UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL & PLANT HEALTH INSPECTION SERVICE

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OKLAHOMA CITY MEMORIAL CONFERENCE CENTER

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BIOTECHNOLOGY REGULATORY SERVICES
STAKEHOLDER MEETING

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Wednesday
November 16, 2016

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The Stakeholder's Meeting met in the Conference Room at 4700 River Rd., Riverdale Park, Maryland, at 9:03 a.m., Dick George, BRS Communications Group Chief, presiding.

PRESENT

DICK GEORGE, BRS Communications Group Chief
MIKE FIRKO
IBRAHIM SHAQIR
ANDREA HUBERTY
CHRISTIE BERTONE
JOHN TURNER
ALAN PEARSON
SUBRAY HEGDE

ALSO PRESENT
COLLEEN WOOD, Communications Specialist
RICHARD S. COKER, Communications Specialist Robin Wilcox, Communication Specialist
ERIC FORD

C-O-N-T-E-N-T-S

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

9:03 a.m.

MR. GEORGE: Good morning. If we could get started, if you could take your seats please.

Okay, if you could please take your seats. Thank you.

Good morning, everybody. I'm Dick George, Communications Group Chief here, Biotechnology Regulatory Services. I'm glad to welcome you to our 2016 Stakeholder's Meeting, our annual opportunity to share information, receive feedback and answer questions.

First a couple housekeeping details; please set your cell phones to vibrate or turn them off, please. We have coffee and water on the table in the back of the room. Down the hall, out this door, down past the elevators, on the first left is the cafeteria, if you'd like to have something else to eat or drink.

You should have received an agenda, plus a list of local lunch spots when you

registered this morning. Today we have both a morning and an afternoon session. The morning session will end around 11:30 and we will allow 90 minutes for lunch to allow plenty of time for you to get out to lunch if you choose and back in time for the afternoon session on Weed Risk Assessments which will start in the morning.

As usual we are broadcasting our meeting, so we must remember that we have a sizable contingent who are not visible, but nevertheless very much in attendance. I would ask all attendees that are here today to wait until we get a microphone to you before you make a comment or ask a question so that our webinar audience can hear. And I would ask everyone to please identify yourself and your organization if you represent one before you speak, whether you're here in person or via the web.

We have a court reporter here today, his name is Davis Poore, he's over here, who will produce a complete transcript of this meeting. That transcript will be posted to our website

within a few weeks. That's why we need you to please identify yourself and spell your name, especially if it's anything unusual so that our transcript will have it right. In addition, today's presentations will be available on our website within the next day or two. I'm sure most of you probably have that bookmarked, but if you don't, the easiest way to get to our website is to just google Biotechnology Regulatory Services.

We ask that you please hold your questions until each speaker has completed their presentation. We've allowed time for questions at the end of each. Then as I mentioned, for those in the room please wait for a microphone before you speak.

Those of you on line, on your telephone keypad press 1 and then 0. This will alert our moderator that you'd like to speak and we will unmute you and invite you to ask your question. So, again, for online attendees to ask a question, press 1 then 0 on your telephone

keypad.

You can also ask a question or make a comment via the web, if you prefer. On your screen type your comment or question in the comment box and hit Enter. We have someone monitoring this and they'll get your question or comment to us.

One last thing, after the meeting you will receive an email survey. Please take a few minutes to fill it out, we welcome your input.

So, let's get started at this time to take a look at the year just passed and the year to come. I'd like to introduce the APHIS Deputy Administrator for BRS, Mike Firko.

MR. FIRKO: Thank you, everyone for meeting us here in Riverdale or remotely. This is the biggest crowd as I recall for the last several years. So that's good. This has been a really exciting year for us. I think that many of you will be interested in some of the dates that were moved.

So, I'll start with some activities

from the past year, many of these a year ago I talked about how they were coming. I'll give you an update on how they went over the past year or so.

Here we go. So, last year, you may recall, I had a lot to say about the fact that we were involved in upping our regulations. The great news for us is that those regulations are currently at the Office of Management and Budget, subject to interagency review. While a proposed rule is at OMB for interdepartmental review, Executive Order 12866 is in force, which means I'll be talking about that today. It is our expectation that the proposed rule will be published before the end of the calendar year; I show January 20th, because when a new administration comes in, a lot of stuff is put on hold for a while. There is strong support within the current administration to publishing the proposed rules, so I'm certainly looking forward to that.

Now, everybody in here is very

familiar with the technical word 12866, right?

Okay, a few aren't, you know. But what that means is during this period of time when the proposed rule is at OMB for interagency, interdepartmental review. Stakeholders can set meetings with the Office of Management and Budget and provide input to them on any topic related to the biotech regulations at USDA. I know that a few folks who are in the audience today have taken advantage of that possibility and we have more coming up this coming Monday. Those have been very interesting and useful, and I hope if you're interested that you take advantage of that. Because this is another chance for us to get input before the proposed rule is published.

Now, one of the reasons why 12866, which was assigned during the Clinton administration, the Bill Clinton administration, one of the things it does is it leads -- the gain is too high.

PARTICIPANT: He's on his way.

MR. FIRKO: Okay. To revisions to the

proposed rule, so we have gotten a variety of input from interagency partners and we're modifying proposed rule as we go during this process. So, it would be difficult to say here's exactly what it's going to look like when we don't really know that.

Okay, I'm going to talk briefly about each of the four primary operational activities; the first one is a process we call Am I Regulated?, our regulations are pretty clear about what sorts of genetically engineered organisms are subject to 7 CFR Part 340. Nevertheless, for a variety of reasons people may contact us and say, okay, I made this and this is how I made it. Is this a regulated article under the current regs?

Secondly, we get a lot of applications for permits and we get a variety of different notifications for importation, interstate movement or field release. Notification are essentially pertinent because even though it's called a notification it can't really take place

until the notification has been acknowledged by APHIS.

The third is Compliance Review and Actions and it involves monitoring permits and notifications that are in place, doing inspections of those and the course of actions based on violations. So I have some slides on each of these. First of all, Am I Regulated?, that's shorthand for the technical term which is does my genetically engineered organism meet the definition of a regulated article.

I recorded last year that we had done 13, we had completed 13 in Fiscal Year '15, and once we give an answer to the requester, we post both the incoming request and our outgoing answer on the web. On our web page we have a variety of cards here that have that URL on the back of the cards. In Fiscal Year '16 we also did 13, both these numbers are up. Sid Abel did some good improvements on that process and will be doing some additional improvements over the next year. And we currently have eight under review, so we

have fewer in-house than we do here. Some of these have taken a long time, because it may seem like some things, you say to me this is the definition of a regulated article, but many of these turn out to be pretty important policy decisions that we have to make.

Many of them test the very edges of the regulations, they test the interpretations of the regulations. Many of them create challenges regarding our statutory authority, so these are pretty easy to answer, some of them actually take a while. One of these eight is actually older than a year. One of the things I have to do as an APHIS Deputy Administrator, when I get one of these requests there are a couple things I have to consider. One is simple answer, the simple question that was asked, is this a regulated article under 340, but sometimes the implications involved bring other APHIS regulations to bear. So those considerations have to be made too. And you may have noticed in the past sometimes we've given a quick answer versus, regarding 340, but

then said well, we have to look at this other data and let you know about that later.

So, regarding authorizations, this is pretty busy, but just to show you the data about notifications that we receive, how many did we receive and how many were authorized for import only. During Fiscal 16 we received 122 requests for import of regulated articles, 114 of those were authorized. For interstate movement only, 397 received, 339 authorized and for released, 358 and 328. Now, many of you realize that we have a category of authorization that is interstate movement and release. Altogether, I put those under this category of release.

So, if you compare what is the total number that we received, 877 and how many were authorized, 781, that means 89 percent of what we received were authorized. The difference there is the primary reasons for the difference are, one, they sometimes they are wrong, two, sometimes they are not. So, for permits the numbers are smaller. We require permits for all

smaller number of things. Here you see the difference between the total that we received from the 350 is 419 and the total that we have for authorized, a percentage of 76 percent there. The difference there is primarily a greater proportion of withdrawals as opposed to be not.

Can you forward that?

There we go.

If you added the number of release authorizations under notification to the number under permit, the number is 488. This is, again, to show you how that was kind of a deceptive number, because within those 488 release authorizations were over 5,300 different release sites. What that means is that our great staff of biotechnologists, regulatory specialists who have to do checks on proximity to endangered species, you need to do a lot of National Environmental Policy Act work for each of those. So, that's a busy group. And for those 488 authorizations it involved over 50,000 different genetic constructs, each of those being analyzed

separately.

Another type of authorization that I don't think I talked about in previous years, something known as courtesy permits, which is in our current regulation. We issued these courtesy permits to facilitate report of actions that are not actually dubbed regulations. Now, why would we do that? These have been in place for decades, and often someone will present a recorded entry, either they hand-carried something, or the package will show up at a mail location, and Customs and Border Protection will look at this and say, uh-oh, this isn't supposed to come in. But if we have reviewed the request and issued a courtesy permit, then Customs and Border Protection folks at the border say okay, USDA's looked at this, they know what it is, even though it's not a regulated article we're not going to hold it up, because the federal government has reviewed this and understands it's safe.

Again, not a trivial effort on our

part, in fiscal 16 we issued 667 of these. And the folks who are engaged in this activity, so they had 667 permit situations; 665 of these were for genetically engineered Drosophila primarily for the purposes of medical research. The reason that this is a courtesy permit for genetically engineered Drosophila is, Drosophila melanogaster, which is what these really are, are not pests. That's why I say courtesy permit as opposed to a regular permit. One of them was hand carried, a small amount of genetically engineered corn flour for the purposes of research, as a courtesy permit because the material was not viable. And the other one was for about a pound of processed lettuce leaves for research, also not viable. But Customs and Border Protection will see on the manifest genetically engineered lettuce and they might say, oh, wait a minute. Where's your permit for this? So, courtesy permit in a civil case needs more attention.

Now, I spent a fair bit of time last

year talking about our intent to require permits as opposed to notifications for field trials of genetically engineered wheat. During Fiscal 16 we received a grand total of 14 requests. The regulations give us 120 days to process a request for field trials of genetically engineered organisms, 120 days. Our average time for issuance of those 14 was 50 days. Now, this was part of a commitment I had made to the wheat industry, before we implemented this change I talked to them, went to Lake Tahoe and met with them and they were very concerned about the fact that whereas notifications don't take that long, permits take a lot longer, so I said we would do what we could to do them in 60 days, commitment of 60 days, and I'd say that that's cruising along very nicely.

Compliance issues, so it's been a good year for bringing on new talented staff in Biotechnology Regulatory Services. We have added last year four, five, six new regulatory analysts. As part of their duties they actually

conduct field inspections, they also spend most of the time actually analyzing the results of field inspections, working on policy issues for BRS, working on a system to select sites for inspections, so they're engaging in an awful lot of activity.

We now have staff in eight states, plus Puerto Rico, soon-to-be nine states plus Puerto Rico. We will be going to California for the first time. In 2016 BRS, the unit under my control, conducted 60 percent of the inspections. Now, why was that of interest to me to do, instead of 2 or 3 percent of the inspected year, more like 60? Well one of the basic tenets of business process improvement, is minimize the hand-offs that occur. So, if we have folks on our own staff who do nothing all day long but work on biotech issues, who all day long are understanding the regulations and current policies of the biotechnology program, there's many fewer hand-offs, there's fewer whisper down the lane possibilities, and we have found this to

be a much more efficient and improved way to conduct the inspections, to do them ourselves.

Now, one side of this is that over the years we see there that in 16, 30 percent are conducted by our sister program in APHIS called Plant Protection and Quarantine. When Plant Protection and Quarantine program conducted biotech inspections, that was funded by a line item by Congress called pest detection. So the extent to which biotech inspection were getting done by a line item, pest detection per se wasn't getting done by EDU. So, we happen to have extra money around at BRS, so we now use that money to hire people to conduct inspections and analyze the results of those inspections, and it has freed up some of APHIS' allocation dollars to do pest detection for pests that are introduced into the U.S. or pests that are being monitored in the U.S. I hate giving money back at the end of the year, so I want this.

The proportion of inspections conducted by our state departments has stayed

relatively steady over the last decade or so. We meet with these folks, we provide training, it's a very good working relationship we have through the National Plant Board. Petitions for non-regulated status in Fiscal 16, we completed seven in Fiscal 16. Since my performance plan set five, this was pretty good. We now have 125 deregulations that we've done so far. The 125th was done in last month or so, so it was between the end of Fiscal 16 and today. You may recall, because I've spoken about it over the last many years, that our first official process improvement was on the petition process; at the time we implemented that in March of 2012 we had 23 petitions in-house; of those 23 only one remains. That's a petition for a freeze-tolerant eucalyptus, we're doing an Environmental Impact Statement for that, and I'll have a few more words to say about that in a minute.

We also spoke last year about our improved extension process; that's a process that we use when someone submits a petition to us and

it's essentially identical to something that we received in the past and made a decision on in the past. So, we should and do have an expedited process for that since we don't really need to redo everything we did. I'm very pleased to see that folks have been submitting for extension requests as opposed to regular petition requests, because that's less work for us, which means the taxpayers save money and it's less work for the petitioner, and it gets done quicker.

Our turnaround times on these extensions is six, seven months, something like that, we did target about eight months, but we're actually getting them done a little bit quicker. So that's been good for everyone and we save money for the taxpayers.

Other BRS activities; we have a lot of intergovernmental engagements, and I use that word carefully here, I'm talking about other U.S. government agencies. Primarily we work very closely with our Coordinated Framework partners, the Executive Office of the President, primarily

the Office of Science and Technology Policy, U.S. Trade Representative's Office, several others, EPA and FDA. There's a group within USDA called the BCG, the USDA Biotechnology Coordinating Group, and that is a group of representatives from, it ranges month to month from about eight to maybe 12 different USDA agencies who have some level of interest in biotechnology, not just APHIS' program, but activities that they may be involved in. Andie Huberty who you'll hear from a little bit later with the Ag Marketing Services will be engaged in those, the chair of BCD Mike Chetman, who's right here. Michael works out of the secretary's office.

We actually meet every first and third Wednesday of the month, so we meet twice a month. We hear from all of the different agencies around USDA and biotech activities that they're engaged in. Needless to say, we typically have it out here at APHIS, but it's good to hear from all the different programs as well.

And there are a number of IPCs,

Interagency Policy Committees that are run out of one of the groups at the White House. There are two or three or four of them now and we're involved in those. Then, of course, international engagements, and this is different from what some of you may be aware of that our sister programs like Plant Protection and Quarantine and Veterinary Services engage with. Those two programs often engage with foreign countries about movement of particular commodities being exported from the U.S. or being imported from the U.S.

The types of engagements that we do in BRS is a little different because we're not doing commodity; we're particularly talking about biotech regulatory activities in our country and the foreign country. We get every year here in Riverdale representatives from about 20 countries who are particularly interested in coming in and spending some time with us to see what our regulatory program looks like. I am honored that so many countries want to see how we are doing it

and consider it as a model for a program that they are tweaking or building from scratch.

So, looking forward to '17, which we've already started actually, continual improvement of permit conditions. Now, we met with various stakeholders over the last decade or so and we've heard from stakeholders about reception, some inconsistencies and there were some inconsistencies, between previous version of biotechnology quality management system. Permit conditions, let's just say that from an internal business process improvement point of view, we weren't communicating internally as well as we should have, perhaps. We have been working very hard over the last two or three years and in fact Angie and John are leading those efforts to make sure that all the permit conditions that we put on a permit are clear, consistent and enforceable.

Now, that's what's interesting about what we found a few times is that you, if you write a permit condition so vague that you can't

do anything about it if there's what appears to be a violation, nobody's in a good place. So we're working very hard to ensure clarity, consistency and enforceability about the permit, and it's been our practice for, again, at least a decade, I think, that as we are crafting a permit, someone has asked us, I want to do this or that or whatever, as we are creating permit conditions associated with that permit, we communicate directly with the requester. We put together a set of permit conditions, we send them to the requestor, they have to review them, we expect them to initial each permit condition, be sure they've read it, and then hopefully we can reach a situation where we agree that the permit conditions meet our needs completely and the permit requester is able to meet the requirements.

We certainly wouldn't want to have a permit requirement that makes it impossible for someone to do their work. But both of our needs have to get met; we have to make sure that we're

protecting American agriculture, and it's got to be something that the permit requestor can get through. So we actually spend a lot of time making sure that everyone's needs are met on the permit conditions.

We continue to improve our inspection process. We have a new inspection selection process that is more risk-based. I think I've spoken for the last two years perhaps about how the USDA Office of the Inspector General reviewed our process and had several suggestions about how we can improve our process, so we've been working very hard to do a better job with that. We're still doing a signature business process improvement on reports that come out of field trials. So, we continue to improve those processes. And Christie Bertone will be talking a little bit later, who is Branch Chief for Raleigh in one of the compliance branches.

And, again here consistency, we want to be as consistent as possible. I mentioned the risk-based. And we want to -- part of our

business process improvement is to make sure that when we see similar challenges and different field trials, that we respond to them the same way, we want to be consistent with how we respond. We are not done building our staff for risk assessment and regulatory oversight, now the risk assessment piece is different. I haven't talked about that yet today but in the past year, we hired seven new biotechnologists.

So if you haven't met any of our new biotechnologists, this is six of the eight. Please take an opportunity to talk with them on the phone, to go ahead and say hello to them. Thank you.

You may also notice if you're watching USA Jobs, you may have noticed that we just announced that we're hiring multiple ecologists, we got the certificate of eligible candidates last week, so we hope to bring those on very soon, this calendar year. In addition to pure biotechnology, it's ecology expertise.

We will continue to increase the

proportion of biotech specialists hired by BRS. Again, this isn't because we didn't like the way they were being done or anything like that, but we want to be as efficient as possible, have as few hand-offs as possible between actual conduct of the inspection and analysis of the results, and decision-making about the results, and more efficient use of the allocated dollars that APHIS receives for its many functions including biotech regulation, so we're adjusting how those dollars are used. And we will continue the recent practice of conducting unannounced inspections. As you might imagine, this leads to some surprises, for everyone, but I believe it's a reasonable and appropriate part of the regulatory program.

Although I'm not really talking about it today, we are working very hard to move our proposed rule to publication. I am hopeful; like I said, that it will be published as a proposed rule in the next several weeks. Our current regulations are three decades old, and you know,

that's nominated by science through decades and age. And we'll continue to improve APHIS risk assessment systems for plant pests and noxious weeds.

Now, our current regulations have no authority for noxious weeds, but APHIS does have a regulatory authority for noxious weeds, so APHIS has been dealing with noxious weed risk assessment for decades, and we work closely with our colleagues in Plant Protection and Quarantine on weeds risk issues. And as you know, in our petition for non-regulated status and in our regulations, the consideration of weeds is in there. It's listed in the regs, and it's something we do in our risk assessments. So we want to get better at that and anybody who's staying for our Ag Review session will see where we are right now regarding our risk assessment system.

We currently have three petitions for non-regulated status; as I mentioned in 2012 we had 23 in-house, now we have three. They are two

regulated petitions freeze-tolerant eucalyptus, which I mentioned. APHIS completed an Endangered Species Act biological assessments and biological evaluation, we reached a may affect, so we consulted with Fish and Wildlife Service and all those documents are over at Fish and Wildlife Service now and we're working with them to try to reach a resolution. We hope to be publishing the draft environmental impact statement probably during 2017, but some of you may recall I said that last year as well.

We have glyphosate resistant creeping bentgrass in-house now, we are also conducting an environmental impact statement on that. Now, our business process improvement, we set guidelines for ourselves that four petitions that require an EA, which is a relevant to us environmental impact, our target was 13 months for one style and 18 months for the other. Even though we're conducting an EIS on this, we expect to finish this in 15 months, due in part to the fact that we had done an awful lot of work over the last 14

years on this particular glyphosate resistant creeping bentgrass, so we weren't starting from scratch. We published the draft EIS September 30th, we have a 45 day comment period, it ended this past Monday we got, I don't know how many comments we got, or does anybody know? 15. So, we're evaluating 15 comments that we've received.

The third petition that we had in-house is actually an extension request, details that will be provided in a Federal Register Notice, soon.

So great, that's it. A few minutes for questions.

MR. GEORGE: Questions for Mike?

MR. FIRKO: Greg.

MR. GEORGE: Wait for the mic, please.

MR. DONAHUE: Greg Donahue here from Titan. Mike, you mentioned you're doing a lot in inspections and unannounced inspections, but you didn't mention the results of those inspections. Can you tell us what the percentage of violations you found, what kinds of violations, were there

any major violations, what are the results of the inspections both done by your staff and also done by the other staff?

MR. FIRKO: Yes, I don't have slides on that here. There is a very high compliance rate that's tracked by the Secretary's Office, the compliance rate has always been over 90 percent. We do sometimes find things on inspections that get hard. A violation does not always mean a civil fine or something like that; sometimes correction is our major interest to make sure that the problem is corrected. We like to work with the authorized person to make sure the problem is corrected. There are fines that are issued; in '16 I don't think any fines were issued for any problem.

The unannounced inspections do reveal things, but I should clarify this: we're sticklers. When our folks go out, regardless of whether they're in BRS or PBQ or the state, we're taking on hard work. We're comparing what's seen during the inspection with what the regulations

say and what the permit conditions say, or in the case of the notification what the protocols say. The vast majority of problems that we encounter are paperwork problems or court problems, things like that. There is a rare situation where let's say there are volunteers growing somewhere where they shouldn't grow, like a situation we had in Montana and the results of that investigation are on our web pages. I don't know if you've seen those yet. That basically, there was a violation of the Plant Protection Act that was found in that case and warning letters were sent. Those are GEB, so we're addressing GEBs in writing, generally.

MR. DONAHUE: Just to follow up, I guess part of my question was, in 2016, did you find any inspections that would require remediation, so for example, in other words, I understand some things involve a paperwork violation and technical violations of a permit, but ones where I don't want to say there was an environmental impact, but where there was either

an escape or something that require a physical act to be done to remove something from the environmental that impacts it?

MR. FIRKO: Thank you for asking it that way. I should have mentioned that any of the situations that we are aware of that are not as they should be are self-reports, somebody calls us and says I have some volunteers over here and my permit ended two years ago, they're not supposed to be here, we did have one of those. We did not discover it as a result of an inspection; it was a self-report, a farmer contacted us and there's some information on our web about this, this was some genetically engineered wheat that was found in Washington state. 22 volunteers, and after scouring that 400 acre field we found 22 total, and all of the, we found that it wasn't the crop, all that farmer's crop was tested and nothing was found. So, those sorts. Is that what you mean by remediation?

MR. DONAHUE: Right, but my question

is whether you found any of those in your inspections, either in your unannounced or your regular inspections that you did. I understand how when it's self-reported by somebody else who wasn't even doing it, but that wasn't a current field trial. So my question is you say you did a number of inspections, some of those were announced and some of them were unannounced. I understand there were multiple of them compliance, there was some non-compliance, most of which was paperwork violations or other things, I'm asking but are any of those violations that you guys found on your inspection work resulted in any need to ask somebody to do something to correct something that actually has an environmental impact of some sort?

MR. FIRKO: Yes, sure. If we do an inspection and we find volunteers where they're not supposed to be, we stay there until that problem is taken care of, we do follow-up inspections to make sure nothing that escaped the environment of the authorized area.

MR. DONAHUE: Okay, thanks.

MR. GEORGE: Dan?

MR. JENKINS: Hi, I'm Dan Jenkins, Genus PLC. My question is, you guys are really pushing a new way in terms of taking a risk-based approach. You also mention the coordination framework and some of those interagency meetings. How's the coordination going in terms of you guys taking a risk-based approach and interagencies approaching new technology?

MR. FIRKO: We're doing our best to lead global efforts at a risk-based rational approach in dealing with genetically engineered plants. We meet regularly, with FDA and EPA. Some of the stuff that we are doing, we're shaking things up a little bit, might make life a little bit difficult but this is moving forward, change is hard. The Coordinated Framework reviews are very active and I think that in a few years, we'll all be in a better place.

PARTICIPANT: Is that the January 20th deadline as well?

MR. FIRKO: Kirsten's not here. John, did you -- there's definitely a decider finishing the project this calendar year. I don't know any guesstimates right now, comment period has closed, I think there's over 45 comments I've overseen. This is led by the Office of Science and Technology Policy. I do believe that will be wrapped up this calendar year, or the time will change, makes things so exciting.

PARTICIPANT: Thank you.

PARTICIPANT: A question over here.

MR. GEORGE: I'll mention while Mike's making his way over to our questioner, on the web if you have a question press 1 then 0 on your telephone keypad, and we'll unmute your mic, then you'll have a chance to ask your question.

Go ahead.

MR. WEEKS: Thank you, Michael Weeks with Dire. I was curious that the courtesy permits for the most part were for Drosophila or otherwise non-viable; as increasingly you see things moving through the environmental

regulatory process, do you foresee courtesy permits being a method to smooth importation of regulated articles, organisms that don't meet the definition of regulated article in the United States?

MR. FIRKO: So, thank you for asking that question, too, because it reminds me to talk about something else, moving away from courtesy permits. That's because you may recall last year at the stakeholder meeting we invited folks to meet up in my office or in one of the conference rooms here, and one of the people I met with was Kevin Cook, and he's sort of the lead purveyor of managing the movement. He said, please, please, please can you stop applying for courtesy permits. So for the past year --- it's a lot of work, for the past year we've been working with Plant Protection and Quarantine's official liaison to Customs and Border Protection, and we've been working with Customs and Border Protection on a more expedited process to facilitate the importation of items that are not

really regulated. We are in the process of moving towards what's called a letter of no permit needed, but what we --- you know, this is the government, this is bureaucracy, and before we have folks bringing in hand carried Drosophila or sending in a shipment of Drosophila with a letter of no jurisdiction we need to make sure that that will be accepted at the port of entry. We are always happy to entertain requests from people who are importing something that they're concerned might get stopped at port of entry. And either we at BRS or Plant Protection and Quarantine or Veterinary Services depending on what the product is, will work with Customs and Border Protection to make sure that we have the right documents in place to facilitate movement at the border. If it's not a regulated article, we don't want to be heavily involved, but if it helps somebody, we're willing to try.

MR. GEORGE: Other questions for Mike? Any? No?

MR. FIRKO: Thank you.

MR. GEORGE: Okay, in that case we'll move on. For about ten years or so APHIS has been using a system called ePermits for a lot of the work we do. We're now in the process of moving to a new platform which we call eFile. Our next speaker will update us on that process. He's a newcomer to BRS who just started in August, coming to us from USDA's Agricultural Research Service where he was Director of the Office of International Programs. I'm glad to introduce our new BRS Associate Deputy Administrator, Ibrahim Shaqir.

MR. SHAQIR: Thank you. So, thank you very much, and I'm excited to be here. I just want to point out it's been almost three months on the job, but I didn't know it was part of the orientation that I have to sit on a table by myself in the middle of the room. So I guess that's to examine or determine if I came up to the job or not, right?

Anyway, I spent a lot of time with ARS dealing with the research aspect of agriculture.

I'm here dealing and working with Mike at APHIS and great team in BRS on exciting technologies and dealing on addressing the important issues of biotechnologies. So, I look forward to working with all of you.

Basically, you received some information and updates last year, probably the prior year as well, on this system that we're trying to put together to improve our efficiency and productivity when it comes to ePermits. So, as Dick mentioned, ten years of something that is in place requires some updates. As technology is evolving and as a government we have to also evolve and improve our systems in place.

So, we have a complex system here at APHIS; it's a huge and widely varying mission. Our regulatory activities covers animal health, plant health, animal care and of course the Biotechnology Regulatory Services. So, as part of this mission, each year we issue more than 900,000 certificates, accreditation, registration, permits and other licensing. That

stands for basically what we -- much of that is dealt with and issued through the existing system in place that we hope to upgrade using eFile, which where these four program areas would be impacted, animal care, Biotechnology Regulatory Services, Plant Protection and Quarantine, and Veterinary Services.

So, it's quite an undertaking and we have been working hard to get this right and get it in a way that is going to be working. So, this is an integrated -- it brings all these programs together with great varying priorities and areas of specific needs for these programs when it comes to VS, Veterinary Services, PBQ and BRS and animal care. So, there's a lot of communication, a lot of things that, an infrastructure that has to be responsive to much of these needs.

So, as of now I think we have about five technology systems and processes that are widely division and labor intensive, so we hope that eFile system will bring together this in one

unified, integrated system that's efficient and also cost-efficient.

So eFile, it's a complex process of authorization, movement or approval to do business for all APHIS regulated articles. So, these authorizations ensure the safe movement of regulated agricultural articles into and out of, and through the U.S. and are issued by four operational program units within APHIS, which are the programs that I just mentioned.

So, that interface, it's similar to what we have right now, but ultimately this is what you're going to see, and you will access eFile system through our web page and I'm sharing the animal care website because they're the program that's about to be deployed and will go live shortly.

So, nonetheless, IT systems are pretty unpredictable and so we have to do our due diligence to ensure that we have a system in place that's working and operational. We have been testing and we will continue to test and

work with the developers to ensure that many of these challenges and issues that impede the system can be responsive and active with no issues in place.

So, it's been a great opportunity, but also a challenge for us, and we hope to overcome that pretty soon. So, we truly believe that better, to get it right than get it fast, so we're working hard on that.

We still need you; we mentioned last year that as soon as we identify and address all the internal issues, we will reach out to you and I believe you did provide us with your contacts and interests, your expressed interests as well that you'll be helping us in the process moving forward when testing this system.

So, we value and will provide you with the mechanism to do so as soon as possible. So, please be patient; as you have heard, this is a huge initiative and system within APHIS. When we get a better handle on this, we'll provide you the timeframes when you can be of great help to

us.

Thank you and I'll be happy to answer any questions.

Okay.

MR. GEORGE: Any questions?

Hold on one second.

MR. MONDELL: Scott Mondell here. One, I want to say thank you for your continued willingness to reach out to the regulated community and bring us into the loop whenever you're ready.

Thinking about how APHIS is planning to modify the regulations and there's a process moving forward on that, and the software, and the way -- forward-looking statements here, right? So, the way the system currently works and the way it would work in a future state of regulations, is there any thought being put into creating a system that is transitional from one world to the other?

MR. SHAQIR: Well, here's good news; we have a system that's currently working, but as

I mentioned, it's costly, it's working and we're changing that, we're moving and transitioning into this eFile system because of the amount, the level of maintenance and care for the existing system. We will continue to use this system and we will make sure as we transition to the new system, we will have close to as perfect as possible a system in place where we can use, and that's what I can say about that. But your work will not be interrupted; you will continue to submit permits and communicate with us directly, but we will work with you, and your help initially as we extend and ask for your help for the external use kind of face of eFile. You will tell us what's going on and we will ensure that we are addressing all of these challenges in advance.

MR. MONDELL: Thank you.

MR. SHAQIR: Thank you.

MR. GEORGE: Other questions? No? Thank you, Ibrahim.

MR. SHAQIR: Thank you.

MR. GEORGE: As we all know, there's been an ongoing debate for years regarding the labeling of food that is made with genetically engineered ingredients; that debate led to the National and Bioengineered Food Standard Law of 2016 which charges the Agricultural Marketing Service of USDA to develop and implement regulations and policy along these lines. AMS as it's known is totally separate and distinct from BRS, but since there's so much interest in GE labeling, we've invited the AMS person leading this effort to give you and us an update. You may recognize her if you've been coming to these meetings for a while; we're proud to claim Andie Huberty as a BRS alumna and we're delighted she's here to fill us in on the progress of this high visibility initiative.

MS. HUBERTY: Hi. Thanks Dick, that was a nice introduction. Good morning, everyone.

So, yes, on July 29th of this year President Obama signed into law the National Bioengineered Food Disclosure Standard, and then

I was hired to do this on August 7th, and that's what I've been focusing on. My role is to develop policy and implementation regulations for this law.

What I'm going to do in this presentation is I'm going to walk through essentially big picture, the law, go through each of these nine different sections of the law. This will probably be pretty boring because I'm going to essentially just read everything that's going on right here, because we are starting our rule-making process. And I'll talk a little bit about our next steps, but I'm just going to walk through what the law states for each of these sections and then talk about where we go from here.

First, I would like to start with, so where is Agricultural Marketing Service? We are within USDA in the same organization as APHIS, so we're in the marketing and regulatory program, but why put this disclosure program, setting up this disclosure program in Agricultural Marketing

Service? USDA's been very clear that the National Disclosure Standard is not a food safety issue, but it is essentially marketing disclosure, so that's why this law the Secretary has delegated this authority to Agricultural Marketing Service to put this into place. We look at this as we're informing consumers about choices for their food, and again, it is not a food safety issue.

So, definition of bioengineered food; so these first couple of slides will talk essentially about what is eligible, essentially, to be disclosed as bioengineered food. So, first is any food for human consumption that contains genetic material that has been modified through RDNA techniques or genetic engineering techniques, for which the modification cannot otherwise be obtained through conventional breeding or found in nature. Additionally, the law gives the Secretary the authority to essentially set the amount of how much the bioengineered ingredient would result in a food

being disclosed as bioengineered. So, this first definition gives an example of the wide range of issues that Congress raised during the development of this law and has put AMS in the position of essentially deciding a lot of the specifics for the rule.

For example, in this case, the food for human consumption will essentially elaborate on rule-making things like what is conventional breeding, what does it mean to be found in nature, what's the threshold going to be, those are all things that we'll be developing as we go through rule-making. Additionally, things that are food that is derived from an animal that has consumed GMO feed does not need to be disclosed as bioengineered. So, solely because an animal has fed on GMO feed, so meat, poultry and egg products from these animals are not subject to the labeling requirements for this law.

One of the big issues for this law was the preemption of state food labeling standards, and we'll talk a little bit about this, but what

this means is that no state or political subdivision can put into place, or things that are already in place were rescinded that talks to a disclosure standard or a labeling standard that relates to genetic engineering or bioengineered ingredients. States, however, are welcome to adopt the federal law identically into their state law, but they are not --- this law preempts their ability to put in any other types of disclosure related to genetically engineered or bioengineered food.

Again, one of the results of the law and one of the reasons that USDA supported it is to create a single disclosure standard for bioengineered food. At the time Vermont had their law in place, as well as other states were considering, so instead of them having a patchwork of disclosure laws, the national standard allows a mandatory, single standard for bioengineered food. So, the Vermont law had requirements for on-text packaging which is this, partially produced with genetic engineering, that

was language of the law.

One of the other issues with the law was that it came up with, it resulted in some foods being disclosed and other foods not. For example, under the Vermont law cheese pizza would be labeled as genetically engineered, partially produced with genetic engineering, likely due to soybean oil or other corn oil that's used in the dough. However, a pepperoni pizza would not have been labeled under the Vermont law because meat is one of the ingredients. So, any meat product, any multi-ingredient product with meat in it would not have required labeling under the Vermont law. So, under the National Disclosure Standard a meat pizza, with some caveats that I'll explain later, is eligible for disclosure.

Within the law itself it requires USDA, AMS to enact this National Bioengineered Food Disclosure Standard no later than two years after enactment. I'll go a little bit into the process of that, but as many of you know, two years to get regulations in place is pretty

speedy, so we have everything in line to get that done within two years.

The law actually also allows for choice of disclosure, so food manufacturers have one of three choices with some additional choices for small food manufacturers. Food manufacturers can put on-package text similar to how they did it in Vermont; a symbol, a USDA developed symbol or an electronic or digital link such as a QR code or Smart Label.

So, those are the three choices and food manufacturers get to make the choice of how they're going to disclose bioengineered food. These are some examples, so you have the QR code, on-package text on the Lays and the symbol with the T that's the Brazilian symbol for GMO food. We will not have a symbol like that, so one of the requirements in the law is that nothing that, either the text that we use or the symbol that we create, cannot be disparaging toward the technology, and I'll talk a little bit about that in the end a little bit later.

Another requirement that the law puts on AMS is to conduct a study on the use of electronic or digital disclosures.

So --- oops. Thank you.

So, there's been a lot of discussion as the law evolved, or as the bill evolved in Congress about the use of electronic and digital disclosures. So, this study evaluates the technological challenges that consumers may face when using electronic or digital link at the store. If we do determine that there are issues that USDA is then required to put essentially more options on the table that are equivalent to electronic or digital link for the food manufacturers to choose from.

To start this process we've put out what's called a Request For Information in order to solicit interest from vendors in order to conduct the study. We did that in early September and we received some feedback, changed up our Request for Proposals and that was published on October 19th. To lay out

essentially, we're getting contractors to come in to conduct the study. The study, again, has only one year, the study itself needs to be completed by July 29th, 2017, and we're expecting because of the speed in order to get this study completed we're guessing between a half million and a million dollars to conduct this study. And we will get proposals on this next week.

So there are some exclusions within the law itself and these are excluded from the National Disclosure Standard, so food that is served in restaurants or similar food establishments are not required to be disclosed. Very small food manufacturers as we determine it through rule-making are not required to disclose any bioengineered food. As explained earlier, meat, poultry and egg products from animals that consume GMO feed do not need to be disclosed solely because they fed on GMO feed.

Finally, your mental twister for the morning, and I'm just going to read this one; food containing meat, poultry or eggs, if the

predominant ingredient would not independently be subject to the Federal Food, Drug and Cosmetic Act, FFDCA, food labeling requirements, or if the predominant ingredient is broth, stock water or similar solution. And the second most predominant ingredient will not independently be subject to FFDCA food labeling requirements. So, what does this mean? What this means, I have a handy slide here, this is an example; spam, although some people would question whether or not it's actually a food, spam the first ingredient is pork and so it doesn't matter if any of the other ingredients are from a bioengineered food like corn oil or potato starch, whatever. Spam does not need to be disclosed as a bioengineered food in this example.

Another example is the soup, so the soup the first ingredient is chicken broth, so broth, water, stock or other similar solution in that second clause, and the second product is chicken fat which is a poultry product, so this

soup would not require disclosure under the law. So, those are the two examples of exclusions.

So, again, as I mentioned, small food manufacturers will be defined through rule-making and they also get a grace period of one year for implementation. They also have an additional option of providing either a telephone number or an internal website or Internet website for disclosure. They get five options of how they're going to disclose any bioengineered ingredients in their food.

Again, as I mentioned before, anything that we create, any processes that we developed within this law, because of this law, has to treat bioengineered food the same as non-bioengineered food. So, the symbol, for example, the symbol that we develop can't be disparaging to other technology or otherwise imply that bioengineered food is more safe or less safe than non-bioengineered food.

Organically produced foods, if you're certified organic under the program, under the

standard, the law, they can use non-bioengineered, non-GMO or other similar language. They're essentially automatically certified as non-GMO under this standard.

Finally, enforcement; again, failing to disclose food as bioengineered is a prohibitive act and we have the authority to request records and conduct audits and hearings and we do not have any recall authority. So, if food is not labeled as bioengineered and it is, we don't have the ability to recall foods based just on the lack of disclosure.

So, that's the broad summary of the rule or the law. We have an interagency, now interdepartmental discoverment working group that will help us develop the documents that we need in order to stand up the program. We have a lot of public engagement going on, we're having a lot of stakeholders come in, we're giving a lot of these talks just to inform the community of what's going on with this. We have an email address, GMOLabeling@ams.usda.gov, we've already

received 11,000 comments and questions and concerns on that email. We have our website, we also have a gov delivery, our stakeholder announcement, so if you go to our website you can sign up for updates to the GMO disclosure program.

What's next? We are developing an advanced notice of proposed rule-making right now, we hope to publish that by the end of the year. That will list out these areas where we think we can talk or where we need input from the public about how to develop this rule and this program. That's at the end of 2016. As I mentioned before, July 2017 the study needs to be completed. We're estimating a proposed rule hopefully in November of 2017 and again a final rule in July of 2018, so we'll be moving along on this.

If you have any questions?

None?

PARTICIPANT: Where does dairy fall in?

MS. HUBERTY: Where does dairy fall in?

PARTICIPANT: Yes.

MS. HUBERTY: Where does dairy fall in, dairy is not an area that I'm specifically knowledgeable about. Meat, poultry and egg products are covered under different labeling authorities, they're covered, the Federal Meat Inspection Act, Egg Products Inspection Act and the Poultry Inspection Act, so that's why they get a little bit different treatment as opposed to dairy which is under the FFDCA in terms of labeling. So, they would be, in terms of how the law has kind of split out these animal products, they would be covered under FFDCA. To my knowledge, like milk, there's no genetically engineered cows, so it wouldn't require disclosure at this point.

Does that answer your question?

PARTICIPANT: I guess the question was more like, a dairy animal who has been fed feed?

MS. HUBERTY: Yes, products that come

from that do not require disclosure. They're not considered bioengineered, it's not considered bioengineered milk.

PARTICIPANT: We had a question online; could you say again when you expect to release the proposed rule?

MS. HUBERTY: Proposed -- well, expect, hope. So, in order to make a deadline we have a very aggressive time line, and so that would put us in about November 2017.

MR. GEORGE: Other questions?

MS. HUBERTY: Okay, thank you.

PARTICIPANT: Thank you.

MR. GEORGE: Okay, we'll take a little break. I have to say, folks, I've been doing this for five years now, this is the first time we've ever been ahead of schedule. It's a milestone, congratulate ourselves.

It's almost 10:20, so why don't we just pick up again around 10:30 or so?

Thanks so much.

(Whereupon, the above-entitled matter

went off the record at 10:19 a.m. and resumed at 10:34 a.m.)

MR. GEORGE: Hello. Folks, if you could take your seats, we will get started again, please.

Thank you. If you could take your seats, please? Wow.

Okay, folks. We are going to get started, please. Thank you. Thank you. Thank you. Lot of great conversations going on in this room. It is exactly what we wanted.

Okey-dokey. So welcome back. Just a reminder for those of you on the phone, on the web, if you'd like to ask a question or make a comment, please 1 then 0 on your telephone keypad. We will unmute you and invite you to ask your question.

You can also ask a question or make a comment via the web on your -- on your screen. Type your comment or question in the comment box and hit Enter. We have someone monitoring this and they will get your question or comment to us.

If somehow we missed you, if you had a question that you wanted to ask Mike or one of the other presenters this morning, there will be another opportunity. We are a little ahead of schedule, and so when we get through the presentations, if there's something that we missed that you wanted to ask Mike or others, we will give you that opportunity.

Our next segment is about compliance initiatives implemented in 2016 and those anticipated for 2017. Our speaker is Christie Bertone, the Branch Chief for our Eastern Compliance Assurance Branch. Christie is new to BRS, hired officially in June, although she started with us on detail back in March. Christie comes to us from APHIS's Plant Protection and Quarantine, where she was Chief of Staff in Field Operations. Christie?

MS. BERTONE: Good morning, everybody. Thanks for being here this morning in person and online, and thanks to Dick for that introduction.

It has been a -- it has been a fun

year for me learning a lot about this group and what we do, and I want to thank my counterpart, Doug Grant, also, for being a great teacher in this process for me.

In fiscal year 2016, BRS's Regulatory Operations Programs, ROP, focused on enhancing compliance oversight. All of our work fell in this category. Within that, the response to the audit from the Office of the Inspector General played a big role in shaping the work that we focused on. I'll go specifically into some responses that we had for the audit, but then you will see that that OIG audit feeds into a lot of new projects that we took on as well.

We worked this year on reviewing reports that are missing and late, and this is a continuation of the Business Process Improvement from 2015, so that is our BPI Phase II. And thirdly, we worked hard to enhance our inspection program, some of which Mike alluded to and I will go into as well.

This is the -- the audit from the OIG,

and I think it is such a pretty picture to sum up some -- some of the work that we have taken on. The recommendations from this audit were designed to enhance the effectiveness and efficiency of BRS. These recommendations helped us find ways to promote continuity and consistency in the work that the BRS employees who conduct compliance activities do.

So we made some internal tweaks to the work within BRS responding to enhancement of compliance oversight, and I will get to the topic that I think all of you like the best, some external tweaks that we made for our compliance letters.

The Notice of Findings letters replaced our Notice of Compliance with comments, and so this was an external change we made. This was -- you know, if you haven't had the pleasure of receiving findings from us yet, you -- you may have seen it from our Stakeholder Announcement, and I'll make a plug for that quickly. If any of you aren't signed up to receive our updates on

the Stakeholder Announcements, just go to our website and I think it's a red envelope that you click, so please sign up.

So these letters, everyone's favorite letter, they intend to be a way for BRS to communicate with you, the stakeholders, on issues that our inspectors have seen. These issues are not currently a compliance issue, but the inspector wants to share a concern about something in the future that could lead to a compliance issue.

Both the internal tweaks and the external letter changes were ways that we responded to the audit, and they went a long way in enhancing our compliance oversight. In fiscal year '16, we took on several projects that followed through with our Business Process Improvement for compliance, the BPI Phase II. Rick told me not to freak out if the screen does that.

One of the big areas we focused on for the BPI last year was to review our Volunteer

Monitoring Reports, the VMRs. And specifically for VMRs, we developed a formal process to track, review, and analyze these for the data that is inside of those, and with that good data, we are able to do things. We are able to use the data to inform our inspection selection process. We have been able to select sites based on the data we see in our VMRs.

We can also use that data to revise our Supplemental Permit Conditions. Revising the Supplemental Permit Conditions is an ongoing project between ROP and the risk analysis group. John Turner is going to go into detail about that next up.

Another area we focused on for BPI this past year was to find a way to gain access to the data in emailed or mailed-in planting reports, so the staff was able to find a way to efficiently enter that data into the -- the database, and that allows us to do these efficient and quick searches that is much more consistent than we were able to do without the

data being entered. And so while these two projects are part of our BPI, they are also part of a response to the OIG audit.

The third main area we focused on in fiscal year '16 was enhancing our inspection process. As Mike mentioned, we brought on six or seven or eight reg analysts. We really beefed up our staff who are conducting these inspections in the field. We committed these resources to the staff, and Mike again said we conducted more than 60 percent of the inspections in fiscal year '16.

Also, my counterpart Doug Grant and I worked on a process. We implemented and documented this more risk-based approach to our inspection selection process. Additionally, we have added more of a focus on looking at post-harvest sites, incorporating the data from the VMRs for inspection selection, and considering the compliance concerns, and conducting follow-up inspections as needed. These three areas really work together to lead to a more robust inspection program for us.

And so I'm really moving through this quickly. If -- this past year, 2016, we took on many projects, so the plan for 2017 is to go through these, evaluate what worked well, what is working well, and then make tweaks to anything that is not, all the while keeping an eye to consistency, continuity. BRS is going to continue these high percentages of inspections, and we will go into BPI Phase III looking at field test reports. We will evaluate those in similar ways we did with the VMRs this year.

And so as I'm wrapping this up, I just want to say again thanks for having me today to share initiatives with you. It has been a -- it has been a great honor, and I will open it to questions. And I know -- but I'd be happy to take any questions you guys have.

MR. GEORGE: Questions for Christie?

(No audible response.)

MR. GEORGE: Anything online?

(No audible response.)

MR. GEORGE: Thank you, Christie.

Many of you are familiar with what we call our Supplemental Permit Initiatives, which we are revising. John Turner, Director of our Biotechnology Risk Analysis Program, will tell us more about the changes. John?

(Pause.)

DR. TURNER: Thanks, Dick, and thank you all for coming today. It's a great crowd here. Good to see you all.

So as he said, I will be talking about permit conditions, and so just as a reminder, what we're not talking about are notifications, which are sort of a different route of authorization where we sometimes look at design protocols. We are looking at permit conditions.

And as we assign permit conditions in BRS, we sort of think about them in three tiers. There's something called standard permit conditions. They are in the Code of Federal Regulations. They're in the regulations. They apply to all permits, so we're obviously not doing anything with these. We're not changing

them and don't really see a need. They are highly applicable to all permits.

But those same regulations say -- and any other conditions that the administrator assigns, so with nearly all permits, or all that I know of, there are also supplemental conditions that go with the standard conditions, and you will see in the middle tier it says "Standard" Supplemental Conditions, so that may sound a little strange to you.

There are different types of permits. For instance, you have maybe the interstate movement of a genetically engineered arthropod, interstate movement of a genetically engineered plant. You could have the field release of a genetically engineered microbe, or the field release of a standard genetically engineered plant, field release of a pharmaceutical-producing plant, so we have developed over the years some standard conditions that go with those various categories of permits.

And a lot of what I am talking about

today are going to be revisions to these standard supplemental conditions. And then the final one on the bottom, for any permit we get, they all get an individual evaluation, and we can -- can and do apply unique permit conditions to individual permits based on the specifics of the permit.

So a little about how we work: bottom left, BRAP, that stands for Biotechnology Risk Analysis Programs. That's the group that I had. We do the scientific reviews. The new biotechnologists that you were introduced to this morning and others evaluate the permits, notifications, and we analyze the risk, and it is our primary duty to assign then the permit conditions. So that is done in BRAP.

But then the applicant gets the permits. Inspections and compliance is under a different group, so there is a handoff, and if there is non-compliance, of course they will determine the nature of the non-compliance, how severe it is, and what needs to be done about it.

And the ultimate goal then is to protect plant health. But the main point of this is there are two groups that have to work together here.

So as we work together, I think we have had a great working relationship over the years. Maybe the -- the clip art is an exaggeration. We haven't had any train wrecks, and we don't want any, so -- but you can certainly -- we found some areas where it could use improvement.

One is permit conditions are not clear. They cannot be clear sometimes to the applicant who receives them -- not sure exactly what they might need to do -- or the inspector reads the permit conditions that our group assigned and isn't clear what they mean.

They can be non-enforceable, and that can relate to the one up above that. Either it is not clear: it says it must be an adequate distance to prevent mixing, and he says well, how do you enforce that? What is adequate? So in that case it is not clear.

Other examples of things being non-enforceable is we sometimes have recommendations in the permit conditions, so we recommend that if you're going to feed this to animals, you consult with FDA. Well maybe that's a fine recommendation, but it's not a permit condition. We cannot enforce that. It's a recommendation. So that's an example of things that are non-enforceable.

There is inconsistency of language across permits, so if we're talking about volunteer monitoring, if we are talking about packaging, to the extent we can in these various permit types, we want to use consistent language.

And we need conditions that are effective. You know, the bottom one is really where the rubber meets the road. An example, it says "Seed Dormancy" up there. If you have a crop with extended seed dormancy, you want to make sure that the monitoring periods are adequate to account for that. We'll talk more about that a little bit later.

So in order to improve these, there was -- there is an ongoing project, actually, with my group, BRAP -- that is, again, Biotechnology Risk Analysis Programs -- and ROP, Regulatory Operations, the ones that do the permit conditions. So this initiative was started in 2015, and it is really -- the project looking at permit conditions is really a part of a larger initiative to improve the working relationship and get a tighter working relationship between these two groups, and we meet very regularly, at least once every two weeks, and sometimes more often than that, to discuss these things.

So going back to the things that can go wrong, the goals of this project, to improve permit conditions, to make sure they are clear, make sure they are enforceable, make sure they are consistent, and make sure they are effective. And effective can go a lot of different ways. You can add permit conditions, you can enhance them, or sometimes, we saw permit conditions that

were there that were not effective. They didn't do anything. So in some cases, you will just be removing them. But those were the goals of the project.

So this is going to be very high level, talking about some of the changes that you will see. As I -- as I mentioned, they have been streamlined to remove things which are unenforceable. Primarily things which are recommendations or not strictly enforceable have been moved to other places, either to guidance or the acknowledgment letter, to somewhere other than in the permit conditions, and we have tightened up the language to make it more consistent.

There are some new reporting requirements. Interim reports are now required if it is a multi-year permit or if monitoring is going on for more than one year, so the monitoring example, for example, if someone is monitoring for three years, if they are finding large numbers of volunteers in the second year,

we want to know about that early on.

And constructs must be submitted with planting reports rather than in the Field Test Report that comes at the end of the season so we know what is in the field during the growing season.

Some other general changes, requirements, for this one, we have clarified the conditions for confinement and monitoring. So requirements are either specified in the supplemental conditions or methods submitted in the permit application or in attachments are clearly cited in the permit conditions, and we ensure there are no -- there is no ambiguity or contradiction.

So let me unpack this a little for you. As you may know, when you fill out a permit, the applicant has to state how they are going to keep something confined, how they are going to keep it identified. So they have a description of how they are going to keep it confined.

Then, sometimes, our permit will always -- our permit conditions have confinement conditions, and there can be situations where they are not exactly the same, and the applicant or the inspector is saying are they supposed to do it the way they described in the permit or the way we described? So we need to make that perfectly clear.

If it is their description, then we cite back to that. If it is ours, then we state it. And we are going to be looking at these to make sure there is no ambiguity or contradiction in what the permit conditions are.

With respect to location of regulated material, we want to be notified of destinations of -- of all viable material, so permit conditions, for instance, if you're doing an interstate movement, will specify a certain location. If it goes somewhere else, that is possible, but we need to be notified.

And storage reports and final disposition reports are required if material is

retained after the field test report submission, so this is very common, and we realize people are going to want to keep materials -- want to keep seed sometimes indefinitely, and you can do that, but we need to know where it is, and there is no -- no annual reporting requirement on that as long as it stays in that condition -- in that location, but if it goes somewhere else, we need to know.

Volunteer monitoring and plant backs: so by plant back, before I get into this, we are talking about you have a field test with regulated articles. Typically, in the year after that, then you would be monitoring, but sometimes, that same area is planted back under a new permit, so there is more regulated article there, same crop, you can't start monitoring yet.

So under the new permit conditions, you're going to have to identify sites which are planted back under new authorizations which effectively delay when you are going to start volunteer monitoring. You have to identify

whether all or part of the site is planted back, and if it is only part, then the part that is going to be planted back needs to be identified with GPS coordinates, and you need to provide the new permit or notification number authorizing the plant back.

So this again is so that the inspector knows why the volunteer monitoring has not started. It is again planted in a regulated article in that same location.

Now, the following are specific for wheat: permits now are going to specify how equipment is cleaned and the required recordkeeping. This will be in the permit conditions rather than us just relying on SOP and design protocols.

Annual Volunteer Monitoring Report is required if monitoring exceeds one year, and we -- and typically, with wheat, it is going to exceed one year, and monitoring continues until no volunteers are found in two consecutive monitoring intervals.

We talked -- I just mentioned that if volunteer monitoring was going for more than one year or for however long it goes, we need reports. We are going to be very specific in how we report volunteers. We need quantitative data on how many volunteers were found, not descriptors like "some" or "few" or "none" or "many." And -- and as we attempted to understand some of the issues with -- with wheat and volunteers over the years, we looked back at a lot of monitoring reports, and we found that they were not very useful in understanding how many volunteers were found.

Sometimes, it just says volunteers removed. We said how many? And they said, well, it could have been a lot, could have been a few, maybe it was none. If we found some, we removed them. So it was documentation that they did something, but not the type of information that was useful for us for understanding the volunteer situation, so we're going to be specific in what kind of numerical data we want for volunteer

monitoring.

And I think that's all I have, again keeping us on record time. Got a nice list of restaurants out there, so --

(Laughter.)

DR. TURNER: -- for your -- for your long lunch, but we have plenty of time for -- for questions.

MR. MUNDELL: Thank you. Scott Mundell, DuPont Pioneer. Thanks very much, John, appreciate it.

So a section of what you talked about sounds like new report types. Is that accurate, or is this additional information or changes to specificity of information to report types that are already being submitted? If they are new report types, is the ePermits system going to be modified in a way that again we can try to upload that information? How are you going to manage information transfer?

DR. TURNER: So I don't know the answer about the ePermits and how that will be

built in. I think the annual and interim reports for multi-year tests and monitoring are essentially new requirements, and I -- as I understand it, our current system will handle as it is those additional reporting, the way we receive information now. I am talking about the current ePermits system.

PARTICIPANT: Hello, this is Grove Bannon, and I think this is either for Dr. Firko or Dr. Turner. On the inspections that Dr. Firko talked about, we use a lot of third-party providers, and if these are truly unavailable, in such instances, they could be out of the office. They are small third-party providers, and you may show up to a locked door.

DR. TURNER: I think that's about our inspections, essentially. Maybe you or someone in compliance?

MR. FIRKO: So unannounced is a relative term. We do call to make sure someone will be there before we go to it. That typically happens in the morning. The inspector will be in

the vicinity and call and say, will -- is someone going to be available in the next hour if I get there in the next hour or two? So yeah, we've been experimenting with this over the years, and yeah, we knocked on a lot of doors, and nobody answered, so we have learned from that to at least give a short amount just to make sure someone is available to host.

PARTICIPANT: Okay. Can you still hear me?

DR. TURNER: Yes.

MR. FIRKO: Yes.

PARTICIPANT: All right. Second question: on the -- this is back to the section after the volunteer monitoring period, because I am sticking specifically to -- we have a notification system, with inspectors out in the field where there hasn't been a problem, and the stakes have been removed because it was past the volunteering monitoring period, which was one year. In house, we actually used two years. But now for a three- or a four-year volunteer

monitoring schedule, and then after that point, if we achieve zero results where you spend two or three months with zero volunteers, and then the stakes are pulled on it at the end of those three or four years, can we expect to see -- can we expect, pardon me, to see an inspector in those fields? Because they don't like it when the stakes have been pulled out, but if it's a three- or four-year volunteer monitoring period, we should be okay.

MR. FIRKO: Could you distill that to a shorter question?

PARTICIPANT: Yes. Can we -- if we -- for instance, if we have a four-year volunteer monitoring period for wheat, and then we're okay at the end of that period, we pull the stakes out of the borders that designate a relief site, do you think we can expect to see inspectors back in that field say in year five or year six or year seven due to what happened in Washington and Montana in 2013 and 2014?

DR. TURNER: He is talking about our

survey where we went back.

MR. FIRKO: Right. So the situation with Montana was that was a self-report. In terms of if there is a four-year monitoring period, we would not expect to be back after -- beyond four years if there had been sufficient periods of no volunteers.

In an effort -- after the recent incidences with GE Weed in Oregon and Montana and then in Washington, we are desperately trying to get more information, but we would not be visiting sites where that had been previously regulated without authorization from the people who had been authorized to do the field trials. Does that answer your question?

PARTICIPANT: Yes, it did. So we're okay to pull the stakes out after that four-year period where nothing has been filed, where we have achieved the objectives.

MR. FIRKO: Yes. Once the monitoring period is done, and if you have cleared the appropriate number of no volunteers, yes, you can

pull the stakes up.

PARTICIPANT: Okay. Thank you.

PARTICIPANT: Hi, John. It's Michael Weeks with Dire. I had a question regarding the disposition of material after the final field test report is submitted.

In a situation where we would then -- where we reported on the conclusion of the trial and the fate of the material, and then we would pull a new permit, essentially, to claim that material again sometime in the future, does there need to be a linkage made between the old permit and the new permit that the harvested seed from that old permit is now being planted under a new permit? Or does it start anew, now that we have a new permit?

DR. TURNER: I think in that situation, it -- we do not necessarily need the linkage, but we would need the closeout of the old permit. It has either been destroyed or replanted.

MR. MUNDELL: Scott Mundell from

Dupont Pioneer. Also, I want to clarify the last statement that you made because I think probably all seed companies, certainly speak for Pioneer, we will harvest something and perhaps keep that seed in storage on a shelf for years, so when you say when a permit is expired, or notification of a permit in this case, we can say that we can keep that in storage for a long time. It does not have to be replanted or destroyed --

DR. TURNER: It can be kept indefinitely. If that's the disposition, that it is in storage, that would be fine, and you would state that in your final report.

MR. MUNDELL: All right. Thank you.

MR. GEORGE: Other questions for John? No?

(No audible response.)

MR. GEORGE: Thanks, John. Okay. We have time for a very leisurely lunch. However, before we do that, since we do have a little time, I would invite anybody online or in the room, if you had questions earlier that you would

like to ask of Mike or anyone else, we have a little time right now to do that. I think we had somebody online who missed a chance to ask a question earlier.

I would invite you to ask your question now if you care to by pressing 1 then 0 on your telephone keypad or letting us know via the comment box, so let's give folks a minute or two to see if there is another question there.

PARTICIPANT: Are we in the same room this afternoon?

MR. GEORGE: Yes, yes, yes, we are in the same room here this afternoon at 1 o'clock. We will talk about Weed Risk Assessment. I will mention that we have a cafeteria out here down the hall and to the left, past the elevators and then it is your first left. There is another cafeteria, actually one that I am told is much better, in the NOAA building, which is at the far end of our parking lot in the back, and it's a beautiful day for a walk. And -- what?

PARTICIPANT: It is this way.

MR. GEORGE: Yes, okay, I am pointing in the wrong direction. I've betrayed my sense of direction, which is pretty bad. At any rate, the -- the NOAA cafeteria is -- I am told is much better. It's a beautiful day for a walk across the back of our parking lot, that one, right.

MR. SHAQIR: Can we access the NOAA cafeteria without the government ID?

MR. GEORGE: That's a good question.

MR. SHAQIR: We need ID?

MR. GEORGE: There is some question now I am hearing about -- photo ID, you can get into the NOAA cafeteria, I am hearing. And there's food trucks, okay.

Also, I will mention that there is a list of local restaurants that is at the front desk. You can take a look at that, if you care to. Some of them will actually deliver food here, and pretty quickly. Jimmy Johns, I am partial to Jimmy Johns. They will get you a sub over here in no time.

(Laughter.)

MR. GEORGE: So -- so we'll see you back here at -- no questions, Rick, nothing came in? Hold one second. We may have a question that we can address.

(No audible response.)

MR. GEORGE: Okay. So I'm going to ask you all to just sit tight for just a second because part of our purpose today is to give everybody an opportunity to ask what is on their minds, and so since we have a few minutes, we will see if we can solve this little freeze up that we have.

No? Okay. Thanks everybody. We will see you back here in this room at 1 o'clock.

(Whereupon, the above-entitled matter went off the record at 11:10 a.m. and resumed at 1:01 p.m.)

MR. GEORGE: Okay. We're going to take our seats, please, and we'll get started. Lots of great conversations going on. This is a good thing. I hate to break it up.

Thanks again, everybody, for being

here today and for being with us this afternoon.

I do want to mention a little note for those of you that are online and listening in. I've been telling you to hit 1 and then 0 on your telephone keypad if you have a comment or a question. You need to wait until you hear a little announcement that says that we're opening up the lines.

So there will be a point where we say, okay, we're open to questions. And then there will be just a slight pause. Then you'll hear that little recorded voice. And then you can hit 1 and then 0 to ask a question, and we will unmute your mic. So thank you for your patience on all of that.

So this afternoon's session is about a Weed Risk Assessment System. Our presenters are both branch chiefs here at BRS. Alan Pearson heads up our Plant Pest and Protectants Branch, and Subray Hegde does the same for our Plants Branch.

First, though, to provide some context

once again is APHIS Deputy Administrator for BRS, Mike Firko.

MR. FIRKO: Thank you for rejoining us this afternoon. In the slide I mentioned --

UNIDENTIFIED SPEAKER: Just a minute.

MR. FIRKO: Just a few slides, as Dick said, to provide some context.

(Off mic comments.)

MR. FIRKO: So why did we create a Weed Risk Assessment System for genetically engineered plants?

The primary reason is, and I may have talked about this last year, there are a lot of great Weed Risk Assessment Systems out there, but for a variety of different reasons they don't work very well for genetically engineered plants.

They work very well at the species level. They work very well when we're talking about species that is in a foreign country and we're worried about that species getting to the United States. And we want to look into, you know, if it got to the United States, how bad

would that be, what's the likelihood that it would get here, and how bad would that be.

But what we're typically dealing with is plants that are agricultural plants already and the difference between the agricultural crop and the plant we would be evaluating is one gene.

And there really aren't systems out there that deal with that kind of question. So we feel that we needed something customized for our particular needs.

So potential uses, we have received multiple requests to list as Federal Noxious Weeds genetically engineered plants. So we used a tool when we did that analysis. But the tool wasn't designed to be used for that sort of question.

The tool was designed, like I said, to address the question, there's a plant over there, what's the likelihood it's going to get here, and how bad would that be. We're talking about something that would purposely be put into agriculture.

So we realized when we started getting petitions for listing genetically engineered plants as Federal Noxious Weeds -- FNW, Federal Noxious Weeds -- that we needed a sharper tool.

In our current petition process, when we get petitions for non-regulated status of genetically engineered plants, like I said this morning, we always look at the weediness.

It's authority granted to APHIS in the Plant Protection Act. That authority is not currently in our biotechnology regulations. But, like I said, it's mentioned in our regs that weediness is a concern. And in our Plant Pest Risk Assessments, we always have a section on any weediness concerns of a plant in our NI regulated process.

So all the species that people have submitted to us have great, very real weediness concerns. Now, that isn't necessarily something that we would deal with under 340 because there is no weediness authority in 340. But it is something that APHIS may consider applying a

different regulatory authority to.

And, of course, if we incorporate noxious weed authority under 340 at some time in the future, we need to be positioned to be able to do a risk assessment of genetically engineered plants.

So the first three of those, we could use a new tool for those right now. And we could potentially use it in the future with 340.

So why did we create it? Well, we needed a more systematic approach in our current petition process. We do the analysis. All of our Plant Pest Risk Assessments for deregulations are on our Web site, all hundred -- I don't know if all 125 of them are there. But, yes, John Johnson said, yes, all 125 back in 1994 or so, right?

So you can see how we've dealt with noxious weed risks in those PPRAs. We want to have a better system. I mean, the federal government is all about business process improvement and efficiency and trying to do as

much as we can with the resources that we have.

And as I alluded to, there -- the questions that we have to ask when we're evaluating a genetically engineered plants, some of them are different from the questions you've asked when you're talking about something that's in a different country coming to this country.

I think last year I mentioned, the best example I like to give is volunteers. If you look at most of the existing Weed Risk Assessment Systems, if the plant volunteers somebody, that's something you need to be afraid of. If the plant volunteers somewhere in an agricultural field, that's something that is worrisome.

Well, if we have a genetically engineered plant in agriculture, agricultural plants volunteer. I mean, they just do that.

If you're planting corn in a field one year and the next year you're planting soy in that field, chances are you're going to find some corn volunteers the next year. It's part of

operating. It's part of farming. It happens. It's not a deal killer.

So the way that we need to look at those with a Weed Risk Assessment System for genetically engineered plants is different, the way we rate those volunteers.

Now, there is a heuristic model of risk analysis that APHIS adopted several decades ago. And you'll find it in Society for Risk Analysis and several others. And it says risk analysis is made up of three components, risk assessment, risk management, and risk communication.

It's a little bit of jargon. But I hope that we stay true to that jargon today because it helps understand exactly what we're talking about. Specifically, risk analysis is not the same as risk assessment. Risk assessment is part of risk analysis.

Today we're here to talk about risk assessment only. I'm sure that there -- people would love to hear, well, how will you make your

decisions. Well, decision making is part of risk management. And we're not really going to talk about, well, how do you make your decisions.

There's several reasons for that. One is the decision is based on the organism in question. It's not based on some theoretical, yes here, no here. It depends. It depends on the plant. It depends on the context. It depends on operational feasibility to be able to have some impact. It relies on a lot of different things.

But I believe that we will have plenty to talk about for two hours just talking about the risk assessment itself that we put together and the 50 questions that we'll ask and information about how we will rate the findings based on those questions.

So that's it for me, and introduce Alan Pearson and Subray Hegde. So, first Alan? Okay. Here he comes.

MR. PEARSON: Well, thank you. Good afternoon. Mike's given an introduction that has

covered some of what I'm going to cover. So you'll hear some things twice. And that's good, because then you definitely get it.

What we're going to do today in talking about this Weed Risk Assessment approach for GE plants that we're developing is first just give a little bit of background and then review some key concepts underlying that approach.

And then I'm going to turn it over to Subray, who will get into more detail about the approach, specifically in the questions we ask, and so on.

And then at the end of that, we'll have plenty of time to answer any questions that people have.

So just by way of background and what is our current approach, for example, when we get petitions for non-regulated status to assess the weediness of GE plants.

Well, basically we take a descriptive or an observational approach right now when we assess weediness of a, the weediness potential of

a GE plant in which we provide -- and you've all seen some of our PPRAs.

We provide a general narrative that compares the agronomic properties of the GE plant and a control plant or suite of control plants, typically non-GE plants. Although, you know, previously deregulated GE plants could potentially also act as comparators.

In this revised approach that we're developing, we're trying to take, as Mike said, a more formal and systematic approach to Weed Risk Assessment.

So we're developing a set of questions that will enable us to systematically identify any meaningful differences between a GE plant and its control, and then if we do identify any meaningful differences, to assess the risk implications of those differences.

So we ask questions both about biological characteristics, characteristics that have been nationally and internationally recognized as indicators of weediness. And we

ask a set of questions about impact characteristics based on what we're trying to protect, which is agricultural plants and agriculturally important natural resources.

There's a few key concepts that underlie our approach. And so what I'm going to talk about next is just some -- first a little bit more theoretical aspects, sort of the stages of invasiveness and weediness in plants and the context dependence of weediness. And then talk a little bit more about challenges to using current Weed Risk Assessment tools and models for the assessment of GE plants. Mike's already discussed this a little bit. And finally, end up with some general concepts underlying our new approach.

And my apology in advance if I cough. I seem to have this lingering cough from a cold from a couple weeks ago. And that just happens, so you'll hear me probably.

So, moving to the theory. So. this slide presents a general overview of the stages

of weediness and invasiveness. And I believe this was a handout available on the table outside to you. So if you don't have a copy now, you should be able to pick up a copy later.

Basically, invasion can be thought of as -- plant invasion can be thought of as a multi-stage process that's proceeds from introduction or arrival of plant or its propagules to some new location through colonization, which is the survival of individual plants. And then through naturalization, which involves the survival and reproduction of those plants that enable a self-sustaining population to persist. And then on to spread, where propagules from that population basically move outside the area where the population exists, which is in essence moving back to the introduction stage, if you will, but not in a new location. And if that process, if that takes hold, then populations begin to spread into new areas.

There are barriers, represented by

these vertical blue lines, moving from one stage to another so that many plants and plant taxa that are, for example, introduced will never really colonize. A few will. And of those that colonize, many will never get to the naturalization stage, but a few will, and so on.

Human action actually often results in the first barrier being skipped, often intentionally. When plants are cultivated, you have basically intentionally introduced that into a location. And, of course, sometimes unintentionally when seeds, for example, get imported into a country for a plant that wasn't there, just unintentionally, accidentally, as contaminants or so on.

Establishment, as shown, it connects individuals to populations, as I've described. So colonization really refers to the establishment of individual plants. Naturalization refers to the establishment of populations.

And when doing Weed Risk Assessment we

have to keep those distinctions in mind, because oftentimes you'll read about establishment and you'll have to figure out what's being discussed. Is it plant establishment or population establishment?

Once a plant population is established, we typically call that naturalized, as shown here. So basically a plant has become naturalized here if it's established in a new location where it hasn't already existed. And once those naturalized populations start to spread into additional new locations, they're typically termed invasive.

Now, impact is not part of the continuum per se, but rather it's a consequence or an end result that may occur or may not occur.

Moreover, plants can have impacts even if they don't advance through all the way across the continuum. And that's what we've indicated by the word "weed" here at the bottom.

So, for example, even native plants can be weeds if they colonize non-native

habitats, if they get into agricultural fields, for example, and have negative impacts on the desired attributes of those habitats. So the terms "weed" and "invasive" are not exactly synonymous.

The other thing that we'd like to point out is that weediness and invasiveness are highly context-dependent.

So they are a function really of interactions among a species' traits or traits of the plant taxon being evaluated, the ecosystem environmental features in the location where the plant is occurring, the number and size of introductions that occur, and random events.

Moreover, no two ecosystems or species work in the same way. So, different species can behave in different ways in different environments or in different habitats. And so there's a lot of context dependency that goes on here.

So, turning to some of the existing Weed Risk Assessment models that Mike talked

about. Since around the 1980s, researchers, and later regulatory officials, realized they needed some objective, standardized ways to characterize plants that they were having to evaluate in order to determine, for example, which plants to let into a country -- or if you're at a state level and the plant's not in the state, perhaps which plants to let into a state, which plants to keep out. So if you're concerned about invasion risk and so on.

Or if you already have weedy or invasive plants in an area, to do some prioritization: where are we going to put our mitigation resources, our time and our money, what's the most important thing to try to take action against?

And so this led to the development of various checklists, questionnaires, and screening tools, and so on, collectively known as Weed Risk Assessments.

There's sort of two categories of Weed Risk Assessments: the pre-border or exclusionary

Weed Risk Assessments. And there, the most prominent are the Weed Risk Assessment developed in the 90s in Australia, and a more recent Weed Risk Assessment that's been developed here in APHIS within PPQ.

And then there's post-border Weed Risk Assessments, which, again, look more at mitigation. So you've already got a weedy or invasive plant present. Australia has done a lot of work in that area as well. I throw up another example, for example, some work that's been done in California.

The Weed Risk Assessments focus primarily on species' traits that have been identified in sort broad meta-analyses that don't necessarily account for all the complexities that I discussed in the previous slides.

But just to take an example, pre-border Weed Risk Assessments, what they do typically is they list a large number of characteristics and criteria that had been correlated with invasiveness. And then they set

sort of thresholds, such that plants that meet a certain number of characteristics are categorized as posing a high weed risk, and plants that don't are characterized either as low weed risk or there's sort of an in-between category called "evaluate further."

The post-border Weed Risk Assessments also score. But in that case, instead of assessing in the context of thresholds and whether a plant has exceeded a threshold, they score in order to rank order plants for prioritization of risk mitigation.

Now, there's several challenges, as Mike mentioned, to using existing Weed Risk Assessments and applying them to GE crop plants.

First, of course, is, as I've already alluded to, a weed is not necessarily the same as an invasive plant. But many of the existing Weed Risk Assessment models were really developed with invasive plants in mind. And they could almost be considered invasive plant risk assessments.

Second, crops often share certain

traits with weeds. For example, crops could be developed to produce high amounts of seed or high amounts of biomass within a short time. And that's characteristic of many of the world's worst weeds.

But crops generally are not known to persist in the environment. So just because they share some of those traits doesn't mean that they're actually weeds. And so that complicates analyses that are based solely on traits.

Another challenge comes from sort of history and experience. So, as we know, most of the crops that we deal with have a very long history in the U.S., some of them well more than a century, two centuries. Whereas these, for example, pre-border Weed Risk Assessments, they're typically designed to assess the risk of new introductions and typically non-crop plants.

So the pre-border Weed Risk Assessments purposely ignore the known behavior of a plant or a species in the country where you're doing the risk assessment. They look at

the behavior outside and try and use that to try to predict what might happen inside.

But, as I've mentioned, the domesticated crops in the U.S., for example, are already present for a long time. They're grown typically on a much larger scale than new plant introductions will be grown on. They're grown for different purposes than the objects that are the subject of these traditional Weed Risk Assessments.

Thus, it's our feeling that we need a modified approach for assessing weed risk of GE plants, one that takes all of these differences into account and doesn't simply rely on sort of decontextualized thresholds to characterize and categorize weed risk.

So, just a couple slides on our conceptual approach, and then I'll turn it over to Subray who will go into more details.

Basically, what we're doing is we're still taking, as we have in the past, a comparative risk assessment approach in which we

ask, do the new GE traits increase the level of risk or give rise to new risks compared to the risk posed by the non-GE or other comparator plant? If you have, let's say, a previously assessed GE plant that's been found not to pose a substantial risk.

And so we have a two-step process. In the first step of this process, we conduct what we call a baseline Weed Risk Assessment, essentially a Weed Risk Assessment of the non-GE plants. So you can imagine, for example, a baseline Weed Risk Assessment of corn. And this provides us an understanding of the non-GE plant and its behavior in the environment.

And then in the next step, we conduct a GE Weed Risk Assessment, building off of the baseline, in which we identify and assess any plausible effects that we find of the GE trait on the baseline characteristics of the plant and on its interactions with the environment and the valued entities.

So the baseline and GE Weed Risk

Assessments have the same elements in them. We ask the same questions. And we're really doing a comparative assessment.

Now, you'll see here that I talk about plausible effects. So what do we mean by plausible effect? And how do we approach that in a GE Weed Risk Assessment?

Basically, when we're doing a GE Weed Risk Assessment, to be documented as an effect, a plausible effect has to be based on knowledge of the mechanism of action of the introduced trait and/or the intended phenotype of the introduced trait.

So we're not simply saying, "you know, somebody's put this trait into this plant, and it could do anything, and we have to be concerned about it."

No, we try to understand what's being engineered, what the intended phenotype is. We look, if we know the mechanism of action, to look at that and see whether there could be any unintended phenotypes based on what we know about

the plant and about that gene and its mechanism of action.

So we really try to take a knowledge-based approach to identifying plausible risk assessment -- plausible, I'm sorry, effects.

We recognize that most GE plants, to-date, are derived from cultivated plants that are typically very well characterized, and that most of the characteristics of the parent are going to be retained in the GE plant. And almost all of the questions in a Weed Risk Assessment of the GE plant can thus usually be readily answered from knowledge of the parent, knowledge of the environment, and of the intentional modification.

However, where there is incomplete data about the introduced trait and its potential effects, if there could plausibly be a change in the risk characteristics based on the intended phenotypes of the mechanism of action, then we will document that during the comparative review.

We then use these documented differences to form the basis for determining

whether there's plausible pathways to harm, or risk scenarios.

Now, sometimes you'll hear risk scenarios referred to as exposure scenarios or risk or exposure pathways. Sometimes the term "conceptual models" is used. All these are basically describing the same thing.

Basically, these risk scenarios describe the relationships between the source; so this would be the GE plant; the valued entity, say, some agricultural crop or agriculturally important natural resource; and the causal pathways that lead from that source to the potential harm to that valued entity.

So, in other words, the risk scenario is a working hypothesis about how the plant expressing an introduced trait may affect agricultural plants or agriculturally important natural resources, which are what we call our valued entities.

Importantly, although on this slide, you know, we've shown a generic risk pathway,

when we're conducting an actual GE Weed Risk Assessment, we're not coming up with generic risk scenarios. We're trying, as much as possible, to give specific scenarios based on specific characteristics of the plant, the introduced trait, the receiving environment, and the interaction among these, including the possible ways in which valued entities could be exposed to the GE trait.

So in the last two slides I'm just going to give you a couple of examples of plausible risk scenarios to identify the kind of thing that we might see.

So, the first one is not a specific example. It's a little more general. But let's say, for example, you have a transgenic crop that produces an increased rhizome number. Okay? The increased rhizome number could be that it actually didn't produce rhizomes before. It's been engineered now to be rhizomatous. Or it could be that it had very few rhizomes, but it's got a lot more rhizomes now.

Those rhizomes could disperse into non-agricultural habitats. So that's part of a causal pathway. And as a result, that crop could persist in the agriculturally important habitat due either to the greatly increased number of rhizomes that get produced, or increased fitness in those rhizomes, or the fact that, you know, it never used to produce rhizomes before.

As a result of that, the population could increase in abundance. And as a result of that, you could have a reduced success of desired plants. And that would be the potential harm.

Now, obviously, you know, I'm not thinking of any specific example here. So when we are faced with a specific example of a pathway, like this, we would get a little more detail and a little more specificity, you know, at each step as to exactly what's happening.

The next example is taken from a paper by Hokanson et al., published earlier this year. We've modified it just a little bit. And it is a specific example. It's an example -- and it was

in an African context, but we thought would be useful to share with you here. It's an example of a transgenic cassava that's been engineered to be resistant to cassava brown streak disease.

So, in this risk scenario, the first step that happens after you've introduced this resistant plant into the environment is, for example, gene flow to the wild relative, Manihot glaziovii.

And then we ask, is CBSD-resistance a new trait in glaziovii? In the areas where glaziovii occurs, is this a new trait? Is CBSD then a limiting factor of the population size of glaziovii? And if it is, you can then ask, does having this trait render a glaziovii more difficult to manage, for example? And does it now occur in, you could say, agriculture fields?

And if it is more difficult to manage, could this increased abundance result in the loss of crop yield, of other valued species, or ecosystem services? It depends really on what your protection goal is at the end there.

So this is the example that we thought would be a good example just to show what one of these plausible -- a type of plausible risk scenario that could then be evaluated.

And from this point, then, we would go in to try to evaluate a plausible risk scenario in more detail.

Now, I want to point out that, in many cases, it may be that there is no plausible risk scenario that comes up when we go through the Weed Risk Assessment process.

And so many times we will not get to this stage because we'll find there are no substantive differences, no plausible effects that lead to plausible risk scenarios. In some instances, there may be, and then we would look at those in greater detail.

So now I'm going to pass the microphone over to Subray, who will go into more detail about the Weed Risk Assessment System and the various questions that we ask.

MR. HEGDE: Thank you, Alan, and also

Mike.

So I think Alan gave you a really, really good conceptual framework why we are doing this one. And mine is a little mundane, you know, the bucket list of, you know, things we are to do whenever, you know, we do these Weed Risk Assessments.

And as Mike suggested, or Alan said, yes, we did this Weed Risk Assessment earlier. It's not something new. So what is new about this one?

I think, and I don't want to say it loud, but I think it was kind of, you know, hand waving approach, very expert opinion. It's not really that we followed any systematic approach. But we always called ourselves a science organization, science-based approach.

But you always know that there's always a cognitive bias if you always follow an expert opinion, because there is sometimes, what you call, people become very dogmatic. They'll say, you know, if I say it, then it should be a

weed because I'm a weed ecologist, right?

So that's why, you know, it is not really scientific. We really want you to follow a method, a systematic method which will be consistent, which could be applied to every crop indicated. That way, you know, we are not arbitrary and capricious in our Weed Risk Analysis.

So we wanted to make it more science-based. So, one of the approach, there is 25 background questions and risk assessment questions. What are these questions? Okay. Did we really invent or discover these new questions? No.

So, as Alan suggested there are already models available. You know, we looked into these questions. But we did not use all of them. You know why, because they're dealing with entirely different type of plants. These are domesticated plants. These are not plants which are naturally selected or the real weedy plants. So that's why.

You are thinking, you know, why should we use the existing system where there are, what do you call, the paradigm is slightly shifted. Completely domesticated plants, most of the people never did a Weed Risk Assessment for highly domesticated crops.

So that's why we see why we are doing, whatever questions we are asking, and how we are responding to those questions. That is, though we ask the same questions, but the response we are collecting may be slightly different.

Okay. For example, here, so there are the background questions, which I will probably go into the detail. But why are we asking? This is not important, because this is just for administrative information, baseline taxonomy, and sexually compatible relatives.

These background questions are used to answer weed risk questions. So that's why. Like, for example, do we know where exactly this crop is domesticated, where exactly, you know, first domesticated, were there any sexually

compatible relatives? Some of these things will help us to answer the questions which are related to weed risk questions.

Okay. The first one is plant history. So why do we want to collect plant history? We really want to know where exactly it was domesticated in the first place, and when it was introduced into the United States. And do we know about, you know, type of plants? So, which I will explain later when we really ask some of the questions of the plant biology, ecology, agronomy, management, ecology, and GE trait.

So let me take one by one. Okay. See here, so let me make very clear. So why we are different than what exactly Australian Weed Risk Assessment and all those people do?

As I said, you know, there's a paradigm shifting in our asking. Most of the plants, when you do Weed Risk Assessment, you consider those are the natural plants which are selected through natural selection.

Hence, you have a predictive power,

because what happens to your plant, which is naturally selected and if it produces more seed, okay, it's fitness trait. It has more rhizomes. Maybe it is a fitness trait, right?

But what happens, if, see here, your paradigm shifted, it is an artificial selection now. Like we are selecting plants for the higher yield. Okay. It is a fitness trait. Mostly it is a fitness trait.

But is it really for the domesticated plants now, because by selecting and within five years you created a new variety. Probably it has a lower fitness now because plant doesn't want to produce a million seeds, but we want it.

So now all the reasons that are put into seed, probably it lost some of the fitness trait. It may not protect itself from the biotic and near biotic stresses. So that's why.

See, we shifted this paradigm. Okay. That's one difference. We shouldn't just borrow the criteria and apply it to domesticated plants.

So here I'm taking, you know, why a

taxonomy scope and why I'm giving this background is there is a difference between a plant which is selected in nature and a plant which is selected in agriculture.

If you take a rice germ blossom, there are 10,000 probably. That is, do you really want to cover all of them in your Weed Risk Assessment? It can be shortest rice variety. You have the tallest rice variety. You have the weedy type. You have a plant type, lowland type, rainfed. Which one you are really dealing with?

Why are we interested? Let us say you start with a crop, a GE. But it is so specific, right? If my Weed Risk Assessment wants to cover everything, which is so difficult because you find all kinds of life history traits.

That's why we really want to know what exactly we are dealing with here. For example, corn here. GMA, it has both a wide progenitor and it also has activity type. But if you look at the life history, see, they don't look alike. Like corn has a very tight cob. And if you look

at this intake, it is all in a open in fluorescence. And see, it just falls. But that is not the activated type. And now so it is a little weedy, but not maize.

That's why we really want to say which one we are really dealing with so that we can focus our responses for all this weed risk question to specific to those group of plants which we are really interested, not everything under the sun, because some crops have, you know, germ blossom which is weedy.

For example, a canola. For example, if you take canola, there are two types of canola. And also there are different types of species of canola. There are three species of canola, for example, Brassica napus, Brassica rapa, Brassica juncea.

But which one we are dealing with, because napus is sun pollinated. Rapa is outcrossing. And juncea is really small, but it doesn't -- completely not outcrossing or selfing type. That is, it has entirely different

reproductive traits. So how do you score it then? That's why we want to know which one we are dealing with.

Napus, really napus there are two types, winter types and spring type. Which one, because why it is important, they might have entirely different life histories. We really do not want to mix up these two life histories and do a Weed Risk Assessment which might have entirely different outcome. So that's why.

So we really want to put our scope to a specific variety or cultivar of the elite cultivars, like maize. If you look at the history of maize, which is in 10,000 years or 8,000 years ago, which has a very narrow genetic base when maize select it, right?

Now, if you look at the corn and most of the corn today is five or six elite lines in the last 50 years. Most of the hybrids have the same base.

So it's so easy to probably do a Weed Risk Assessment for corn but may not be for rice,

because rice and sorghum, they are so wide, same species, right? But they have entirely different types.

Sorghum bicolor, you have a grain sorghum. You have a sweet sorghum. You have a fodder sorghum. They look completely different for the life histories.

So that's why it is very important that we scope our taxonomy in such a way that we know what exactly we are dealing with when we are responding on weed discussions.

And the second one is when you're saying, you know, it's a limited plant within and below the defined taxonomic level, that is when we decide, like rice, you know, we are not talking about red rice here, weedy rice. We are talking only about cultivated rice.

So also if it's Japonica or Indica type, they are different life histories. Then if it's a Japonica type, yes, we are dealing with that short, dry type of rice, not Indica type.

Okay. Sexually compatible relatives,

this is -- people are highly confused by this one, because when we say sexually compatible relatives, first it has to cross with the particular species, then produce seeds at least issue survives.

But it is so general. When we say compatibility, it is 1 percent, 5 percent, or 100 percent?

Like sorghum, it crosses with shattercane 100 percent. It's sexually compatible. But it can also cross with Johnson grass. But what is the percentage? Maybe 1 percent.

So we want to define that point also because what are the degree of compatibility? And with that they are weedy or invasive ,and with that it is in the years, because all this are very important for Weed Risk Assessment.

But I really want to explain, when we say sexually compatibility, it is not 100 percent. We really want to know, because this helps us for assessing the risk scenario. The

possibilities, the plausible pathway, all those things depend on some of these things.

So if there is a sexually compatible relatives, for example, sorghum or rice or, you know, some of the native biofuel species, then we really want to know that there are sexually compatible relatives in the United States.

If they are not there for corn, then the question doesn't count, you know, Weed Risk Assessment type. But we have to separate Weed Risk Assessment, if there is one. Okay. It would be hard to do it. You know, we do not want to extrapolate whatever we have done for a crop plant to the weed if it's sexually compatible. We have to do separate Weed Risk Assessment for those. And we did it sometime.

Plant history, and as I said, you know, this has nothing to do with weed risk per se, but this gives background information. Area of origin, and when it was introduced into the United States, that is very important, because there are sleeper weeds. You must have heard

this one, right?

Plants do not behave as weeds for long. They persist. And suddenly they become weed after some time, which are called, you know, sleeper plants. And we do not know the reason. People have speculations. So that's why when it was introduced into the United States, if it has been cultivated for hundreds of years, it has never escaped, then we have a very high confidence that it may not have any weedy traits.

Plant biology and ecology, this is equally important because the biggest problem is ecology, the one which we do not have really a big handle on because plants behave so differently.

Let me give you an example. I was working on a species. And it has, in the center of origin it was never weedy. It was to escape, and plants will die out. Every two years it will die out. It will escape. It will die out.

It was introduced into California. And within 100 years we have a weedy relative of

this crop in California.

Then we wanted to know, okay, then will it become weedy in other parts of the United States. We did a common parent experiment. We put it in Michigan, the same plant. Parents, we knew the parents. We knew the hybrid, that is weedy. And we put it in Michigan, plant dies. Weed doesn't survive that plant. But it is a weed in California. See, it is so difficult to sometimes to predict because of this ecology, the environment. So we really want to know this ecology problem.

Agronomic practices used in cultivation, and management practices, this is also included because we are dealing with an agricultural plant and its impact. You know, these practices are also involved in our Weed Risk Assessment.

Okay. Another one is, so why we are doing all these things? So you might be wondering. Again, you know, I will come back to the same thing, systematic approach.

Here we are following, what you call, deductive reasoning. We took all these characters, and we want to have a predictive model, right? That's what science is, that you want to have a system which can predict. You know, that's what science is. That's why we are doing some of these things.

Current and potential distribution means, remember here, when we say this one, it is not the cultivation. For example, you can grow sorghum in North Dakota. But when do you grow it in North Dakota? Not in the cold season. When it is really warm, because in the cold season this plant won't survive.

So when we say distribution, current, not the man-made; that is, whether it can survive without human intervention. That is, did we see this plant surviving without human management?

So that's what we want to -- why do we want to know this one? Because this is an indicator whether this can survive, then persist, then become invasive. These are the different

stages.

That's why, remember, now our paradigm shift here is it is not under human cultivation. It should be naturally whether it can survive.

But people, most of those people say, oh no, you know, you are dealing with corn, domesticated plant. It should never survive. You know, why you are really worried about, right?

But always there are counterexamples in science. For example, somebody said sorghum. Show me an example where it can survive outside. We've never seen it. You know, it's highly domesticated.

You got an example. People go on a walk. Then somebody asked, it looks like sorghum, you know, on the side road. Okay. See, there's a counterexample for what we believe so far.

That means, yes, it can survive. Just like that's why we want to know, if you already know that the plant can survive, then it gives

more predictive power for us whether it can spread.

So that's why, you know, we want to highlight what is the potential distribution of this plant, whether there are any records of the plant surviving without human intervention.

We generally develop maps with, you know, rainfall and also hardiness. I think like, you know, maps really helps us, you know, better than just writing 1,000 words. That's why, you know, this picture, it really helps with decisionmaking and risk management. I think you should appreciate this. You know, we are taking a very systematic approach.

Okay. Current and potential distribution. Do we have an example of this one, because a lot of people ask us, you know, when we do a Weed Risk Assessment, let us say, okay, where it is cultivated, like sorghum. And I'm just giving you sorghum because it's a really good example and nothing to do with sorghum people, because people blamed us using sorghum,

you know. But probably there's a better example.

Sorghum is such a hardy crop, such a beautiful crop if you have seen, right? It is so colorful, you know, seeing the plants.

Okay. Now, where it is cultivated in the years, for many political reason are the reason sorghum can't be cultivated in many places. They don't cultivate it simply because only a few places it is cultivated. Okay.

Can it grow in other places? Okay. People said, yes, it can grow in North Dakota. But, no, can it grow without human invention? Okay. Probably not, because you need a minimum soil temperature to grow sorghum otherwise you don't get a sorghum crop.

So that's why, you know, these are the things, where this is currently growing, what is the potential if it is without human assistance, where it can grow unassisted, where it grows unassisted in a climate match.

Well, the third one is, even if it is not grown in the United States, do we have

evidence in anywhere in the world where it can grow in such a climatic region, very cold climate, in a cold temperature, highly rainfed condition. It doesn't like waterlogged condition.

So the example here is whether we can have a predictive power collecting this information, because more predictive power we have, better decisionmaking we can do.

Okay. GE trait, yeah, all we are doing is the, you know, Weed Risk Assessment of GE trait, right? People always say, I always have a counterexample whenever people say people come up and say, it's a corn. How can you make a corn a weedy plant, right? Yes, that's correct, you know. So they think that phenotype enough.

When we say GE trait, we want to know the mechanism, what happens to the phenotype, and is there a pathway to risk, right?

I will give a couple examples. People always ask, okay, see here, we're really not exactly looking at only weediness, whether

there's an impact, which I will come to later. Okay.

So, here, really, most of the domesticated crops cannot be weedy. We know that. But is there a potential weediness we can create? Oh, yes, there are examples.

If you really want to know, all the major crops have a feral population somewhere in the world, means still they are not completely got rid of their wild characters.

Okay. For example, rye, which has a wild rye still. Take a barley, there is a wild one. Rice, there is a red rice. Means, you know, most of the crops they have the wild relatives, means if you let -- you know, there was an experiment when I was doing Ph.D.

They wanted to do de-domestication. If I leave the plant in the wild, will it take the wild characters again? Yes, some plants do, like canola probably because it is not completely domesticated.

Yes, what we are doing that's a GE

trait, what is the intended phenotype, okay, the mechanism of action by which phenotype is conferred and other potential phenotypes.

Okay. Somebody came up with, okay, a plant which produces 100 percent more biomass because of the one gene. It's a really desirable trait for the company, but -- okay.

So why are we interested in this? Okay. So evidently it has 100 percent more biomass. According to the Weed Risk Assessment, this is a weedy character because of really high fitness character, because 100 percent more biomass means it has so much, you know, potential to survive.

But I'm not going to give the results because, you know, we have not tested this one. But what I mean to say here is we really -- because of the phenotype, though it is a fitness trait, but we always at the end look at the risk scenario, is it really going to affect.

But this is what we look at for the GE trait. Most of the GE trait, what you guys are

doing may not have a fitness trait. But there are certain GE traits really has the very high fitness traits, which, you know, I may come, I may not come at the end because some of them are CBI probably.

Okay. These are the risk questions we ask. See, if you look at it, we have 15 biology questions and 9 impact questions.

Oh, this is very important. Most of the people who do a Weed Risk Assessment, why they do it, what are the impact of weediness? The risk assessment, you know, came from a chemical risk assessment model. In the chemical risk assessment model, they always worried about toxicity, impact of toxicity. And here what we are worried about is impact on agriculture crops. So the impact is different, though the model really came from toxic studies in the beginning.

So we have how many -- I can't see. There are 16 biology character and 9 impact characters. And I will cover, you know, some of them. And I also want to know how exactly we

score them, okay, in terms of how exactly we respond to these questions and how we score them for the weediness.

Okay. How these characters are evaluated, do you really have to have information on all of them? No, because it's a comparative approach. Probably 90 percent of the things we already know from the baseline information. Like corn, soybean, canola, we already have this information, either through the literature or through experiment or through the existing application. Those informations are already there. We are not expecting anybody to collect all this information.

Okay. So this is known weediness, current weed or invasive status, whether it's a weed. Most of the domesticated crops, no. But there are always exceptions. Some people, you know, submitted a weedy species saying, you know, we really want to use this because this is really a good biofuel crop. So it gets a very high rating if it's already a weed.

Weedy and invasive relatives, so does it have any, you know, weedy relatives? Yes, there are a lot of crops.

You see the last year in Crop Science. You know, Crop Science, there was an article. How many of the crop plants have weedy relatives or wide relatives? Means we know. Some of them have already weedy relatives.

Then the competitive growth ability, because these are the things which come from the model already existing and we've just borrowed it. Competitive growth ability, so this is really important. See, the competition in wild, it is when we say this one, not in agriculture.

For example, we grow plants in such a dense population, but in other things which -- because it is human assisted. See, it's ability to establish an existing vegetation without human assistance. Ability to grow in dense thickets, shade tolerance, and life forms.

Why did we take these other things used in the earlier Weed Risk Assessment model

which has a really predictive power? Like if it's a viny type, there are more viny types which are weeds. See, that should be included.

Ability to grow in dense thickets means it's really competitive. That means with other native plants.

Ability to establish an existing vegetation means it can survive and it can compete. Those are the weediness traits. But we really want to look at whether the domesticated plants have these traits.

Okay, reproduction. Was there time to reproductive maturity? But there are two things. Some of the plants, when you put stress suddenly, they flower and produce. Oh, that's high fitness traits.

But there are plants which can withstand stress and does not produce seed, but it will produce next year. Both are, you know, weediness traits. But it's context-dependent.

Then reproductive potential. This is a very hard part to answer for agriculture crops

simply because agriculture crops are selected to produce more seeds and more biomass for a particular. But is it a fitness trait? Yes, for a natural plant.

Now, weed is a context now. If it produces more, is it really fit in the sense of, you know, Darwinian evolution? That probably we have to test. Just because it produces 100 more seeds, it may not be more fit.

Then, dispersal, this is important whether it's a natural or artificially selected plant; simply because you disperse more, you have more chance to establish in a different habitat that gives more opportunity, yes.

And the dormancy, which is equally important, because if you are more dormant, then you have more chance to avoid stress and you can germinate when things are really favorable. This is really a fitness trait.

If somebody submits a rice plant, a weed, which can have a ten-year dormancy, then we want to really look at it because it can survive

long and better.

And regeneration ability, yes, this is another most important fitness trait. You damage the plant again and again, but it can come back, returning. So that is a fitness trait, means it has more survival chance.

Then stress tolerance, all of them are fitness. It doesn't matter whether it is in agriculture or a natural plant, but all of human, not human assisted.

Remember here, flood and drought tolerance, poor soil, cold, and biotic stress, The acid we put because it is all without human assistance, because when you said drought tolerant corn, people say, oh, is it a more fitness. But even drought tolerant corn, you really irrigate. You put more fertilizer. It will survive.

Then, you know, why do you want to call it as a drought tolerant? Probably it can withstand loss of 10 percent water. But still it is human assisted. No, we are not talking about

that drought tolerance; without human assistance.

Okay. Then is the second part. See here, all of this weed risk, what we are doing is whether it has an impact. That is, we do the Weed Risk Assessment, then there are certain impact question.

For example, see the basis for impact question is protect agriculture plants and agriculturally important natural resources from significant damage caused by noxious weeds.

Okay. What are agriculture plants? The plants which we really want to grow. There may be a plant which is not agriculture. When you start cultivating, it becomes agriculture plant, right, which has a value.

Second is -- see, there is a second part, which is a little bit difficult and lost, that is agriculturally important natural resources. It can be soil. It can be, you know, water. And it can be variety of, you know, non-target, you know, beneficial insects. Everything is agriculturally important.

That means one is very specific, another is really broad. So we want to see the impact on those things from the weediness. That is, we have to show a pathway to impact, plausible risk scenario. So that's what we want to know.

The first part is very systematic. Second part is already decided: what impact we really want to look at it. These are the impact questions.

Agricultural plant yield, whether it's an impact. Like, for example, by growing a plant, a GE plant, is it going to affect the agriculture plant yield to the competition, for example?

And agricultural plant product quality. I'm not going to explain everything because some of them are self-explanatory. I will only pick some of the important things how we respond.

Harm to agriculturally important organisms, pollinators, predators. This is very

important. What if, you know, you produce a pollen-specific, insect-resistant trait which will also affect pollinators? So that's what we are looking at. That is, is it going to affect agriculturally important natural resources?

Competition with other plants, abiotic change in hydrology, for example, these questions we already ask. If you grow a plant which is deep rooted or which can withstand water loss, which is drought tolerant, would it suck up more water from the existing, you know, resources and reduce the water table? Then it is affecting agriculture resources.

Change in soil quality, this is another. Like you can grow a GE plant. You select it in such a way that it doesn't need extra fertilizer, but it can make it barren. It can suck up every nutrients and still survive and make plants unsuitable -- no, the soil unsuitable for future agriculture.

Is it a theoretical scenario? No. If you know, this is happening. It made plants, the

place so barren people could not grow other crops.

We have examples for this, some of the things we already listed here. It's not theoretical anymore.

Change to fire regime, by growing your plant, whether it will be really change the fire hazard. This will be borrowed from the other Weed Risk Assessment model.

Physical obstruction, because some of the biofuel crops, if you grow, I don't think, you know, even the birds and snakes can't crawl, it grows so thick and it obstructs everything, you know.

Let us say you grow Arundo, which is really, you know, a good biofuel crop but it's a weed. If you grow that one, probably after three or four years the rhizomes become so big it may not be possible to, you know, do some cultivation in that plant because it's full of rhizomes and it's so hard to even move, so physical obstruction.

Okay. This is the concept we wanted to tell. Okay. So I'm collecting information. Okay. And here what we wanted to say, what you call, this dogmatic bias, you know, if you know the expert opinion.

I just want to give you an example why this concept is so important when we collect evidence-based. Okay. Here there are two things.

When I collect a response, there are two things that are important, how certain we are in saying that. You know, you may disagree with me. You know, I say, oh, it has a dormancy of, you know, ten years. Okay.

Like canola for example, you know, there are reports that, you know, it can be, dormancy can last ten years. But some people say every dormancy is two to three years. You know, it is highly domesticated. Okay.

Now, how do we really want to, you know, reconcile these differences? So that's how certain we are in whatever response we provide to

this weed discussion, because it can change. Certainly I can make a particular plant weedy with evidence if we are really not certain about the response.

So a risk assessor evaluates and communicates the degree of certainty by assigning ratings to each of these 25 questions. And the documenting certainty is different than documenting risk.

For example, if I do not know that, you know, it has a dormancy or not, that doesn't mean we are talking about risk here. I'm not certain about this particular trait. It has nothing to do with risk here, because risk is an entirely different thing, because, as we know, the weed, not a particular trait between plant risk. It can be a syndrome sometime because that's why, you know, we do not have a predictable based on only one trait.

Okay. How do you say certain? There are two things, reliability and applicability. So under this one, I have a publication in, let

us say, Nature about canola. And somebody writes about canola. And they say canola has a really, really high dormancy. Okay. Published in Nature, right? But where is the experiment here Okay. So reliability and applicability means how reliable just a statement.

Let us say we have an extension journal for example. Somebody, you know, really studied canola and the dormancy. He took different varieties, put it in the soil for five years. Every year he, you know, looked for whether it is still viable.

See? So that is the difference. It is the reliability of this, that particular publication, not just, you know, the quality of, what do you call, how important the journal is, whether that result is reliable.

Second one is applicability. What other type of information? Is it really applicable for the question I'm asking.

For example, someone says here -- this is very common, especially in GE. Oh, it can,

gene flow can occur to the wide plant. Okay. Now, when I'm scoring now, so did they really do an experiment, or, you know, what kind of experiment they have done, you know?

Let us say they say, you know, gene flow occurs because, you know, under the second record somebody already said, because they might not have looked at the experiment, what they have done.

Okay. And to say gene flow occurs, the question is what kind of experiment did they do. And even if the gene flow occurs, sometimes, you know, people really want to look at, okay, are they really saying they're sexually compatible, or are they just .0001 a percent that you found.

So you have to really look into the experiment in the publication to say whether, whatever I'm saying, is it really applicable to the question I am asking.

So we look at the both of them to the certainty. This is very important, because the

way we score, whether it is a high risk, low risk based on some of these traits, might change the Weed Risk Assessment. That's why this is very important, how certain.

This also helps our decision makers. I'm just saying, you know, there is a risk for plausibility, but I'm not certain. Certainty is low. So then our decision makers will think about it, you know, before making a decision, because how certain we are in making a particular decision.

Okay. Now, I've come to there's a final one I think. Yes. All right. Coming to why we are beginning here again and coming back to the same. We have this hand waving approach of expert opinion when we do Weed Risk Assessment, not really following a very systematic approach.

But we believe, you know, if it's a science-based organization, it should be systematic. It should be consistent. It should be predictable, right? That is science. That's

the -- normally we call it, you know, a direct inference based on what we know and that we can predict certain things.

So that's why, you know, we are taking this more systematic approach. People always come back, you know, it's a corn. Why are you doing this one? It has nothing to do with corn here.

There are a variety of these regulated articles. You really want to put the same filter for all these things.

So we don't want, expect corn to become weedy. But we can say that, see here, it has a predictive power. Corn and soybean will never be weedy. But if I put switchgrass on miscanthus, it's a different issue.

But they were all tested on the same scale. It's no different. It's systematic and consistent. And it should be able to predict whether, you know, based on the number of traits which are tested by other Weed Risk Assessment model.

Helps assessor identify critical weediness and impact characteristics for a given species, that means this is what we are doing. Let's us say you include the dormancy. You include the dispersibility. You increase the biomass and everything. Yes, we really will know how the risk scenario, because these are the traits, has very high fitness. Would it really affect now weediness traits?

See, this is really predictable based on, and that's why we don't want a laundry list of traits you have to collect. We really want to, you know, narrow down. What is the risk scenario? Which characters can it really affect the weediness here?

Identifies characteristics of GE plants that could plausibly increase weed risk, comparative assessment. So this is what we want to do, finally narrow down and, depending on the GE trait, is there a risk scenario.

Very systematic here, you know, it's not random. You're not asking, okay, for one

question for plant, another question for another plant. Based on our analysis, what is the risk scenario, or is really a risk scenario?

Help identify important knowledge gaps, this is very important. Rather than asking you to collect a bucket list of, you know, laundry list of traits, now we know based on certainty. Let us see, oh, I have a concern.

Okay. Can you do only this test if we really want the data? You know, I'm not saying that we are asking for data or, you know, we want to collect data. We really want to know which data we can collect, see if we can narrow down, which is based on rational, deductive thinking, not random you are asking for, collect data, let us see which data we want.

Or, you know, even for the risk assessor, do not go on a wild goose chase. This is what we want to really look for, this particular GE plant.

Okay. So that's what we did. Again, I want to say why we are doing, you know. It is

really, you know, whatever decision, just want to give you a couple of examples to make the point very clear why it is more scientific and systematic than, you know, it's not an expert opinion. Just want to give you, you know, two -- some of the celebrated examples about science, why it should be systematic.

If you have heard a famous study, Richard Leaky, who is the famous paleontologist who worked on, you know, human evolution. And nobody can question him because nobody really worked on paleontology in so many facets. And he used to publish in Nature.

And when Sir John Maddox, who's a famous Nature editor, when I was attending his talk, he said, you know, why sometime expert opinion can really derail science. Why I'm saying expert opinion? Because sometimes we followed expert opinion for weediness and even for the GE plants. We called them, you know, do you think. So sometime it is really misleading.

John said, you know, he wanted to

bring peer review system to Nature because it's gentleman's club, old boys' network. So people, you know, if you know you can publish it in Nature that time.

So he said, he asked Richard Leaky, you know, we want to develop a peer review system. Can you mention two people who can review your paper?

And Richard Leaky said, you know, if you are sending it for a peer review, I'm not submitting. Then John asked why. He said I am the expert. If I say so, then it should be true. Why peer reviews?

See, this cognitive bias, you know, if you become, you know, you say something, then it should be true. So we want to avoid that. We want to put everything in a scientific, every plant should be treated. It's not in just expert opinion.

Second, there is an advantage here. People always ask, did you do Weed Risk Assessment? How did you do it? Right?

We said, yes, we explained it on plant-based risk. It's like writing an essay story. And, you know, we just write that if corn is there, it's not a weed, right?

But it is not possible for every species. You really want to have some predictive power, right? This we can do now.

Based on the domesticated traits, I can really say I've collected all this information for corn. It can never be weedy based on, you know, all these things. You know, I'm not just making it up.

But at the same time, then maybe another species, which can be weedy but same set of characters. So that's predictable we want to have.

But we will have 100 percent predictable, may not be. That's why there's a decision making. As Mike said, it depends on certainty, whether there's a management, you know, practice available, all those things. But at least I can provide Mike these other things.

You guys can make a decision.

So, but we are very confident saying that, you know, why we think this is a risk. Because we looked at all these traits, that's why we think that it's a risk, you know, plausibility.

Now, I'm not making it up other than, oh, I think so. No, I believe so. No.

So that's why, you know, this is very important, not to suddenly make every plant risky. No. Have a systematic, consistent approach so that we can say, yes, we did, you know, a science-based risk assessment, not, you know, just the hand waving.

So I hope you know we tried to give you, you know, why we are doing it and how it is useful. And I think, you know, it's really a science-based.

But, you know, biology is difficult. It's not physics. Everything is not black and white. Sometime, you know, weediness we see a corn is not a weed. There are a lot of shades of

gray in between. Then our decision makers will look into it, you know, what kind of, you know, decision they will make.

Thank you very much.

OPERATOR: Your conference is now in question-and-answer mode. To summon each question, press 1, then 0.

MR. GEORGE: We have a question on the phone.

MR. STEELE: James Steele from Pioneer asks, how will the separate WRA for the sexually compatible relatives be used in the assessment for the GE trait?

MR. HEGDE: How --

MR. STEELE: How will the separate WRA for the sexually compatible relative be used in the assessment for the GE trait?

MR. HEGDE: Mike, yes, because difficult questions will be answered by Mike.

MR. FIRKO: So our plan is if the initial assessment identifies as sexually compatible relatives, and if, as Subray was

talking about, if you look at it and you look at the likelihood that the GE won't introgress, if it's 1 percent, that's one thing, if it's 100 percent, it's another.

But in the case of a genetically engineered plant, the sexually compatible relatives, we're actually looking at three different risk assessments, the baseline, the genetically engineered plant, and sexually compatible relatives that could potentially obtain the trait.

And the decision, we'll consider all of the them. So you went too far on the decision part there.

MS. FLANELY: Gretchen Flanely with Sherpa 360. So a follow-up question would be this Weed Risk Assessment model and the questions here were developed for cultivated crops. And I'm not sure how then a weed then goes for a cultivated crop model.

MR. HEGDE: Can I answer that one? Yes. See, Gretchen, haven't you asked the same

question when we visited?

MS. FLANELY: Yes, I think so.

MR. HEGDE: Yes.

MS. FLANELY: We got a different answer last time. The first one was --

MR. HEGDE: Okay. Gretchen, it's a very good question. You asked how Weed Risk Assessment model is applied to cultivated crop, right? That's what your question is?

MS. FLANELY: Well, you're saying this is a new model for cultivated crops.

MR. HEGDE: That's correct. See --

MS. FLANELY: But now you're running a weed through the cultivated crop.

MR. HEGDE: Okay.

MR. PEARSON: It hasn't worked for wild relatives basically.

MR. HEGDE: How we do it for wild relatives, well, that is very simple because, see, your uncultivated crop, most of the answers depend on all those biotic, abiotic factors, whether without human assistance.

See, if you have a weedy plant, then the scoring is very easy, because all the behavior, whatever is from the weedy plant, is not with, you know, human assistance, right? We are not talking about volunteers here.

Give you an example, like for example, you want to look, sorghum is the best example?

MR. PEARSON: No, that's not the best --

MR. HEGDE: See, here, this stem easily is for weedy traits. And it will be easier for us to do this model for the weedy traits because they're all naturally selected, right? You can easily score it. Whatever is the information already available on this weed you can just plug in. But the difficulty is for scoring for the crop plants.

(Off mic comments.)

MR. HEGDE: Yes. That's why, you know, this one is different for crop plants.

(Off mic comments.)

MR. PEARSON: Let me just add, again,

the key here is that for almost all these questions we ask it in the context of without intentional human assistance.

So often times, you know, with the crop plants the answer is pretty much there's nothing.

MS. FLANELY: No, the question is you developed a new systematic approach to look at crops, right, and to evaluate weed risk in cultivated crops, correct?

MR. HEGDE: That's correct.

MS. FLANELY: So I understand that. What I'm taking away from this and the question is, if you're going to run the wild relatives through a cultivated crop model now, because that's what --

MR. PEARSON: I think that's what we're not communicating clearly. A key part of developing this for crops was incorporating two things, one the experience we already have in the U.S., okay, and because almost the crops we're going to see we have a lot of experience in the

U.S.

And many of the sexually compatible relatives, obviously, we're not going to assess sexually compatible relatives that aren't in the U.S. because those are not relevant to our concerns. So we have some knowledge base in the U.S. of the sexually compatible relatives.

And two, this concept of without human intentional -- without intentional human assistance, that's a key change from most existing Weed Risk Assessment models.

So I don't know if that helps clarify it. So a sexually compatible relative, if it's a weed or not, if it's growing on its own without intentional human assistance, we can answer the question.

And for a crop, similarly, if it can grow on its own without intentional human assistance, it would get one answer. And if it can't grow without intentional human assistance, the answer is going to come out differently.

So I don't know if that helps, those

two factors help resolve that dilemma or not. And, you know, if you have more questions about that, you know, we can discuss that in greater details.

But I want to make those two points, that those two things are the key shift, taking into account the U.S. experience, and then framing the questions in terms that without intentional human assistance.

MR. FIRKO: Let me just say something, too. And I'm not so sure that it's accurate to say that this was a system built just for cultivated crops.

MS. FLANELY: That's what I was hearing.

MR. FIRKO: It's a system that is focused more on cultivated crops than our other system. But my slides, being a primary thing here is that it's a way to look at genetically engineered crops.

And if you have introgressions from a genetically engineered plant to a weedy relative,

that plant isn't genetically engineered per se. If we just put a trait into that weedy relative, that only got there because it's a sexually compatible relative.

That doesn't mean that the model cannot be used for that. Yes, I wouldn't characterize this, and I don't think we've heard this characterized as a model for cultivated plants.

It is a model that is, that accounts for cultivated plants like no other one has in the past.

MR. HEGDE: I think, I just want to add to what Mike said. Our responses are different. See, I think that's what you are wondering, you know. This is already used for Weed Risk Assessment. This is not something we invented, right?

Our responses are different because -- let me give you an example, drought tolerant corn, for example. If you say, you know, it may -- drought tolerance gets higher risk rating.

But it may not get higher risk rating here simply because when we say drought tolerant, can it survive without human assistance?

If it is not, then really it doesn't get high risk rating. But for a weed to get a high risk rating, because it's already drought tolerant, that is the difference. The response is different.

MR. NESBITT: Hi, this is Clint Nesbitt from BIO. Subray, you were talking about extensions as being expert opinion versus peer review. Do you have any plans to have this model published for external expert peer review before you start using it?

MR. HEGDE: Mike.

MR. FIRKO: The model's currently under peer review, external peer review being managed by ORSD (phonetic), USDA ORSD. We need to enter that first and then see what we're going to do with that.

We thought about a possibility of publishing of it in a peer review journal. But

these things can be complicated by the fact that we've already presented this material as a poster at a scientific meeting. Some journals won't be so happy to publish it if it's already been presented as a poster at a scientific meeting.

So once we get through the ORSD external peer review, it's an anonymous peer review.

(Simultaneous speaking.)

MR. FIRKO: What's that?

MR. NESBITT: But it's not independent. It's still part of USDA's current --

MR. FIRKO: The reviewers aren't necessarily USDA. It's being managed by USDA, but it's a OMB style external peer review. OMB isn't necessarily doing those things very much.

So there's an agreement between ORSD, which is the USDA agency, USDA office, and OMB. And OMB acknowledges the procedure that ORSD is using as OMB style external peer review.

MR. REDING: Hi, I'm Keith Reding with

Monsanto. Is this model set up for the decision tree type of format where you get answers very quickly, that you don't have to go through every single one of these questions?

And the reason I'm asking that, it relates to throughput. How many of these can you, how many thousands of these can you run through in a maybe a month time before, planting season this far?

MR. HEGDE: Yes, yes.

MR. FIRKO: So, of course that's something that we've thought about a lot. One way to approach that is we get five products a year. And people want to throw every idea that they might have in front of them. Yes, the first few years it's going to be pretty tough.

If people want to know the answer to a question, for something they're really interested in, we can handle that.

Now I'm not sure why you would ever get thousands. We've never gotten anything like that. Right now we've got four of these

petitions for non-regulated, for listing as Federal Noxious Weeds.

We've gotten from the "am I regulateds?" three or four where we look at and say we need to do a risk assessment on that. And we get five petitions a year.

MR. READING: So the overall context of my question, I was thinking as an outcrop risk assessment whether I'm regulated, you know, either in the system and then you get out, or if you decided up front you're not in the system. It's the -- what are the options in the Notice of Intent?

MR. FIRKO: Well, we're operating under our current regulations right now. So you're asking a question that goes to what does the future hold and what does the future reg look like.

(Simultaneous speaking.)

MR. READING: So this model that we're discussing is only for petition risk assessment --

MR. FIRKO: As I said in my opening, there's four brief reasons that we need to use it now for things that we're doing. And a possibility is if we have to regulate it in the future, it may be useful if we incorporate noxious weeds in the future.

(Off mic comments.)

MR. HEGDE: Gretchen, yes, she --

MS. FLANELY: So kind of a two-part question. Have you run some of the baseline crops through to date? And two, based on that, what are you finding the timeline to run that through and come out with an output and how really sure an output is coming out?

MR. HEGDE: The first question is yes, we did some baseline already through. Second one I'll let Alan answer. Alan?

MR. PEARSON: So the second one, there's not a completely clear, straightforward answer. The baselines take time. And we really want to dedicate that time to them because all GE plants' Weed Risk Assessments will be launched

off of those. So we want those to be really solid and well done. And our staff can complain about their bosses and how mean we are.

But it's also a little more complicated because we're still, you know, this, the development process around this Weed Risk Assessment System has been iterative.

So we've been kind of doing and developing and learning as we do them and then developing more. So it's kind of still, you know, we're still in that process.

And that's one of the reasons we're presenting to you today to see, you know, where we are, these are what we've got, and hear your questions about that. And so that, you know, gives us some more information as we go. But it's not a finished product yet.

MR. KERSHAW: It's Joe Kershaw (phonetic), Office of Government Affairs. Well, first on the peer review question, on the publishing of peer review I'm just going through from USDA CPHST who did the risk assessment, Weed

Risk Assessment CPHST. His was published and, you know, I think was referenced here in this presentation. So I really encourage you to go through that process.

And I have this email here, you know, including your vision on a poster, you know, with that, will that really prohibit someone from publishing. So that would be something I really encourage.

As far as a question, you know, I recall on the Notice of Intent, you know, the discussion and responses regarding the definitions of what's biotechnology and, you know, biotechnology products.

But here we're really focused on genetic engineering. Can you give us -- so what's your definition of the genetic engineering or genetically engineered --

MR. HEGDE: Current one is recombinant DNA technology and --

MR. FIRKO: It's in our --

MR. HEGDE: Mike -- yes, whatever is

in.

MR. KERSHAW: Okay.

(Simultaneous speaking.)

MR. FIRKO: There is a definition that says products that were created using recombinant DNA technology and the plant test was involved in their production, either as a factor, a donor, or a recipient to get that information. That's our current --

MS. CULLER: Hi, Angela Culler, Monsanto Company. Can you talk a little bit about how this isn't a current extension process?

MR. HEGDE: Current extension?

MR. CULLER: The extension of deregulations, does it?

MR. HEGDE: It's --

MR. FIRKO: No more than a --

MR. HEGDE: No more regular here.

MR. FIRKO: I mean, an extension is a different type of petition. And in the petitions, weediness is looked at as per the regulations. Our decisions are not based on

that.

MR. PEARSON: Additionally, I mean, so extensions are usually, they're extensions off of previous determinations.

So the main question we look at in the extension is this new event or this new genetically engineered organism similar to a previously deregulated or antecedent organism? And if it is, then we're basically saying the conclusions from the previous assessment apply to this as well.

So if you're asking would we use this and go through this whole thing when we do an extension, if it's similar, no, because we're going to be launching off the previous.

UNIDENTIFIED PARTICIPANT: Question, you guys said that your staff has gone through about five of these already?

MR. HEGDE: No, not just five.

UNIDENTIFIED PARTICIPANT: Okay.

MR. HEGDE: Several.

UNIDENTIFIED PARTICIPANT: Several?

MR. HEGDE: But we don't want to give, because even the several went to several iteration.

UNIDENTIFIED PARTICIPANT: Oh, okay.

MR. HEGDE: Yes. Like, you know, corn probably would be ten times. So --

UNIDENTIFIED PARTICIPANT: Will those be made available just to see how they work with all these 50 questions in line where they went or a subset thereof on -- not all the iterations are going to be on there, but where the latest one might stand. So will they be made available at some point?

MR. HEGDE: Mike.

MR. FIRKO: At such time that many of these are used to inform a decision, that information will be made available.

And since we're not making any decisions in BRS right now based on weeds, the decisions that we have been associated with -- for example, we received, APHIS received petitions to list some genetically engineered

plants, field grass, corn, soy, sorghum, as Federal Noxious Weeds.

The responses that we just made to those were made according to CFR 360. And those were made available on PPQ's web site.

Those were based on a different model. They were based on the model that APHIS uses currently for Federal Noxious Weed Risk Assessments.

What we talk about here is not a decision tool at this point. So we haven't made any decisions on that yet. At such time that we make a decision based on this system, the risk assessments will be made available.

(Off mic comments.)

UNIDENTIFIED PARTICIPANT: So can you guys talk about the CPHST Noxious Weed Risk Assessment model? And my understanding the way that that was developed is that, you know, it's got a various amount of sort of factors than the one we use today. So when did they figure out kind of weightings to those risk factors was to

sort of do a professional analysis of the --

MR. HEGDE: Right.

UNIDENTIFIED PARTICIPANT: -- noxious weed. They come up with the weightings of various plants, and then they test them. That gets a separate set of noxious weeds to develop whether the model was predictive or not.

So have you done something similar with this type of model? If not or if so, how did you figure out the weightings of these various factors that you're considering and whether that is truly predictive of whether something is a noxious weed or not?

MR. HEGDE: I think that's a really good question. We thought about it. But only difference here is we do not have the true control, like GE plants becoming weed. Let us say no.

In the Chinese (phonetic) model, there's no weed really to compare, right? So that way, you know, you can demarcate. But our true control really is whether there are GE weedy

plants which we can plug into the system to see which one is really weedy. Then you cannot demarcate. I don't think we have that one, true control.

But can we use existing weeds? Yes. But they're not true controls.

UNIDENTIFIED PARTICIPANT: So --

MR. PEARSON: Let me elaborate also a little bit on that. And I've pulled back up this slide.

What we're doing here is quite different than what the CPHST model does. So you talked about weights and validation and so on.

And you might recall, when I was presenting some of the background on this Weed Risk Assessment, I talked about that system in a way, if you want to think about a framework that underlies that system, it would be, you know, this kind of framework in a general sense.

And what they have done is come up with all these questions that they've put weights on and they've put scores on. And they have

these thresholds. And you're above the threshold, you're high risk. You're below a threshold, you're low risk. And they categorize that way.

And that's another way in which we think that approach doesn't actually work for what we need to do.

And so we've moved away from that kind of scoring and threshold approach and really much more towards this approach of seeing are there differences, plausible differences. Do those lead to plausible risk scenarios? And what are the -- and how do we evaluate those scenarios?

And as I think we've tried to stress, we're not doing sort of a wild goose chase here. We want this to be evidence-based.

We expected in many cases we're really not going to have plausible risk scenarios, and that's going to be the end of it. In some cases we may, and we're going to need to do some more assessment.

And then however decisions are made,

we're not talking about that today. And that falls into the risk management bucket. So this is just the assessment process.

So in that way it's a different beast, if you will, than the CPHST Weed Risk Assessment model or the Australian Weed Risk Assessment model.

MR. FIRKO: So let me go back to the comparison of the risk models. He was really lucky because there is an extremely rich literature out there about weeds, about thousands and tens of thousands of plants and are they really bad weeds, are they intermediate weeds, are they not very weedy.

And he was able to run several hundred of those plants through where the weediness was already known, and he was able to validate this model that way.

We're reconciling these anonymous reviewers right now to some degree because they've raised the same issue.

So if we're developing a system where

we want to say we've genetically engineered something or -- and you want to look at that particular plant, or you've genetically engineered something and it has moved into a sexually compatible relative, how many examples are there where a look at that weed was created that way?

So our ability to do that kind of a validation is essentially nil right now, because I'm not aware of any examples where somebody genetically engineered a plant and turned that plant from a non-weed into a really bad weed or someone genetically engineered a crop plant and there was introgression to a sexually compatible relative and that became a much worse weed.

So we have a real problem with validation here because there isn't a body of scientific information out there about what happens in terms of weediness when you genetically engineer a plant.

MR. HEGDE: I think it's a really good question because my hypothesis is, you know, you

know, generally do not become weedy right now.

(Off mic comments.)

MR. GEORGE: Any other questions?

MR. HEGDE: Okay. Are we done? Okay.

(Off mic comments.)

MR. GEORGE: Please. That's why we're here.

(Off mic comments.)

MR. HEGDE: We promise you one thousand if you got a question.

UNIDENTIFIED PARTICIPANT: So we asked this question when we met with you back in September, but I'm curious. Will there be a similar design of a systematic way on the plant pest risk assessment?

Since you're trying to make this a more systematic way to look at weedy, the weed risk, will you do something similar, or will there be some changes going forward on plant pest risk assessment?

MR. HEGDE: I think this doesn't really apply to that one. But relatively

speaking, that's easier because you can quantify. And we have already, you know, we do it different way because -- let's give an example.

Is it a pink ball (phonetic) when we do damage? And you can really quantify it. But the methodology, you know, are we developing new one? Mike will answer that.

MR. FIRKO: We have put together the uses that we're looking at plant pest risk. It's very different.

APHIS has been focused on plant pest risk very intensively for decades. And within APHIS there are tens of hundreds of risk assessment approaches that are used.

Like Alan I think also said, it seems much easier to look at the scientific literature on an arthropod or a mollusk or a microorganism and being able to answer the question, is this a plant pest just seems to a lot easier for whatever reason.

What we're tackling is a much harder question not only for base species of plants but

for things for which we have no experience like corn that's got a trait that it never had before.

So, yes, we do have a new system to look at plant pests. It's more designed at is it a plant pest or is it not.

And with our history of having our regulation be based on that, we have much more experience. But, yes, we're going to have a new system at some point in the future.

Right now our needs are to use the plant pest as a measurement or as a donor or as a recipient. So it's pretty simple.

MR. WIESENMEYER: Thank you. Mike Wisenmeyer (phonetic). So I think you said this earlier, but I just wanted to see if I understood it correctly, because the current issue with extension petitions, do they have the level of information that you need in the model that's currently submitted to make with some certainty a decision on the biology-type questions in the second half of the circuit?

MR. PEARSON: For extensions? Yes, I

mean, so, I mean, the answer on extension petitions is that the question doesn't, shouldn't come up, because extension is, the decision on the extension petition is based on is this organism that you've placed in front of us similar to something we've already made a decision on.

If it's similar to something we've made a decision on, we're going to make the same decision.

MR. WIESENMEYER: Because there has been --

MR. PEARSON: Because it is already been, all that data came to us before. So the operative question on extensions is very different. And, you know, we need enough data to be able to conclude that this is similar to the antecedent organism.

MR. WIESENMEYER: But on petitions generally the current level of data provided to the agency would be sufficient to have with some certainty.

MR. HEGDE: Yes.

MR. PEARSON: That's been, that's our, from having looked through several, that's our finding.

I think one of the things Subray pointed out as one of the advantages of this possibly in the future is that it might help us narrow into where are the areas of uncertainty or where are the areas where we perhaps don't have as much information as we want.

So the developers can target a little more their research to those areas perhaps rather than giving us a huge amount of information as we often get in new petitions now. That may be something in the future, you know.

(Off mic comments.)

MR. FIRKO: Don't be shy. There's 15 more minutes.

MR. SORA: Nick Sora (phonetic) with AR Sciences (phonetic). I wanted to add to the discussion around peer review a little bit. What that really comes down to is the scientific

compensability of the user.

So my question is more on the process by which you arrive at the list of 25 questions or whatever it is. Did you work with weed scientists at WSSA or agronomists to figure out which was the existing questions and various models do the most? Is there a plan being made to publish more in the future?

MR. HEGDE: Yes, and that's a -- normally the weed scientists will look at their publications. I think that is easier. And also, you know, we -- but only internal, like the weed scientists within APHIS. But not really, we did not go out yet, because this is not public yet, whatever we are developing.

And I think if it really goes peer review outside, probably, you know, we will get a lot of, you know, input from those people.

Right now, I think, you know, we got something in ORSD. It went as probably a weed scientist. We don't know because it is anonymous.

But did we really proactively went out and ask? No. We looked at the publications, and we decided what are the characters.

MR. PEARSON: There are extensive publications that have looked at these kinds of things. And, of course, we also did have the advantage of the earlier Weed Risk Assessment models, so the Australian, the CPHST, and several others we've looked at.

Of course, we've talked about how we're doing something a bit different. But some of the questions, some of the underlying characteristics are pretty well established now in the literature.

So we've really taken a very broad look at that. We have also interacted with our colleagues within APHIS at looking at that. So --

MR. FIRKO: This is our, this is the first time that we've really gone out to any group and said here are the components of the model. And this is before we're even using it in

any operational sense. We're not there yet. There will be additional opportunities for --

MR. GEORGE: Thanks, guys.

MR. HEGDE: Thank you.

MR. PEARSON: Thank you.

MR. GEORGE: Thank you, Alan and Subray and Mike. A very informative session. I just had a couple small things I just wanted to mention before we close.

You're going to receive an email survey very soon about this meeting. We welcome your input and encourage you to please fill that out.

The presentations for this meeting today will be online probably within the next couple of days on our Web site, which you probably have bookmarked. And if you don't, it's easy to find. Just Google Biotechnology Regulatory Services. You'll get to right there.

And you'll be able to see the presentations. And a complete transcript will also be posted in the next three weeks or so, two

or three weeks to get the transcript up there.

One other thing I'd like to say, if you would indulge me for just a moment, it takes quite a bit of work behind the scenes to put together all the pieces and the logistics of a meeting like this.

And so if you don't mind, I'm going to mention a few names of people who have really worked very hard to make this possible and ask for a nice round of applause after I get through all their names.

And I'm going to start with a couple people who probably are not in the room, and that's Sarah Lively and Gale Jones, who are at the desk and were responsible for a lot of the logistics that make this work today.

Colleen Wood, who is sitting over here who has worked very hard with all the presentations and all of the logistics here, Eric Ford, who's helped over here, Robin Wilcox, who's at the computer over here working very diligently to make all these pieces fit together, and, of

course, Rick Coker, who is our main man in terms of like getting all this technical stuff together and making it work.

And I'm looking over my list because I don't want to leave anybody out. And also I would like very much to thank all of our presenters today who I think did a terrific job of sharing some pretty important information.

So if we could get a nice round of applause for all of those folks, I'd appreciate it.

So I want to thank you again for coming. We welcome this opportunity to share information with you and to get your feedback and comments.

And that's it for me. And I think Mike has maybe one closing comment. Thanks so much.

MR. FIRKO: In closing, thank you very much for coming and joining us.

For me, one of the difficult parts about this meeting, there was so much I wanted to

say that I couldn't really talk about this afternoon as much as this morning. I hope that very soon we can a different type of conversation about some of these issues.

MR. GEORGE: Thanks, everybody. Thanks for coming.

(Whereupon, the above-entitled matter went off the record at 2:52 p.m.)

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C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: Biotechnology Regulatory Services Stakeholder Meeting

Before: USDA/APHIS

Date: 11-16-16

Place: Riverdale Park, MD

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

Neal R. Gross

Court Reporter