

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

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

2 9:03 a.m.

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

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

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

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

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

1 registered this morning. Today we have both a  
2 morning and an afternoon session. The morning  
3 session will end around 11:30 and we will allow  
4 90 minutes for lunch to allow plenty of time for  
5 you to get out to lunch if you choose and back in  
6 time for the afternoon session on Weed Risk  
7 Assessments which will start in the morning.

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

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

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

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

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

1 keypad.

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

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

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

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

22           So, I'll start with some activities

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

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

22 Now, everybody in here is very

1 familiar with the technical word 12866, right?

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

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

21 PARTICIPANT: He's on his way.

22 MR. FIRKO: Okay. To revisions to the



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

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

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

1 until the notification has been acknowledged by  
2 APHIS.

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

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

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

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

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

3 So, regarding authorizations, this is  
4 pretty busy, but just to show you the data about  
5 notifications that we receive, how many did we  
6 receive and how many were authorized for import  
7 only. During Fiscal 16 we received 122 requests  
8 for import of regulated articles, 114 of those  
9 were authorized. For interstate movement only,  
10 397 received, 339 authorized and for released,  
11 358 and 328. Now, many of you realize that we  
12 have a category of authorization that is  
13 interstate movement and release. Altogether, I  
14 put those under this category of release.

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

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

7 Can you forward that?

8 There we go.

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

1 separately.

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

22 Again, not a trivial effort on our

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

22 Now, I spent a fair bit of time last

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

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



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

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

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

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

21 The proportion of inspections  
22 conducted by our state departments has stayed

1 relatively steady over the last decade or so. We  
2 meet with these folks, we provide training, it's  
3 a very good working relationship we have through  
4 the National Plant Board. Petitions for non-  
5 regulated status in Fiscal 16, we completed seven  
6 in Fiscal 16. Since my performance plan set five,  
7 this was pretty good. We now have 125  
8 deregulations that we've done so far. The 125th  
9 was done in last month or so, so it was between  
10 the end of Fiscal 16 and today. You may recall,  
11 because I've spoken about it over the last many  
12 years, that our first official process  
13 improvement was on the petition process; at the  
14 time we implemented that in March of 2012 we had  
15 23 petitions in-house; of those 23 only one  
16 remains. That's a petition for a freeze-tolerant  
17 eucalyptus, we're doing an Environmental Impact  
18 Statement for that, and I'll have a few more  
19 words to say about that in a minute.

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

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

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

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

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

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

22 And there are a number of IPCs,

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

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

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

3 So, looking forward to '17, which  
4 we've already started actually, continual  
5 improvement of permit conditions. Now, we met  
6 with various stakeholders over the last decade or  
7 so and we've heard from stakeholders about  
8 reception, some inconsistencies and there were  
9 some inconsistencies, between previous version  
10 of biotechnology quality management system.

11 Permit conditions, let's just say that from an  
12 internal business process improvement point of  
13 view, we weren't communicating internally as well  
14 as we should have, perhaps. We have been working  
15 very hard over the last two or three years and in  
16 fact Angie and John are leading those efforts to  
17 make sure that all the permit conditions that we  
18 put on a permit are clear, consistent and  
19 enforceable.

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

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

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



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

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

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

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

10 So if you haven't met any of our new  
11 biotechnologists, this is six of the eight.

12 Please take an opportunity to talk with them on  
13 the phone, to go ahead and say hello to them.

14 Thank you.

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

22 We will continue to increase the

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

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

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

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

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

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

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

1 years on this particular glyphosate resistant  
2 creeping bentgrass, so we weren't starting from  
3 scratch. We published the draft EIS September  
4 30th, we have a 45 day comment period, it ended  
5 this past Monday we got, I don't know how many  
6 comments we got, or does anybody know? 15. So,  
7 we're evaluating 15 comments that we've received.

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

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

14 MR. GEORGE: Questions for Mike?

15 MR. FIRKO: Greg.

16 MR. GEORGE: Wait for the mic, please.

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

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

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

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

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

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



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

4 MR. FIRKO: Thank you for asking it  
5 that way. I should have mentioned that any of  
6 the situations that we are aware of that are not  
7 as they should be are self-reports, somebody  
8 calls us and says I have some volunteers over  
9 here and my permit ended two years ago, they're  
10 not supposed to be here, we did have one of  
11 those. We did not discover it as a result of an  
12 inspection; it was a self-report, a farmer  
13 contacted us and there's some information on our  
14 web about this, this was some genetically  
15 engineered wheat that was found in Washington  
16 state. 22 volunteers, and after scouring that  
17 400 acre field we found 22 total, and all of the,  
18 we found that it wasn't the crop, all that  
19 farmer's crop was tested and nothing was found.  
20 So, those sorts. Is that what you mean by  
21 remediation?

22 MR. DONAHUE: Right, but my question

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

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

1 MR. DONAHUE: Okay, thanks.

2 MR. GEORGE: Dan?

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

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

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

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

10                   PARTICIPANT: Thank you.

11                   PARTICIPANT: A question over here.

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

17                   Go ahead.

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

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

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

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

20 MR. GEORGE: Other questions for Mike?

21 Any? No?

22 MR. FIRKO: Thank you.

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

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

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

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

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

15 So, we have a complex system here at  
16 APHIS; it's a huge and widely varying mission.  
17 Our regulatory activities covers animal health,  
18 plant health, animal care and of course the  
19 Biotechnology Regulatory Services. So, as part  
20 of this mission, each year we issue more than  
21 900,000 certificates, accreditation,  
22 registration, permits and other licensing. That



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

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

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

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

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

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

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

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

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

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

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

1 us.

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

4 Okay.

5 MR. GEORGE: Any questions?

6 Hold on one second.

7 MR. MONDELL: Scott Mondell here.

8 One, I want to say thank you for your continued  
9 willingness to reach out to the regulated  
10 community and bring us into the loop whenever  
11 you're ready.

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

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

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

18 MR. MONDELL: Thank you.

19 MR. SHAQIR: Thank you.

20 MR. GEORGE: Other questions? No?

21 Thank you, Ibrahim.

22 MR. SHAQIR: Thank you.

1                   MR. GEORGE: As we all know, there's  
2                   been an ongoing debate for years regarding the  
3                   labeling of food that is made with genetically  
4                   engineered ingredients; that debate led to the  
5                   National and Bioengineered Food Standard Law of  
6                   2016 which charges the Agricultural Marketing  
7                   Service of USDA to develop and implement  
8                   regulations and policy along these lines. AMS as  
9                   it's known is totally separate and distinct from  
10                  BRS, but since there's so much interest in GE  
11                  labeling, we've invited the AMS person leading  
12                  this effort to give you and us an update. You  
13                  may recognize her if you've been coming to these  
14                  meetings for a while; we're proud to claim Andie  
15                  Huberty as a BRS alumna and we're delighted she's  
16                  here to fill us in on the progress of this high  
17                  visibility initiative.

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

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

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

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

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

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

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



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

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

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

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

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

1 was language of the law.

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

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

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

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

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

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

4                   So --- oops. Thank you.

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

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

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

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

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

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

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

1 soup would not require disclosure under the law.

2 So, those are the two examples of exclusions.

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

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

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



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

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

13 So, that's the broad summary of the  
14 rule or the law. We have an interagency, now  
15 interdepartmental discoverment working group that  
16 will help us develop the documents that we need  
17 in order to stand up the program. We have a lot  
18 of public engagement going on, we're having a lot  
19 of stakeholders come in, we're giving a lot of  
20 these talks just to inform the community of  
21 what's going on with this. We have an email  
22 address, [GMOLabeling@ams.usda.gov](mailto:GMOLabeling@ams.usda.gov), we've already

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

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

19           If you have any questions?

20           None?

21           PARTICIPANT: Where does dairy fall  
22 in?

1 MS. HUBERTY: Where does dairy fall  
2 in?

3 PARTICIPANT: Yes.

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

19 Does that answer your question?

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

22 MS. HUBERTY: Yes, products that come

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

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

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

11 MR. GEORGE: Other questions?

12 MS. HUBERTY: Okay, thank you.

13 PARTICIPANT: Thank you.

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

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

21 Thanks so much.

22 (Whereupon, the above-entitled matter

1 went off the record at 10:19 a.m. and resumed at  
2 10:34 a.m.)

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

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

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

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

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

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

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

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

22           It has been a -- it has been a fun

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

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

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

22 This is the -- the audit from the OIG,

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

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

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



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

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

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

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

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

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

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

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

4 The third main area we focused on in  
5 fiscal year '16 was enhancing our inspection  
6 process. As Mike mentioned, we brought on six or  
7 seven or eight reg analysts. We really beefed up  
8 our staff who are conducting these inspections in  
9 the field. We committed these resources to the  
10 staff, and Mike again said we conducted more than  
11 60 percent of the inspections in fiscal year '16.

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

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

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

18                   MR. GEORGE: Questions for Christie?

19                   (No audible response.)

20                   MR. GEORGE: Anything online?

21                   (No audible response.)

22                   MR. GEORGE: Thank you, Christie.

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

6 (Pause.)

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

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

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

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

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

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

22             And a lot of what I am talking about

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

1 we want to know about that early on.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



1 monitoring.

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

5 (Laughter.)

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

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

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

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

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

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

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

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

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

9 PARTICIPANT: Okay. Can you still  
10 hear me?

11 DR. TURNER: Yes.

12 MR. FIRKO: Yes.

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

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

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

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

22 DR. TURNER: He is talking about our

1 survey where we went back.

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

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

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

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

1 pull the stakes up.

2 PARTICIPANT: Okay. Thank you.

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

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

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

22 MR. MUNDELL: Scott Mundell from

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

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

14 MR. MUNDELL: All right. Thank you.

15 MR. GEORGE: Other questions for John?  
16 No?

17 (No audible response.)

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

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

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

10 PARTICIPANT: Are we in the same room  
11 this afternoon?

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

22 PARTICIPANT: It is this way.



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

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

9                   MR. GEORGE: That's a good question.

10                  MR. SHAQIR: We need ID?

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

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

22                  (Laughter.)

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

5 (No audible response.)

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

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

15 (Whereupon, the above-entitled matter  
16 went off the record at 11:10 a.m. and resumed at  
17 1:01 p.m.)

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

22 Thanks again, everybody, for being

1 here today and for being with us this afternoon.

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

9 So there will be a point where we say,  
10 okay, we're open to questions. And then there  
11 will be just a slight pause. Then you'll hear  
12 that little recorded voice. And then you can hit  
13 1 and then 0 to ask a question, and we will  
14 unmute your mic. So thank you for your patience  
15 on all of that.

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

22 First, though, to provide some context

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

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

5 UNIDENTIFIED SPEAKER: Just a minute.

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

8 (Off mic comments.)

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

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

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

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

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

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

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

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

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

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

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

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

1 different regulatory authority to.

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

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

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

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

1 much as we can with the resources that we have.

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22           There are barriers, represented by

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

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

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

22 And when doing Weed Risk Assessment we

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 Second, crops often share certain

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

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

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

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

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

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

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

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

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

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

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

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

22 So the baseline and GE Weed Risk

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22           MR. HEGDE: Thank you, Alan, and also

1 Mike.

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

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

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

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

1 weed because I'm a weed ecologist, right?

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

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

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



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

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

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

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

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

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

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

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

22 Hence, you have a predictive power,

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

11 So we really want to put our scope to  
12 a specific variety or cultivar of the elite  
13 cultivars, like maize. If you look at the  
14 history of maize, which is in 10,000 years or  
15 8,000 years ago, which has a very narrow genetic  
16 base when maize select it, right?

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

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

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

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

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

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

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

22 Okay. Sexually compatible relatives,

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

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

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

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

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



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

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

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

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

1 this one, right?

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

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

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

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

1 this crop in California.

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

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

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

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

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

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

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

1 stages.

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

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

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

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

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

1 more predictive power for us whether it can  
2 spread.

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

2 Okay.

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

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

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

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

22 Yes, what we are doing that's a GE

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

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

8 So why are we interested in this?

9 Okay. So evidently it has 100 percent more  
10 biomass. According to the Weed Risk Assessment,  
11 this is a weedy character because of really high  
12 fitness character, because 100 percent more  
13 biomass means it has so much, you know, potential  
14 to survive.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 long and better.

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

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

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

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



1 that drought tolerance; without human assistance.

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

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

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

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

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

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

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

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

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

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

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

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

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

1 place so barren people could not grow other  
2 crops.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22           John said, you know, he wanted to

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

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

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

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

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

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

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

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

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

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

1 You guys can make a decision.

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

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

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

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

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



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

4 Thank you very much.

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

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

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

14 MR. HEGDE: How --

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

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

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

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

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

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

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

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

1 question when we visited?

2 MS. FLANELY: Yes, I think so.

3 MR. HEGDE: Yes.

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

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

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

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

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

15 MR. HEGDE: Okay.

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

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

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

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

8           MR. PEARSON: No, that's not the best  
9 --

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

18          (Off mic comments.)

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

21          (Off mic comments.)

22          MR. PEARSON: Let me just add, again,

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

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

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

11 MR. HEGDE: That's correct.

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

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

1 U.S.

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

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

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

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

22 So I don't know if that helps, those

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

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

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

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

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

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

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

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

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

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

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



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

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

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

15 MR. HEGDE: Mike.

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

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

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

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

9 (Simultaneous speaking.)

10 MR. FIRKO: What's that?

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

13 -

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

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

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

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

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

10 MR. HEGDE: Yes, yes.

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

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

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

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

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

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

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

19 (Simultaneous speaking.)

20 MR. REDING: So this model that we're  
21 discussing is only for petition risk assessment -  
22 -

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

7           (Off mic comments.)

8           MR. HEGDE: Gretchen, yes, she --

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

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

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

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

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

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

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

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

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

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

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

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

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

21 MR. FIRKO: It's in our --

22 MR. HEGDE: Mike -- yes, whatever is

1 in.

2 MR. KERSHAW: Okay.

3 (Simultaneous speaking.)

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

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

13 MR. HEGDE: Current extension?

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

16 MR. HEGDE: It's --

17 MR. FIRKO: No more than a --

18 MR. HEGDE: No more regular here.

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



1 that.

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

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

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

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

19 MR. HEGDE: No, not just five.

20 UNIDENTIFIED PARTICIPANT: Okay.

21 MR. HEGDE: Several.

22 UNIDENTIFIED PARTICIPANT: Several?

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

4           UNIDENTIFIED PARTICIPANT: Oh, okay.

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

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

14          MR. HEGDE: Mike.

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

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

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

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

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

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

15 (Off mic comments.)

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

1 sort of do a professional analysis of the --

2 MR. HEGDE: Right.

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

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

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

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

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

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

7 UNIDENTIFIED PARTICIPANT: So --

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

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

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

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

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

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

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

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

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

22 And then however decisions are made,

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

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

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

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

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

22 So if we're developing a system where

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

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

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

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



1 know, generally do not become weedy right now.

2 (Off mic comments.)

3 MR. GEORGE: Any other questions?

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

5 (Off mic comments.)

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

8 (Off mic comments.)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 MR. PEARSON: For extensions? Yes, I

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

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

11 MR. WIESENMEYER: Because there has  
12 been --

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

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

1 MR. HEGDE: Yes.

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

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

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

16 (Off mic comments.)

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

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

1 compensability of the user.

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

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

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

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

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

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

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

15                   So we've really taken a very broad  
16 look at that. We have also interacted with our  
17 colleagues within APHIS at looking at that. So -  
18 -

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

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

3 MR. GEORGE: Thanks, guys.

4 MR. HEGDE: Thank you.

5 MR. PEARSON: Thank you.

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

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

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

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



1 or three weeks to get the transcript up there.

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

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

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

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

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

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

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

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

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

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

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

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

5 MR. GEORGE: Thanks, everybody.

6 Thanks for coming.

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

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<b>A</b>		
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