxonomy level. It is not at the species level. We found it not useful for the stakeholder. That's why in the revised regulation there is no plant pest list. Regardless, the demand from , the applicants for a plant pest list. We are collaborating with experts in the field to develop a plan pest list at the species level. And we are going to publish it this year or next year.

Speaker 7 01:07:13 So what other things we are really working on. Another thing is multi-year release permit. We have so far provide multi-year lease permit only for perennials because we cannot have a one year permit for perennials because you cannot do research. But we are now here thinking <inaudible> want to provide a multi-year release for the annuals also. I know you guys harvest for one year, annuals don't survive, right? But you don't need to come back for every year, you know, you can retest up to three years. And another one is importation. Importation is really, you know, there's a real limitation. You can have only one point of origin and one point of destination. So that means after you get your material to the United States, of course you want to move into the state again, you need another permit. So rather than that one, you know, we would like to introduce multiple origin and multiple destination for import so that you do not need another permit to more material interstate. We also, you know, we had an old permit guide, but revised regulation is quite slightly different by permits. And also, earlier we have e-Permit for permitting system, now we have eFile. So, we are really updating, you know, permit user guide to match the revised regulation and also the eFile functionalities.

Speaker 7 01:08:52 We are also updating our application and authorization detail pages. For example, if, if people want to know, you know, as I said earlier, for how long, you know, permit, I'm just giving an example, how long the permit is with us, you can just look at, you know, in our eFile, and it would tell how many days it is with us. And also, you know, we are updating the instruction for text for sharing accounts. The, the big companies are companies who are already doing business with us, they have, they know this functionality, but we have a lot of, you know, new applicants and also small developers so they can share an account. When you create an account with an across company, you can can share that account, you know, that feature. Yeah, we, we, we have more explanation of how they can do it.

Speaker 7 01:09:46 Okay, these are some of the tips I would like to share. I know people, you know, especially for release permit, People are always, you know, breathing for time because you do not want to miss your, planting deadline because you cannot just go <inaudible> any time, you know, when you get an authorization. So, but what, there are certain, you know, things we expect from our, our applicants. First of all, you know, if you are moved to the permitting process always come in advance, have a consultation, what are the requirements, how an application is created so it would help you rather than secondly, submitting an incomplete application. Our experience shows, whenever you submit an incomplete application, there is a lot of back and forth, back and forth. It'll unnecessarily delay the application. Rather, it is better to come to us in advance asking for, you know, these questions.

Speaker 7 01:10:44 And, and also some of the, as I said, you know, the delay, as I said out 784 only we authorized 702 on time is because some of the applicants, so I don't need, you know, application this year, but I would submit it anyway. See, we cannot keep it because it affects our timeline. And second one is some people do not respond on time for a particular deficiency or technical information. Then our biotechs cannot do anything about that application. So timely response to the questions is really helps us to expedite your permit application. And also <inaudible>, you can, if you don't want to, you have time to talk to or have a meeting with us, there always, you know, there is eFile job aid and permit user guide, excuse me, you, you can always refer to. And we have a, a recently, as I said earlier, SOP template.

Speaker 7 01:11:45 SOP template is voluntary, but it is clearly helps you what are the critical information needed in an application so that, you know, the, our reviewers don't come back to you again for a question. If you have a standard, once you have it, you can have a, you know, modify slightly if needed. Otherwise, you can use it the, same again and again for the same purpose . And finally, provide information to help us you know, whenever you have a unique organism or some unique kind of features, or unique construct of the trait. For example, sometime there's a limitation how much, you know, how many constructs can apply, you know, how many pages eFile can handle, it cannot probably handle a thousand page application, right? So, because it times out. So let us say you have a thousand construct example, and it is the same location, but you are splitting your application so that you can, eFile can handle, you submitting 10. But we do not know, if you do not tell us, you know, these are all the linked permits. If it's a linked permit, generally we gave it to one or two biotechs because if you give it to 10 people, you may get 10 different questions from, you know, biotechs and for the same issue they may have a different question and delays, you know, providing authorization on time. So always, you know, let us know if there are unique features in an application.

Speaker 7 01:13:15 And this is what we have started doing in a business process improvement. Because permitting process I said we only met 90%. We want to really improve our efficiency and provide timely services to our, our customers. So, we started this business process improvement to modernize and also streamline permitting process. Our objective is, reestablish a risk based, and a familiarity based, approach by reviewing crop trait combination. If you remember, most of the people who are old customers with BRS, they know that we had a, in the legacy regulation, there was a type of

permit called notification. It was very quick, you know, it was based on our experience with the crop and also the trait and also the risk level. For example, we did not allow under permit, under the notification if it's the noxious weed otherwise, if it's a corn with an herbicide tolerant, we said, yeah, we have seen hundreds of them.

Speaker 7 01:14:17 So it's the lowest category. So, we have done that one. You know, in, in, in legacy regulation, and I was checking data, 55 to 75% of our applications were notifications. We had less number of permits under legacy regulation, but now everything is permit with permit conditions. So now that means there's a lot of paperwork even for the reviewers. Now we are thinking, you know, we have already done looked at these familiar crops and traits and the low risk, but it is taking more. We really want to go back even in the permit, what are low risk crops or, you know, high risk crops so that we can expedite low risk crop and trait. Our goal is to, you know, so restore <inaudible>, it should be predictable for our, our applicants so that they have you know, what you call confidence in BRS' permitting process. So that is the purpose.

Speaker 7 01:15:17 We have reached 95, 96% sometime, but you know, it has going back to 90%. We, we covered all of them are under permit. Finally, our approach is to identify opportunities to promote consistent review because people, you know, we have two people or 25, you know, biotechnologist looking at your application. Each biotech might have a different questions. You know, you might ask, you know, I submitted this last year, but why are you asking the different question this year? We want to bring the consistency and we want to address inefficiencies. We want to see bottlenecks. So where exactly things are taking more time. We want to identify that one and also implement a process chain and measure progress bi-monthly. See, you know, how we are doing. So, because we have data, it's easy to find out, you know, how much time we took, where the bottlenecks are , why it is getting delayed.

Speaker 7 01:16:13 Okay, so for permitting business process improvement, what we already did is, supplement permit condition. So, all the permit has supplemental permit condition. If you are moving corn with the herbicide tolerant trait for the last 10 years, why we have to have a different supplemental permit condition. So, we standardize, we can do the same thing. We don't need to add a <inaudible> know modify, right? So, and also we have a dedicated staffer permit review so that, you know, there are more experienced and there will be consistency. So, we are dividing people for different functionalities of BRS, so that, you know, it would be more efficient. And the next step is document current process, for example, in how we are doing. So, we want to have a baseline and, measure, process steps that identify bottlenecks, which I already see where we are really, you know, things are getting, you know, not the way we want it to be. Reestablish risk based and familiarity.

Speaker 7 01:17:18 It is based on, you know, how much familiar we are. If you look at, you know, probably, we have issued 60,000 permits or the authorization in last 20, 30 years, and we are familiar with traits, we are familiar with crops. So, we want to really classify so that, you know, we can expedite and bring efficiency to our permitting review system and select set objective criteria for technically complete permit application. Because in the second or third slide I said from technical completeness and from the submission date. But what is technically complete? We have to have clear criteria for our biotechnologists so <inaudible> they know to declare what is complete so we can be processed. So that, that also we are developing. Improve the communication with applicants to expedite responses so that, you know, our, stakeholders get timely response for their questions. Well, these are some of the resources one could use. They are there on website. And thank you for listening and I'll be answering any questions during question and answer.

Speaker 1 01:18:45 Thank you so much, Subray. I think it's a really nice, example of how in BRS we're, you know, doing the work, but we're also evaluating the work we do and reflecting on what we can do better. So, for our next talk, we have a pair of speakers and it's Michael Stulberg and Suma Chakravarthy, and they will be telling you about regulatory off-ramps for plants. Michael and Suma, take it away.

Speaker 8 01:19:15 Great, thanks Doug. Good afternoon, everyone. So yeah, today we'll be talking about, the fact that there are two main off-ramps for plants, who are permitting requirements of 7 CFR part 340. So, the exemptions, which can be confirmed through our confirmation of exemption request process and the regulatory status review. Neil went over the exemptions, and our, you know, and clearly articulated our proposal for additional modifications. And the confirmation request process is a voluntary process to receive a confirmation letter from us. If the genetic modification does not be one of the required, when the exemptions outlined in 340.1, the plant can be evaluated for increased plant pest risk relative to a comparator plant using a process called regulatory status review. And Suma will discuss that later. So, these processes were implemented in late 2020 and mid-2021.

Speaker 8 01:20:10 How are they doing today or last, last fiscal year I should say? So, in FY 23 alone, we see a diversity of customers coming into these processes as Bernadette mentioned, and Under Secretary Moffitt, mentioned as well, the majority of them are small to medium sized enterprises. These are simply the percentages here on the left. You'll see, in the CR it was 93% in fiscal year 23 for, RSRs completed, it was 80%. And this is in a shift from the legacy regulation where it was mostly the major biotech companies who would submit petitions to us.

Speaker 8 01:20:49 So in FY23, it was really kind of a banner year for the CR, and I hope it's outdone by the upcoming fiscal year. As mentioned before, it would, we issued 40, responses as compared to nine previous fiscal year, and it was only a marginal increase in processing time. So, we processed on average in 51 days for receiving a sufficiently detailed request as compared to the low forties, in the previous years. The reason is not just that we received more requests, but more requests that were technically complete on initial receipt. And this is something that I predicted last year might happen at last year's stakeholder meeting I said this. That since we updated our guide, we've been having more pre-submission meetings, that more of these were going to be coming in complete and our overall time might increase, but, and we also resulted in fewer return requests for modifications that did not, qualify.

Speaker 8 01:21:45 We still process all four of these responses within our regulatory timeframe, well within our regulatory timeframe, which is 120 days, and we do not have any in-house that are beyond 120 days at this time. And we should just be issuing nine today. They're not quite yet posted to the website, but I anticipate that happening today. And it's just showing that the rate that we're receiving these is, is increasing. And so, we hope to, continue processing these on time and to do that, we in the, in the last year internally kind of built up our CR management team. And so, you may have been receiving emails from new names as we developed others rotated responsibilities. And it's a trend continues in FY 24. So, the figure on the right shows that most of the exemptions in FY 23 were our B exemptions that Neil went over. The other type are C exemptions are modified plants with the same plant trait mechanism of action that we previously reviewed in petitions or RSRs. So, this is the slide showing that we continue to see a variety of plants coming in through the CR. We have had, you know, while we have corn, soybean, we've had disease resistant citrus, we've had nine other plant species. It is been really fun reading these. The ingenuity and diversity of plants is really, it is really fun to see, and we continue to look forward to even more in FY 24.

Speaker 9 01:23:26 Good afternoon and thank you for your attendance at this annual BRS stakeholder meeting. I will provide first a high level summary of the RSR process followed by the products which were found not subject to the regulations this year. And then finally, the steps we've taken to improve efficiency. So as Michael indicated, regulatory status review or RSR is for plants which are not exempt from the regulations. It is a two-step process at the first step, which we call initial review. If this performs problem formulation to identify if the modified plant has any plausible pathways to increased plant pest risk, and any sexually compatible relatives which can acquire the trait through gene flow are also evaluated. In case when possible pathways are identified, the RSR will proceed to step two, which is plant pest risk assessment or PPRA. And during PPRA, we will determine the likelihood and consequence of any plausible pathways that were identified in the initial review. Between step one and two, the developer has the option to pause, withdraw, or proceed to PPRA In the last fiscal year, we reviewed the completed initial review for 21 plants of which 15 were found, not subject to the regulations, which are the ones you see here.

Speaker 9 01:25:11 Two proceeded to step two and the others remain paused. We reviewed many different traits such as nutritionally enhanced plants, improved product quality and agronomy traits, reporters for disease occurrence and multicultural traits. We also received plants previously not seen in petitions like chrysanthemum, safflower, teff, walnut, and hemp. Three of these 15 plants were derived using genome editing, and the others contain, introduced transgenes. And so, this sort of mirrors what we are seeing in the CR process. We see new traits and new plants. Building efficiency in completing RSR reviews has been a priority this year. Our staff gained experience as we completed 21 initial reviews, and despite the delays, we've been able to provide responses 27% faster than under the legacy regulations. We are very motivated to increase the rate of RSR completion within the timeline. And there's a list of, different approaches here that we've used towards that goal. Some of our staff are dedicated for RSRs, and the senior science advisors, including Neil and myself, provide support to help finalize the documents that BRS developed. We hired new staff over the last two years, and in order to better manage workload, a new branch was formed within biotechnology risk analysis programs called Plants and Insects Branch, for which Mike Michael is, the branch chief.

Speaker 9 01:27:08 So the last year we've had, rotating RSR project managers to help with coordination. We collaborated with our IT department to develop a platform that will be used for managing RSRs. So, all the documents appropriately, track steps and deadlines, and this IT platform is going through internal testing at this time. Our document preparation process itself has been streamlined and we've, we have reduced internal reviews and handoffs. And finally, we are especially happy to share that we obtain, obtain approval to pilot test an AI tool, which will expedite and automate literature reviews that we perform to write documents. During the pilot test, the ability to extract literature from reliable sources relevant to the topic will be tested. And if the tool returns information similar to what a human would retrieve, we anticipate to considerably save staff time, allowing APHIS also to exploit next gen, innovation, to achieve our mission. And, and I'd just like to take a pause here and, give a shout out to all our internal staff who is collectively, this is a collective success. Everybody's trying hard, they're trying to be creative and find new ways that we can do our work.

Speaker 9 01:28:48 This is a snapshot of pending requests, which we have in house. On the left hand side, you can see that 42% of the requests are for annual and row crops, and more than half are a mix of different crops like vegetables and fruits, trees, oil seeds, and cover crops. On the right hand side are, the techniques used to create the modified plants we are seeing. When we implemented RSR three years ago, most, a majority of the plants we saw contain transgenes. But with time we've seen, genome edited crops steadily creep up, and now it's, you know, about half and half what we see, genome edited and transgenes.

As Alia mentioned before, I recently transitioned into a new role in BRS, it was an honor to work in biotechnology risk analysis programs as branch chief where I helped to implement and wrote the RSR process. It has been very rewarding to see the impact of the revised regulations on the types of crops traits that developers we see. I now hand back to Michael, who will speak to our plans for RSR for the next fiscal year.

Speaker 8 01:30:17 All right, thank you Suma. Right, so what are our goals for FY 24? So, I think the, the most obvious one is completion. So, we want to of course, reduce our backlog, increase the number of on-time completions, and also complete some PPRAs this year hopefully. We also, we want to continue cross training members on different parts of the review process in the hopes of building resiliency, expediting the process. We also want to evaluate the, the RSR processes. Suma mentioned, a lot of the changes that we made in FY 23 regarding our approach to RSRs. We hope to continue implementing these efficiencies, which it resulted this week right in, in the completion of 12 RSRs concluding those plants were not subject to the 7 CFR part 340 regulation. 25% of those were on time, seven of them were under a 90 days.

Speaker 8 01:31:12 So there's still though a lot of work to be done, to clear the backlog and we recognize improvements can still be made. So, we're forming a team to collect and implement process improvement ideas to make additional improvements. And I also want to just acknowledge that the efforts that are being made improved permitting that Subray mentioned, and the, the additional modifications that Neil mentioned will all have a positive impact on our RSR process by, diverting more resources to the RSRs and exempting modifications that are equivalent to conventional breeding practices.

Speaker 8 01:31:53 And lastly, just a couple of suggestions for how you all might be able to help us out. And so, one, the plant-MOA information. If we're not familiar with a plant species, for example, maybe it's not on our plant trade mechanism of action table, you can submit publicly available data about the biology of the plant and if you have questions about the scope of this or what this might look like, right? If we're familiar with the plant, we encourage you to set up a meeting with us before you start your submission. You're also encouraged to submit information, regarding the MOAs. not just linking the MOA to your desired phenotype but citing public literature demonstrating whether any other phenotypes are, expected or not.

Speaker 8 01:32:38 And on the right here, the tips for avoiding return initial submissions. So, you don't like returning initial submissions any more than you like receiving return, submissions. So here are the most common issues we are seeing with initial submissions. One, that to please include, the, the annotations and, and all the nucleotide sequences that are being inserted, including like spacer sequence. And we do not include conclusions about the plant pest risk of the modified plant and not publicly available data outside of what is required. So, we, like I mentioned before, we have a smart group of energetic enthusiast people, enthusiastic people in BRAP we're making some real progress here. We hope to provide this momentum. We have internal support in our ODA office and, and in other parts of BRS. And so, we look forward to a productive FY 24. Thank you for your time.

Speaker 1 01:33:19 Thank you so much Michael and Suma. Well, we've got a few more talks for you before we get to the question and answer session. And our next talk is Laura Andrako, and she's going to give you a compliance and inspection updates.

Speaker 10 01:34:11 Good afternoon, everybody here.

Speaker 10 01:34:14 Great.

Speaker 10 01:34:16 So I began in my new position in June of this year, but I've been with Regulatory Operations Program since 2015 and looking forward to meeting and interacting with all of you in my new position. Today, I'll be discussing some key accomplishments for 2023, including some e-File upgrades and other projects. Additionally, we will go over our inspection data and compliance outcomes. As part of this, I'll discuss some of our most frequent noncompliance issues and our in-depth analysis of compliance patterns. And finally, I'll end on a forward looking note and discuss some new projects that we will be pursuing in 2024. So, let's start with e-File made several e-File upgrades and have included some of the most impactful changes for external users on this slide. Each of these upgrades were requested by stakeholders, or they were discovered in consultation with stakeholders. And we hope that these changes will improve the user experience. First, we have improved XML uploads reports and tables. Previously, users could receive an error message for large XML uploads, and we've changed the system to allow these larger submissions. Next users can delete supporting documents before submission. And finally, our compliance database has been integrated into e-File. This will allow BRAP, biotechnology risk analysis programs, to check compliance status before issuing new permits.

Speaker 10 01:36:10 In addition to e-File updates, BRS has pursued additional improvements in 2023. First BRS published our draft guide for submitting reports and notices in APHIS e-File. It is under that this guide will help provide clarity for issues which we have encountered in the past, and that it'll also be a great resource for those who are new to the regulatory process.

Speaker 10 01:36:35 We welcome all comments. As of this morning, we have received one public comment, so just a reminder that you have until December 11th to provide your feedback on this document. Next, we also hired and onboarded four new BRS inspectors early in FY 23. When an inspector starts at BRS, they go through a rigorous training regarding our regulation and processes. Next, they spend time shadowing veteran inspectors on multiple permit and inspection types. And finally, our veteran inspectors shadow the new inspectors and provide feedback into their process, technique, compliance, evaluations, and conclusions. New inspectors must complete all of these on the job training steps before they're certified to conduct inspections independently. I also want to note that consistency is a primary objective for all of our inspectors. We want to ensure that if any of our inspectors visited the same location, they would all draw the same compliance evaluation. To that end, we provide annual training to all of our inspectors and reviewers, and we also utilize a tiered review process. all inspection reports are reviewed by at least one experienced reviewer before we formulate the final compliance outcome.

Speaker 10 01:38:04 The last project up here is a project we piloted in 2023 to provide proactive compliance, engagement. This is our first year and we still consider this project to be in the pilot phase. During this time, we are evaluating the processes affected this by monitoring how our compliance consultations affected overall compliance. 17 proactive compliance assistance engagements were held in FY 23, and the permittees were chosen for assistance based on compliance history, novelty of the organism, and in cases where they asked to participate. As we move forward, we are considering additional criteria and ways to integrate this program into our enforcement work. So, stay tuned.

Speaker 10 01:39:03 In 2023, we had 855 unique plantings and BRS conducted 711 inspections. On this map, this distribution is typical for the geographic distribution of inspections. States with higher concentrations of inspections generally have a higher corresponding concentration of trials planted. So, as you can see, the highest concentration of inspections and corresponding planting plantings occurred in the Midwest, Hawaii and Puerto Rico. One quick note about this data to help you wrap your minds around it, plantings and inspections don't have a one-to-one relationship. Some trials such as plant made pharmaceuticals and industrials are inspected multiple times a year. In these cases, you would have one

planting with multiple resulting inspections. In this post pandemic era, we have continued to increase our in-person inspections. Travel restrictions were lifted in January last year, and it has been our goal to resume

Speaker 10 01:40:11 n-person inspections at pre pandemic levels, and we are very close to doing that in this fiscal year. We're glad to be back in the field. As you can see, most inspections are conducted in person, but we do continue to conduct some virtual inspections. In 2023, 80% of inspections were completed in person. BRS conducted 461, PPQ conducted 86, and our state partners conducted 24. I will point out that all inspections conducted by PPQ, and our state partners were in person. And in 2023, BRS only conducted virtual inspections. For the 711 inspections conducted 591 were found compliant. 119 inspections detected one or more instances of non-compliance.

Speaker 10 01:41:18 In 2023, we drilled down into our data related to non-compliance. And what probably stands out to you on this slide also stood out to us. We had 82 non-compliances related to records, which is roughly 60% of the documented non-compliance. Since this is an outlier compared to prior years, we wanted to take a closer look at this category and I'm going to share our, excuse me, observations with you on the next slide. But before I move on, I want to provide some examples of the types of issues that fell into some of these other categories of non-compliance. For unauthorized release, for example, we found that although they had a permit when we undertook our inspection, the identified field trial was planted in the area outside of the authorized area for the permit. For issues involving persistence, in some instances, we identified viable material remaining at the field after harvest. And in other cases, we observed flowering volunteers during the inspection. When we reviewed the types of records non-compliance that we detected at the time of inspection, we noted equipment cleaning records were out of alignment, and this was both when compared to other record types, but also, based on a comparison of previous years non-compliance trends.

Speaker 10 01:42:55 So what is required in the equipment cleaning record,

Speaker 10 01:43:00 Who cleaned when and where it was cleaned, methods used, and whether viable material was recovered from the equipment and when viable material was recovered. Also, whether it was retained or if disposed, the method and location of disposal. And FY 23, we added the requirement that you document whether you recovered viable material and what you did with it. We realized that we could have improved the process used to update our requirements to better highlight the change and to ensure time for adjustments in business practices. We openly discussed this change at our stakeholder meeting last December, and after that, the data indicates a decrease in instances of non-compliance associated with this requirement, and that was especially true for organizations that were in that audience. Our takeaway from this analysis is that we need to engage and communicate about impactful changes to ensure developers have time to adjust to the changes and provide training for field staff. We'll also improve how we monitor compliance trends to identify challenges early and ensure consistency across our inspectorate. When we reviewed the types of information that was missing from equipment cleaning records, we found two areas that need improvement. The first is consistently recording the recovery and disposition of material, and the second is recording all equipment used and cleaned at the site.

Speaker 10 01:44:44 So after all this discussion, you might be wondering why we review records. The reason we look at records is because we can't be there every day. Records provide us some visibility for activities that occur when we are not there and allow us to evaluate compliance. So, for example, reproductive confinement activities are those that ensure that the risk of pollen flow is mitigated. Activities may include a separation distance, temporal isolation, stopping flour or pollen production. So, for example, detasseling, or controlled pollination. And an example of that would be flower bagging. BRS

must ensure that these activities were carried out in accord in accordance with the permit conditions. And this is even when inspectors inspect at a time when reproductive confinement is not occurring. Records also document important activities at critical control points when loss of containment is most likely to occur. So, an example of this, can include when it can include equipment related to planting, field maintenance, and harvest. Inspectors are almost never present during equipment cleaning. So, records are an essential way to ensure that permit conditions were followed during this critical control point. It is also well recognized that good record keeping is the backbone of a strong compliance program. For example, record keeping is essential in any stewardship or certification programs including ISO certification. So, record keeping plays a similar, similar role in BRS' oversight of regulated activities.

Speaker 10 01:46:29 Our projects slated for 2024 are part of our effort to help prevent instances of non-compliance from occurring. One of the projects we worked on in 2023 was a draft guide to reports and notices. In the coming year, we look forward to receiving your feedback and then publishing the final guide. We're also undertaking a business process improvement in 2024. As part of the BPI, we are working on process improvements to ensure inspection frequency is risk proportionate. So, in 2023, two thirds of our inspection occurred on corn and soybean, and we aim to balance inspections to orient inspection resources on higher risk activities.

Speaker 10 01:47:17 Next, we plan to streamline internal inspection procedures. Many of our procedures were developed at a time when most of our inspections were being conducted by PPQ and our state cooperators. And now that we've transitioned to a model where BRS conducts most of the inspections, there's an opportunity to streamline internal inspection procedures. And to that end, we've just begun undertaking our review, so stay tuned for changes. And finally, we plan to update our enforcement strategy to reflect changes based on the new regulations, or excuse me, the revised regulations. Lastly, I already mentioned our data-driven proactive compliance assistance project. This project remains in the pilot phase, and we are considering adding additional criteria and ways to integrate this program into our enforcement work. That's it. Thank you.

Speaker 1 01:48:21 Alright, thank you so much, Laura. I do want to make, just one quick point that if you're interested in reviewing and commenting on our draft guide for submitting reports and notices that is available on the Federal Register through December 11th for you to review and make comment on. And our next speaker is Chessa Huff Woodard. Very excited to have her with us exploring regulatory off-ramps for modified microbes. Take it away, Chessa.

Speaker 11 01:48:52 Thank you Doug. And good afternoon everyone. My name is Chessa Huff Woodard. As was just mentioned, I am the branch chief for policy, program and international collaboration. We are a multidisciplinary team that's comprised of attorneys like myself, program specialists, and science advisors, and we undertake everything from regulatory policy analysis to CBI reviews of FOIA and also, international, support in technical diplomacy. So, with that today, I'm happy to share with you all, a project and operational goal for this year, which is exploring regulatory off- ramps for, modified microbes. This afternoon you've heard presentations in regards to Executive Order 14081, as well as our current regulatory off-ramps under, our regulatory framework, which includes CRs and RSRs. So ,with that, BRS does, plan to embark this year on a stakeholder engagement strategy. And that is really aimed at hearing from you all, some of your critical thoughts, ideas, framed around a RFI that will allow us to build upon that.

Speaker 11 01:50:09 So how do we, what are our goals this year? Really we want to continue to address feedback. We've had our microbes guide and you all have provided, impact or impactful insight in comments for us in the past, and we hope to as appropriate address those throughout this effort. We also

have the RFI, that was spoken to earlier for Executive Order 1 4 0 8 1, where there were also significant comments in regards to microbes and potential off-ramp opportunities therein. And then also we want to continue to, fulfill our, promise to you all as far as our preamble from the finalized rule, to really think about how we can continue to develop opportunities for, regulatory off- ramps for microbes. But then also what do we do with that information once we get that. We want to develop a contemplated framework. And this framework will allow us to think about what opportunities we have in order to develop appropriate, risk-based, efficient and, off-ramps for modified microbes, under our current regulatory framework.

Speaker 11 01:51:23 So how do we intend to do this? We have a very ambitious schedule here, and as the project manager, we definitely continue to, work collaboratively across our program to ensure that we have all the pieces in place to to, to develop a RFI that will be appropriate and to seek the types of responses that we'll need from you all to shape a contemplated framework. So, we intend to do that by the end of March of 24, which is this fiscal year. And once we receive that, that feedback and comments from you all, it may inform and provide us additional opportunities as appropriate to have additional and increased, engagement with you all to make sure that we have the, the feedback that we need. And so, once we do have that feedback, we will review, analyze, and thematize or categorize that feedback to ensure that as we scope our future documents, that we have all the pieces in place that they're done and recorded in a way that, ensures that we have captured everything appropriately.

Speaker 11 01:52:27 And then what we will do by <laugh>, September of next year, one, we will have developed a contemplated framework and that will be a document internal for us, that will allow us to really think about, what we have shaped based on your feedback to see how we might be able to, utilize that for future rulemaking. And then also as appropriate, we will, work collaboratively with our partners PPQ here in APHIS, and then also with EPA under executive 1 4 0 8 1 to identify any potential non-regulatory solutions that we may be able to implement. So, although I've been before you all briefly, I hope that you'll find that this year we'll have a lot of impactful projects and that the microbe, modified microbes project is one of them, we definitely want to continue to collaborate with you all. We're grateful for you being here today. And so, as the RFI does roll out through the Federal Register, we definitely encourage you all to submit your comments. And if you have any questions for us during that time, put them on the record. So, thank you so much. Have a great afternoon. Bye-Bye.

Speaker 1 01:53:44 Thank you, Chessa. And our last speaker before we get to the Q&A session this afternoon is Jessica Mahalingappa, and she is going to share with you about some of the great work that BRS does in the area of international engagement. Welcome, Jessica.

Speaker 12 01:54:07 Thanks everybody. And, and I, just to introduce myself to those I haven't had a chance to meet. I am the associate deputy administrator here at BRS, and one of my major areas of responsibility is in international engagement. And as Chessa mentioned, we do have a small team here, including Chessa, Suma and some others who are dedicated to this. And you've heard a lot, this afternoon about some of the domestic priorities and some of the changes and activities that we've been engaged in. People at BRS are very busy. I don't think I can overstate that at all. At the same time, we do realize that all these activities are being done in the context of enormous global change in the area of biotech regulation. New, new countries are, are, are, thinking about how they're going to regulate biotechnology, countries that have, regulations in place are modifying how their approaches.

Speaker 12 01:55:08 And of course, we have new technologies that are really increasing the pace of these, of the, of international, activity. So, we are very aware that everything that we do does have global implications. We take that seriously. not only are we a huge producer of products of biotechnology, but

we, we are also aware that we are, one of the biggest exporters of agricultural products, both those that are products of biotechnology and those are, that are conventional as well as one of the biggest importers of agricultural biotechnology products. And so, we're, we're, you know, we have to balance all of that. So, we do try to find the resources to, engage internationally. And I'm going to talk a little bit about what we've been up to and what we'd like to do.

Speaker 12 01:55:59 Okay. The first area of international collaboration that we take on is bilateral, engagements. These are one-on-one, discussions with regulators from other countries, maybe building on past relationships. Sometimes people, like Dr. Hedge or, or Dr. Chakravarthy out at conferences, we'll meet people, and they want to, take a little bit of a deeper dive into what we're thinking about. We also are very interested in understanding what they're thinking about and how they might, be changing their approaches. So, we try to, you know, be available to folks for, for engagements. Sometimes we reach out, sometimes they reach out. But these, these, these are fairly consistent throughout the year, and we've taken advantage of the technology. You know, the pandemic has done something for us in, in really enabling a lot of virtual meetings. So, the list up here is a few countries that we've had some recent engagements with.

Speaker 12 01:57:00 Argentina, Brazil, Bangladesh and the Philippines. All at very different areas in terms of where they are in biotech regulation. One of the key topic areas I want to point out here is genome editing. We know there, there are plenty of new technologies out there, but the one topic that everybody is, is very interested in what we are doing. And we know we have a slightly different approach than some of these countries on genome editing. So, we are there, we want to explain how we're looking at things and also understand how others are to make sure that we have some consistency in applications.

Speaker 12 01:57:41 I also want to point out that a lot of these activities, you know, we're not only meeting folks, what, what that we, might already know, but we're also helping support the efforts of our other US government foreign affairs agencies. So, when I talk about foreign affairs agencies, I'm talking about Department of State, US Trade Representative Office, the US Agency for International Development, and of course our own USDA Foreign Agricultural Service. So, they have very different goals than we do. But there's often a role for regulators, to, to talk and to discuss. And this might be one-on-one engagements with countries. It might be support for reviewing documents, you know, as countries are drafting legislation or other regulations, they want to regulators look at, at that, at that draft, legislation. So we do spend quite a bit of our time, our team, looking at some of these, these documents and, where applicable we'll have meetings, sometimes one-on-one or sometimes with a group, to discuss, how different countries are, are, are maybe making some changes and approaches, and maybe how do we can fit in with some of the goals, be they for exports that, like, for example, with USTR, or for, for example, a food security imperative that USAID might be wanting to fund.

Speaker 12 01:59:08 So we're looking at that, looking at the technical aspects, looking at the regulatory, benefits or pitfalls. So, we want to, we want, want everyone to know that we, you know, we do support that work. And some, some examples of recent engagements that we've undertaken, in country with, specific countries, under these auspices is Japan, Taiwan, Korea, and, most recently Columbia. So, we're continue, we're going to continue to do this. I also want to take advantage to point out, you'll notice we have photos of all these engagements. So, we have, where we, where we can get people together. We like to make sure we document it. A lot of these activities, of course, take place online, but we are, we try to document, and I want to point out that we, we, we do work within the contemplated framework. So, you'll see representatives from the Food and Drug Administration and Environmental Protection Agency as well, so that we're explaining how we work together to, countries and to other regulators so that they understand, because this isn't the same in, in most countries. You know, they might have a biosafety

commission where they're all kind of under one, umbrella. So, we want to, work together with our fellow regulators so people understand our approaches and how we might, sort of achieve some of the same goals, although using a different infrastructure.

Speaker 12 02:00:29 And last but not least, certainly is our multilateral engagement. The Organization for Economic Cooperation and Development is the, the biggest sort of global, multilateral that that really takes on harmonization for, regulation of biotechnology. And we spend quite a bit of time working with that working party. In fact, I have a meeting tomorrow morning at 7:00 AM. So, this is a really great opportunity to talk with countries from all over the world because OECD includes Europe, but also Canada, Australia and Japan. So, you know, major producers and also major importers. And we, you know, often spend a lot of time, Bernadette talked about at the top of this meeting that we spent 19 years. I think Subray spent a lot of that time <laugh>, trying to help get this environmental considerations document, finalized. And one thing that we've learned is that we do get a lot out of these, out of these discussions, even when we don't have major successes like we did last year.

Speaker 12 02:01:36 Just understanding and building that, that common awareness of how other countries might be looking at things. This year we are, we are still actively working with OECD on a number of projects, including some biology documents. And these are the foundational documents that we, we use to, make sure that we're talking, we have the same understanding of the biology of different organisms. This will need to increase the pace of it because as you learn from, from, I think Michael mentioned, and Suma mentioned, the number of new products that we, that we now have that are being produced globally, plants, insects, microbes. So, we need to, we need to keep that, that pressure on and look for resources to, to, to develop these biology documents. And then some other, hopefully we'll make some progress with some other foundational documents that modernize approaches within the countries of the OECD and recognizing that once those, once those products are on the OECD website, other countries are using them, even if they are not currently member countries in the OECD.

Speaker 12 02:02:47 So the, oh, that's the biggest multilateral that we work with that, on our regulations internationally. But there are a couple others I think that are important to point out. The, the trilateral technical working group, that's between the US, Canada, and Mexico. And, this is probably, you know, these are our major trading partners, so it's important for us to be on the same page. Nothing that we do here in the US can, you know, can go forward without, agreement, you know, under understanding with Mexico and Canada. So, it's important that we understand what they're, what they're doing. And so, our goals this year, are to, you know, improve the communication, continue to increase, and our understanding of what they're doing on the technical side, and we have quarterly meetings and, and then one big annual meeting. So, we, we have frequent contact with that group.

Speaker 12 02:03:38 Another, organization, the inter Inter-American, Institute for Cooperation in Agriculture or IICA. They operate through the Western hemisphere, and we know that, you know, countries from Brazil to say, Ecuador, there are really different approaches to biotechnology and different stages where they are. And yet there's a lot of change going on right now. And so, we really want to, to stay in contact with these countries in the IICA. Just a great partner to, to do that with. we had the opportunity to attend an IICA meeting in, late September and really learned a lot and developed some context that we want to build on this year. And then, last but not least of course, is Asia Pacific Economic Cooperation. So, this is a major regional body. The US participates on many levels and, with the understanding that the, that this region is a major agriculture importer. And so, we want to make sure that, you know, that we have, confidence, from those countries in our system, and that any chance that we have to, talk with them that we're building that, awareness and that understanding.

Speaker 12 02:04:50 I just want to finish by saying, that, you know, we, while I, I talked about what we have and understanding that, you know, we have, we have limited resources, for international engagement, and we want to hear from you if you're interested in talking with us. If you're representing a, a, a foreign government, I know there are several, embassy folks online, for example, or from our industry partners, if there's, interest in a country that maybe you don't think that we've been talking to that much, definitely want to hear, hear that. You can contact me directly or, you know, can bring it up during the question and answer session that we're going to have now. So definitely open to feedback on prioritization for the next years. And that's it.

Speaker 1 02:05:43 Thank you so much, Jessica. Now we're moving on to the question and answer portion of the program. If you're in the room and you have a question, you can either walk up to the microphone or you can raise your hand and we will bring you a microphone. Also, for those who are online, please use the WebEx chat feature online. If you have a question you want to enter into the chat, and before you ask your question, please tell us your name and which organization you represent. Also note that if we run out of time and we can't get to all the questions that you have today, we will work to provide answers to those questions, on our website in the coming weeks. So, we, you know, don't want to make anyone feel like their, their question went unaddressed. And with that, who's got a question? First question. All right.

Speaker 13 02:06:51 I certainly do. Hi, Leah Buckman with BIO. Thank you for a great meeting today and thank you for addressing a lot of the points that we had submitted. So, we really appreciate that. Really looking forward, really looking forward to the business process improvements also that you mentioned today. I'm sure that a lot of our members are as well. One of my questions is who, there was a mention of a plant pest risk list. Who are the experts, in the field that you are planning to consult with that list? And will this list be published in draft form for comment ahead of time?

Speaker 1 02:07:25 All right. I think that'll be, Subray will address that question. Rick's got a microphone if you, that would be easier.

Speaker 1 02:07:33 Able to see your, oh, camera.

Speaker 7 02:07:36 Oh, okay.

Speaker 7 02:07:41 Yeah, Leah, that is a difficult question. Anyway, we are, working with, American Phytopathological Society, you know, so many pathologists. Yeah, they really working to develop this one. And it's a cooperative agreement means, you know, we have, we always look at, you know, their product quarterly and it'll be published for public comment when in the draft form. So, you guys have an opportunity to comment on it. Yeah, we are, we are, really happy to have, their, their cooperation on this one because they are the world experts on plant pest.

Speaker 1 02:08:35 Thank you for that question. Evan, do we have any questions online yet?

Speaker 14 02:08:47 The first online question that we have is from Ray Dover, and the question is on exemption AM5, were successive editing previously exempt?

Speaker 1 02:09:01 Alright, why don't you come up, Neil, so they can see you, from the folks online I'll be able to see you.

Speaker 6 02:09:08 So the question was are if successive ex. Could you repeat the

Speaker 15 02:09:17 On AM5 exemption, were successive editing not previously exempt?

Speaker 6 02:09:27 We did not, that's, that's correct. We did not have, a means to address it. We said we would address it through this process and, and now we're, we're addressing it with this exemption.

Speaker 1 02:09:51 All right. Thank you, Neil. All right, who else has got a question? All right, if there's a microphone right behind you, or we can bring you one.

Speaker 16 02:10:02 Hello, Eleni Bickell with Congressional Research Service, do the newly announced exemptions only apply to plants?

Speaker 1 02:10:13 Could you, could you repeat that? Do the newly

Speaker 16 02:10:16 Announced, do the newly announced exemptions, the ones that we talked about today, the exemptions, the five apply only for plants?

Speaker 6 02:10:24 Yes.

Speaker 1 02:10:31 Yes, that's right. They only apply to plants. All right. Oh, Bernadette

Speaker 3 02:10:35 Also point out that they're just proposed, they're not yet in place.

Speaker 1 02:10:38 We cannot use them. Yeah. Yeah, these are just proposed exemptions. We will go through the process of collecting public comments and addressing those before anything is finalized. All right. Another question.

Speaker 17 02:10:53 Thanks Kyle Kunkler with the American Soybean Association. I was curious if you all could talk a little bit more about, and it was helpful getting a breakdown about RSR timeframes. And we know that, you know, just given the, you know, significant quantity of, you know, applications and requests that you all have been receiving, that that's contributed to the significant timeframes. But can, can you all talk about, I mean, it sounded like you have a multi plank plan to try to bring those timeframes down a bit, but can you speak a little bit more about that, about how each of those individual provisions might be helping to bring down those timeframes in the coming year?

Speaker 3 02:11:39 Thanks for your question and, I will invite my team to jump in on any of the aspects that we might miss. So, for the first part, I think what we've worked to do is work together, like types of products, right? I think you're seeing this in the types of releases that, that you're observing as as we're announcing them. The second thing that we're doing is, if we already are familiar with a particular crop type and a trait, and it's very similar, we are going to work that through our system. It's not going to be like a first in, first out, sort of situation. So, we we take into consideration other work that we've done that's highly similar, that might be applicable, with some modification to a new product. The third thing that we're working to do is bring in additional staff to help develop plant reference documents for species that we have are, are less familiar with or haven't previously examined.

Speaker 3 02:12:35 We had some interviews this week. I don't think they went as well as we hoped. but it will continue to be an effort that we do to bring in that staff. You heard a couple of times today that, we have been dedicating staff to particular types of workflows in the past. We really work to provide our teams with the opportunity to work on a variety of different types of projects. This year we, invited them to self-identify what type of work they preferred to do, and we considered that in terms of how we might be able to better align interests, with workflows. And, and we've done that to the extent that we're able to do that. So that's another process, change that we've made. In addition, we've worked to really, now that we've completed almost, I guess now more than 30 of them collectively, we're undertaking an evaluation of the steps of the process that we built out initially.

Speaker 3 02:13:32 And we really are working to, to streamline them and limit, where possible the number of handoffs that we've had early on. We had, I think a, a pretty heavy review on, multiple reviewers from, different aspects for each RSR. And as we've gained more experience and are seeing similar types of things, we're able to have a lighter review touch on certain types of products. The review might be different if a staff member is new to developing or participating in a regulatory status review, but for the most part, we're trying to be specific and not have a one size fit all approach to that. We also think, as Michael noted, that if we're able to move forward with, these proposed exemptions, in some way that it will help kick some of the regulatory status review requests that we have in that bucket out and into the confirmation, process, we see that, we, we knew early on when we proposed our exemptions and and established them under the revised regulations that they were narrow. And we certainly see many types of modifications that could be accomplished through conventional breeding that are now in the regulatory status review process. So, I think that'll be another aspect where we'll hope to make up some time. Those are the, the things that that come to mind for me. Michael, have I missed anything in particular? I, I think that's it. Yep.

Speaker 17 02:15:02 Very helpful. Thank you.

Speaker 1 02:15:09 Alright, we've got a few minutes left for questions. Do we have any more questions coming online?

Speaker 15 02:15:17 Yes, we do. There's a question from Chris Anderson from Biogemma. Is there a template for RSR available on the BRS website?

Speaker 3 02:15:38 There? There isn't a template plate per se, but we do have a regulatory status user guide that's posted on our website. We updated it last December and, and, posted back to our website. So, you should be able to find it there. We can provide a link to that reference document as we post materials to our website to make sure that you have it. After these meetings are concluded, we always post the materials that we shared with you in our presentation form and the handouts that we have in the room and we can make that, regulatory status review link available at that time as well.

Speaker 1 02:16:17 Alright, I see that you've got one. John, go ahead.

Speaker 18 02:16:21 I, Doug, I'm John Cordts. I'm a consultant and I work for, I work for a number of clients, and they have, they have interest in sub submitting permits. And RSRs, you talked about a, a backlog of RSRs Bernadette. Can you, can you give us a ballpark? How many, how many were backed up?

Speaker 3 02:16:45 I think it's less than 50. Is that right Michael? You know the number? Huh?

Speaker 3 02:16:50 What's that? That <Inaudible>

Speaker 3 02:16:51 Pending? Yeah, pending about that. Less than less then. Yeah. -

Speaker 19 02:17:04 Hi. I am Fan-Li from the American Seed Trade Association. Just a question on the proposed exemptions. Once it's finalized and we hope it's going to be finalized, how much, how much work would that reduce from the permitting and the RSR process? Do you see things coming off the off-ramp with those exemptions?

Speaker 3 02:17:25 So we did a, a back of the envelope calculation on this and, and I think, Michael did we say like maybe 15% or so, 15 to 20% would, would come out, assuming that we hadn't already got to them other ways, by that point we also think that there are some, there could be opportunities to, rethink the way folks have developed plants in a way that would allow them to capitalize on the

exemptions if they were finalized. So, there could be additional opportunities is my point. That would be a low end.

Speaker 0 02:18:06 Alright, thank you. Thank you John and Fan-Li for those wonderful questions. Looks like we had another one online.

Speaker 15 02:18:14 Yes. The next question online is, are two or more deletions made at the same genetic locus exempt from the regulations according to the new exemption?

Speaker 6 02:18:29 Yeah. The que the question was, are two or more exempt, two more deletions at the same genetic locus exempt? If they're in this, if they're in the same gene and they contribute to one loss of function, then that would be exempt if, so I, I think the answer to that question is yes. W what, what we are not exempting are, say, gain of function or substitutions that may, may change the function of the protein. You would not be able to make two or more modifications of that time and be that type and be exempt.

Speaker 0 02:19:13 Alright. Other questions from in the room? You're going to have to wait almost a whole other year probably before you get this chance. Again, other questions online?

Speaker 15 02:19:28 Yes, there is. Can someone exp expand, expand on what is meant by finding valuable material after harvest and examples of this non-compliance?

Speaker 1 02:19:45 So I think that question has to do with, you know, something that we might document as non-compliant for persistence in the environment. And, you know, after trials harvested, there are post-harvest field operations that take place. And you know, the key thing for us is to prevent viable material from remaining, excuse me, remaining in the environment that could, sort of pose a risk of persistence or spread. So that's the kind of thing that we're looking for, during inspection and in particular, you know, we want to verify that those post-harvest field operations have been conducted. And you know, we also do inspections sometimes the following year and we check those records again to make sure that we don't have volunteers and, flowering and potentially shedding pollen that that could cause a problem. So that's, that's what we try to look for during our inspections.

Speaker ? 02:20:54 So can you touch on volunteer monitoring?

Speaker 1 02:20:57 Yeah. So, we have, we have, you know, volunteer monitoring requirements for the season following a regulated field trial. And it depends on the crop species in terms of how long that lasts, but they're generally set up in a way that you have to monitor at a particular frequency and for the length of that volunteer monitoring interval that's specified in the supplemental permit conditions. And that's really to ensure that if there is a little bit of viable material like seed that's left in the field after harvest, we know that you can't remove every single grain, from a field after a trial is terminated, but that, that material, that we are making sure to check for and prevent that material from growing and reaching maturity the following year so that we cut down on risks of potential cross-pollination. And I see that we have another question. Just,

Speaker 17 02:21:55 You all have presented, some very helpful, materials today and I'm just curious, I mean, especially given that there's a couple open comment periods right now that some of these materials could really help assist with, are you all planning on making these available publicly anytime in the near future?

Speaker 1 02:22:11 You mean the slides?

Speaker 17 02:22:12, The slide decks and everything like that? Yes.

Speaker 02:22:13 Okay. They, they will be made available. I don't know what the timeline is for that, but also, is this being recorded? I don't remember if this is being recorded. Yeah, yeah. So, the stakeholders meeting is recorded, and the slides will be available. It'll take us a little while to get those processed and kind of up on the website, but yep, we will do that. All right. Well, I'm going to, hand it over for our closeout or final remarks and adjournment. Thank you everyone from being here today. And also, you know, if there are additional questions like I mentioned, you can feel free to submit those and we'll make sure to get those, those, responses in the coming weeks. And we'll, one, once again, BRS' deputy administrator, Bernadette Juarez.

Speaker 3 02:23:08 Thanks, Doug. Thanks. You've done a great job keeping us on schedule and, and seeing this event for us, so I appreciate your help there. I also want to give a big shout out to the IT staff who has helped carry this out. It's very difficult as many of you know, having a seamless hybrid work environment and they've achieved it today. So, thank you. Thank you for your effort and your contributions. I also want to thank all of my team in the room who have both supported this event and literally helped run it. So, I appreciate all of the work that you've done before today and today, and I thank all of you in the audience for having an interest in our program and sticking it out throughout this agenda. We've delivered it I think, on time and so I won't keep you any longer. We hope you found this helpful and insightful, and we appreciate your attendance. Thanks.