U.S. DEPARTMENT OF AGRICULTURE

ANIMAL & PLANT HEALTH INSPECTION SERVICE

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BIOTECHNOLOGY REGULATORY SERVICES
STAKEHOLDER MEETING

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WEDNESDAY,
NOVEMBER 18, 2015

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The Biotechnology Regulatory Services Stakeholder Meeting met in the Conference Room, 4700 River Road, Riverdale, Maryland, at 9:00 a.m., Dick George, Moderator, presiding.

PRESENT

DICK GEORGE, Moderator
SID ABEL, APHIS Assistant Deputy Administrator for BRS
JANET BUCKNALL, APHIS Associate Deputy Administrator for BRS
MIKE FIRKO, APHIS Deputy Administrator for BRS
MICHAEL MENDELSOHN, Senior Regulatory Specialist, Microbial Pesticides, EPA
ROBERT MERKER, Supervisor, Regulatory Group B, Office of Food Additive Safety, Division of Biotechnology and GRAS Notice Review, FDA
JOHN TURNER, Director, BRS Biotechnology Risk Analysis Program

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

9:15 a.m.

MODERATOR GEORGE: I apologize for the delay. We think it's very important that the folks who are online who wanted to attend the meeting also have the opportunity, so it's worth taking a few minutes to figure that out. So thanks so much.

Good morning. I'm Dick George, Communications Branch Chief here at Biotechnology Regulatory Services. I'm glad to welcome you to our 2015 BRS Stakeholder Meeting. This is our annual opportunity to look at the year past and the year ahead from a biotechnology regulatory perspective.

First, some small but important details. Please set your cell phones on vibrate or turn them off. There's coffee and water on the table in the back of the room. Down the hall, out this door to the right past the elevators and then the first left is our cafeteria if you'd like a different beverage or something to eat during the break.

You should have received an agenda of a list of local lunch spots when you registered this morning. Our agenda is a little different this year. The meeting itself will end at noon. This afternoon, some of you have signed up to talk individually with BRS leadership about our current thinking regarding our regulations -- if I stop talking that sound goes away -- which you'll hear a lot more about this morning.

If you haven't signed up and decide this morning that you would like an individual session this afternoon, please go to the registration desk to sign up during the morning break.

We do have a few slots left. We're giving preference to those who are here in person, but no one will be excluded. If you're on our webcast and would like to schedule an individual session by phone, please send us an email with your contact information and we'll contact you to schedule the session either today or in the next week or two. Send your email to brs.stakeholders@aphis.usda.gov.

Today we're webcasting, so we have to remember that we have people who are on the phone, not visible, but nevertheless very much a part of our meeting. I would ask all attendees that are here today to wait until we get a microphone to you before you make a comment or ask a question so that our webinar audience can hear, and I would ask everyone to please identify yourself and your organization, if you represent one, before you speak.

We have a court reporter here today who will produce a complete transcript of this meeting, and that transcript will be posted to our website within a few weeks. That's why we need you to please identify yourself when you speak and spell your name, so our transcript will have it in writing.

In addition, today's presentations will be available on our website within the next day or two.

We would ask that you please hold your questions until the speakers completed the

presentation. We've allowed time for questions at the end of each presentation. Plus, your question may be answered in the balance of the presentation. Then, for those of you in the room, please wait for a microphone before you speak. If you're online and you'd like to ask a question, on your telephone keypad press "1" and then "0." This will alert our webcast moderator that you'd like to speak, and we'll unmute you and invite you to ask your question. So for our online attendees, to ask a question, press "1" and then "0" on your telephone keypad.

One last thing. After the meeting, you'll receive an email survey. Please take a few minutes to fill it out. Your input matters to us. And there's also a comment box in the back of the room. If you'd like to write us a personal note or whatever, place it in the box and we'll be sure to receive it.

So with that, we can get started. At this time, I'd like to introduce the APHIS Deputy Administrator for BRS, Mike Firko.

MR. FIRKO: Thank you. And thanks to everybody for joining us here today. I think this is the largest group we've had, at least for a while. So I'm going to be talking to the group twice today. First, this morning, I'm going to talk about things that happened during 2015 and then a little bit on what we have in 2016 and then a second session just about our current thinking of where we'd like to go with new regulations.

So, of course, the past year has been a very interesting year, and it's always interesting in biotechnology. I have now been, I actually started at APHIS in biotechnology. Then for a few years in the early 2000s, my biotech function was in plant protection and quarantine. At that time, it was one of nine functions that I had. That's because when the biotech function came back to PPQ and it became abundantly clear pretty quickly that they hadn't all been solved, so BRS was created.

(Whereupon, the above-referred to matter went off the record at 9:22 a.m. and resumed at 9:22 a.m.)

MR. FIRKO: So I just wanted to start with a very brief down memory lane. In the 1970s, the National Institute of Health was one of the first organizations to come out with anything public from the government on biotech. This is a non-regulatory program. They put up guidelines. The way that they have an influence is that a lot of medical research in the United States is done by NIH. And if you want to get your grant money from NIH, you abide by the regulations. It's not a regulatory program, but it's a way to have an influence.

In 1986, the Executive Office of the President came out with this document. It laid out a bunch of solutions and tenets, and it described who the different players were in the area of the regulation of biotechnology.

And then a year later, the USDA came out with its first regulations, 7CFR 340. I may slip into the 340 jargon. Whenever I say 340, I'm talking about our regulations.

The regulations have remained

essentially the same in terms of what is the basis of the regulation was to establish authority. There were a couple of tweaks in the 90s that created a notification process, and then in '97 that was expanded.

So what do we do in biotechnology regulatory services? We have four primary operational things that we do. There's a bunch of other little things that we do: international engagements, dealing with FOIA requests, lawsuits, and things like that. But the four primary operational issues are we answer regulatory status inquiries. This has been happening since 1987, and, for the first 10 or 15 years, lots of decisions were made about regulatory status over the phone or through emails. There's some records from those days. Not all of it was codified. Today, starting in, well, before 2011, we created a very specific process that I'll talk to you about in a few minutes.

We evaluate applications for regulated activities, such as importation of regulated

articles or moving regulated articles, whether it be a plant or an arthropod. We have a compliance program where we make sure that the conditions of the authorizations are being followed. We conduct inspections and enforcement activities, and we consider petitions for non-regulated status. This last one seems to be the one that gets most of the attention.

We, like I said, for the last five years, we've been putting all of our decisions related to Am I Regulated on our website. You can get the specific address for that on the back of my business card or on a version of this there's about 100 of these cards on the back. And if you type in that you are directly sent to the Am I Regulated page and see all of the incomings and outgoing responses for the past five years. In '13, six of these were answered. In '14, three. This year we've done ten so far.

Our permitting program continues to run very efficiently. The regulations state time frames regarding our performance, and we hit those

performance measures 90 percent of the time.

To give you a feel for the size of the permit notification, it's a pretty busy slide, but we have notifications here, permits on the lower end. In each case, it lists how many requests did we receive and how many of those were authorized. And then the three regulated activities in columns, importation only, interstate only, and release, which may also include interstate.

So one of the things that you see is, under notification, the numbers across, 322, 396, 436, are fairly equal. You'll see that, on average, 9 percent are not authorized, 91 percent are authorized. When you get down to permits, you see that the distribution across the three types of regulated activities is quite different, where there are four times as many authorizations for field use as there are for importation.

Now, let me call your attention to two numbers here, this 391 and the 181. Those are field uses authorized under notification and permit, so that number is 572. But since there can

be multiple release sites under each authorization, regardless of whether it's permit or notification, the number of sites that were actually analyzed by us is nearly 12,000, and that involved nearly 50,000 phenotypic designations, crop phenotype combinations.

So if you just look at the number of authorizations that are grouped by biotechnology, it really doesn't do justice to the fact that they're doing an awful lot of review of an awful lot of different genetic constructs.

I mentioned this, I think, the last couple of years. So despite the fact that we authorized 11,938 release sites, only about one-third are ever planted. That's 25 to 33 percent usually. So we're spending a lot of time doing National Environmental Policy Act review on all of these 12,000 sites, including a lot of review for a lot of different reasons, and then they're never planted. So that takes a lot of our time.

On the compliance side, we have been focusing in 2015, starting in 2014, on our

compliance program. I mean, we did solve the petition issues. I mean, I'll show you some of the petitions which were taking an enormous amount of our time and we had a big backlog. That problem is essentially gone. So we were able to focus more on our compliance program.

Now, the staff realignment that I refer to here takes a couple of different, it's shown in a couple of different ways. I'll say more about that in a minute.

So in 2014, we started doing more inspections. The number of plantings that we actually visited is a fraction of the ones that are authorized. It's actually not a large fraction either. So we thought it would be helpful to get on to field a little bit more. I had a nice invitation to go out to the Panhandle of Texas and visit the site. Thank you.

'15 is not over, but the numbers look like they're going to be similar, about 1700 inspections this year. But we're going through a transition. Anybody who is involved with

receiving permits or notification knows that the group that is called Biotechnology Regulatory Services that issues the permits and does follow-up is not the same group that typically goes out and does the field inspections. And up until about 2014, about 80 percent of those inspections were done by a different part of APHIS called Plant Protection and Quarantine. And the reason that we had gotten to that point was because Plant Protection and Quarantine has people in all 50 states and in all territories.

It became pretty clear to me that we should look at a different model for how we do inspections. One of the issues was a side duty for many of these folks. In some years, they weren't able to do any inspections whatsoever. In some years, many of them did one. And those folks never had an opportunity to excel at their job because they just weren't doing the job very often. I mean, if you do something once a year, once every two or three years, it's hard to do the best job.

So we had started a transition in BRS

where we are hiring regulatory analysts who have as part of their job field inspections. They do inspections for less than half their time, and then they come back to the office and analyze the results, write the reports, figure out what all that means. And in 2015, we had gone in BRS from doing about 5 percent of the inspections to about 40 percent of the inspections. The state departments of agriculture do some of the inspections, about 10 percent. State departments of agriculture will probably continue to do about 10 percent, but the proportion that were conducted by folks who report to me in the chain of command, as opposed to a different part of the agency, is going up. And I hope to get that number up to around 70 percent or 80 percent, not including the ones that the state does.

I'll have a slide about a business process improvement that we've been working on. Notice the "S." This is the compliance business process improvement. It's called "S" for signature because the Secretary of Agriculture was

personally interested in this, and we report directly to the Secretary on how we're doing on our improvements in our compliance program.

I'll also talk about GAO engagement that is nearing completion and an OIG audit that has been published already. So the SPI, the primary objective, as it shows there, is to do a better job drafting reports. And here are the current performance goals that we have for doing that. There's a number of different ways that we're going through an inclusion process with new SOPs, do work instructions. We're going to do a better job of managing the data that come in as a result, and we're going to feed that information more efficiently into decision-making for authorizations and other things.

So the GAO -- I'm sorry. That's Government Accountability Office. It's not part of the Executive Branch. It's an outside group on the Executive Branch, and they don't use the term "audit." They use the term "engagement," but it kind of feels like an audit. We have completed the

exit conference, which means the investigative agencies who were involved in this met with GAO. They covered us with more questions if they had any questions left after all the questions we answered over the last year. But they still asked questions, and they made it very clear in the exit conference that their primary issue with APHIS was our compliance program. And they definitely support change in our regulations as a means to improve our oversight program.

So the OIG audit, this is the USDA Office of Inspector General. It's kind of like USDA's internal affairs. The most refreshing moment I had within OIG, a manager at one of our entrance interviews, he said, "Look, I just want to be clear. I'm not going to say anything good about your program. That's not our job. Our job is to find problems in your program and help you fix them." Well, we can do that.

So the report from OIG was published in October. It had 13 recommendations. It's available on the web. You can find it real easy.

You can Google "USDA OIG" and it gets you right to a place and you choose audit reports and I think the first one is it. It's real easy to find.

So I'm going to give you a quick summary of the 13 recommendations. They not only want us to publish the regulations, they want the date. They're very specific about that. There are still elements of the 2005 audit that remain open because it was made in response to their 2005 audit to make new regulations, so we haven't done that yet. So some of the recommendations in the current audit are do what you said you were going to do ten years ago.

It's clear that they're telling us that we need better oversight about what we're planting, otherwise known as environmental. They tell us we need to improve our incident management work. We need to be -- when we're issuing authorizations for regulated activities, we need to look at the history of the requester and make that part of the decision. Specifically, if there are multiple incidents or episodes of non-compliance, that

should weigh into the decision about whether to issue a new authorization.

In several of the recommendations, OIG is interested in our new IT system, and Janet will be talking about our new IT system. And they're also interested in us having a better petition tracking system. So those are the results of the OIG audit.

Now, our response to OIG, most of which you'll see in the report because the report that's on the web includes our responses, first of all, we agree with all the recommendations. I mean, they got into our program and into all of our databases. They saw exactly what we do, what we don't do. Many of these things that they had recommended we do we had already started to work on. We agree with the recommendations.

And the three primary actions we are taking to address those recommendations: we are creating new regulations. That's going to resolve several of the recommendations. We're going to create a new IT system for managing our business.

In other words, issuance of authorizations. One of our biggest challenges in BRS and in other programs is that there's been this conception that, once you issue a permit, you're done. Well, of course, for us, an awful lot of what happens in IT systems, which is basically a workflow manager, we come in in the morning, we pull the system up. It says, okay, you've got these permits to review, you've got these inspections to do. It's a workload manager. There are lots of things that we can't do in our current system, and if we want to do any tweaking to the system at all we're talking lots and lots of money. So we need a new system that we can be in better control of. And OIG saw immediately that we needed a new system to perform many of the functions that we need to perform and the signature process improvement, which I already talked about.

Now, this is something that I wanted to talk about today because we just went through a public comment period and got a lot of interest from all sides, as is typical with anything biotech.

It's interesting that these issues are so polarized, and whether we're publishing a notice or a proposed rule or just putting anything out for comment, we really get, it's a bipolar distribution. There's a group of people who don't think that we should ever authorize anything related to biotechnology, and there's another group who thinks we should get out of the way completely, and there's really not very much in the middle.

So the current status of the proposal, there's the title of the proposal, and this is simply to say instead of authorizing outdoor plantings of genetically-engineered wheat under a notification process, they would be authorized through a permitting process. It was published in September. The comment period closed in October. The comments we received, 167 submissions. But wait for it: how many commenters do you think that was? Obviously, some of these submissions represented input from multiple different individuals.

The single largest comment was you should not allow any outdoor planting of genetically-engineered wheat, period. But if you're going to, do it under permit. Thirty-five were supportive of the move from notifications to permits but with strict permit conditions. Fifteen supported continuing use of notifications, and nine are just difficult to categorize.

So just like with the 2008 proposed rule where the comments were very polarized but everybody pretty much agreed that we didn't do a very good job of explaining ourselves, that happened here, too. People seem to agree that we didn't do a very good job of explaining why we were doing it. So I'm going to spend some time doing that.

First of all, I have a handout that's going to come out. I think we might have one for everyone. And what this shows, this is a two-sided list of things that currently require a permit, as opposed to a notification, for field trials. Also, please note that some of these listings are

very large groups of things, not single species. For example, at the bottom of the front page, it says all fruit trees, e.g. apple, citrus, banana, papaya. The next one says all other trees. That's a lot of species right there. Those all require permits.

And this is to put into perspective, because I was at the wheat meetings the day before last, I guess it was, I met the National Association of Wheat Growers and U.S. Wheat Associates, and somehow they had gotten the impression that wheat was the only one. Well, no, wheat is not the only one.

So other times that we may issue permits instead of notifications, we do it on a case-by-case basis. And this list, things are on this list for a variety of different reasons. Some of them were by request, some of them are based on, most of them, actually, are based on risk. You see that the issue of being a perennial, as opposed to an annual, is part of the decision. Some have always required permits, some have been added to

require a permit. So it's quite a mix of things. But case-by-case, we have, in many cases over the past few years, moved from notification to permit. We've done it many times over the years.

Currently, many species that don't require a permit, like soy and some of these other things, are authorized under a permit if they are a large-scale planting because larger-scale means it's more difficult to manage persistence and dispersal. And like I said, we also sometimes get requests specifically to be under permit because of the benefits that come with that.

Again, to put this into perspective, in 2014, we issued a grand total of 21 authorizations for field trials from only 11 different entities. So, clearly, some of those authorizations were to the same group. So 11 entities are potentially impacted by this.

Long before we published the notice in the Federal Register, we contacted all of these entities. We've been in contact with them for many months. I don't think it would be fair to say that

they all like the idea, but I think they understood the need and why.

So why now? Well, after the Montana wheat discovery and announcement, Senator Tester from Montana started the GAO study that I talked to you about. There is an ongoing USDA OIG audit. Both of these groups are saying you need to tighten up your management of field trials. And what's the most visible one we've got right now? That would be wheat, wouldn't it? It's been suggested that we wait until we have new regulations. Well, we proposed in 2008 that we were to do away with the notification process and only have permits, and we're probably going to propose that again.

But we're not going to have any regulations for three or four or five years. Our current regs are 28 years old. We tried in 2008. So it takes a long time to move regs in the system. So in the interest of protecting the U.S. wheat industry, we don't feel we can wait.

So this is an interesting topic. After the second public announcement of the detection of

genetically-engineered wheat where it wasn't supposed to be and working with the Secretary's office and the Undersecretary's office, a plan was put together to basically start inspecting all field trials of genetically-engineered wheat. So we've been doing that. Let me just say we've been surprised of the cavalier attitude that we've seen at some of these locations.

Also why now? This is a good time to increase confidence in biotech wheat because what I'm hearing from the wheat industry is that they are very interested in moving genetically-engineered wheat because of the benefits to the marketplace. You know, after the Oregon wheat announcement, I spent a couple of days in a room with Japanese negotiators, and they were going to shut down all trade of U.S. wheat. Pacific Northwest wheat growers were very concerned about this.

What the Japanese wanted to hear from me was that we had very tight control over the field trials of genetically engineered. I didn't have

much to give them because these field trials are under notification, and I'll show you some of the details about what that means to be under notification.

So we got out of that meeting, and the U.S. wheat continued to flow, but those were not three fun days with the Japanese regulators.

So, again, why wheat? When we have these situations like we had with Oregon and Montana, it puts our wheat exports at risk. Regardless of what you think about genetic engineering or biotechnology, our trading partners care about it. So a big part of our decision-making was protecting the U.S. wheat export market.

The primary science issue is that it became more clear to us in working in both the Oregon incident and the Montana incident that one of the special things about wheat, and it's not only wheat but I think it's fair to say that it was underappreciated, is that in a dryland situation with no till, you can have wheat seeds sitting in

the soil for years. So if you have a two-year monitoring program for volunteers, there may not be any volunteers until year three or four or five. So if you quit looking after year two and they start popping up in year three or four, you completely missed the opportunity to prevent persistence in the environment of a regulated article. And we have references about this science issue. He's one of our new branch chiefs, and he's got the scientific references for this.

So what's it mean, permit versus notification? They both constitute regulation, same application tool. They're both subject to inspection. They're both subject to the same enforcement actions and fines, same regulatory goals. Like I said, primarily, prevent persistence in the environment of a regulated article. That's the goal in both cases.

In notifications, regulatory authority is extremely minimal. The regulations have performance standards, which, in short, are make sure that you keep the regulated materials

sequestered and separate from the non-regulated material, make sure you can identify it as the regulated material. Make sure it doesn't persist in the environment, and volunteers should be managed. It doesn't say must, it doesn't say how. It just says volunteers should be managed. There's not much room for error.

We cannot specify conditions. We cannot mandate or even request site-specific requirements. And there's only a single report that's required to go to BRS and APHIS within six months after completion of the field trial. So not only is there very little communication and collaboration in working out the details going on, irrespective of design protocols that may be worked on, for the most part, those are not site specific.

So permits give you an opportunity for much better clarity and much better collaboration. The clarity piece, the regulations are much more specific about what information needs to be provided with a permit application, and APHIS can work with the applicant to create a set of permit

conditions that meet everyone's needs on a case-by-case basis.

For example, with wheat, what we could do with permitting is somebody is growing wheat and has a GE wheat field trial in Florida or Puerto Rico or Hawaii, the likelihood of persistence in the environment, the likelihood of seed dormancy is extremely low. We can build that into permit conditions. The need for monitoring for volunteers goes way down in out years because in those situations where it's wet and warm, the seeds are going to germinate. If you're talking about Oregon, Montana, North Dakota, some of these dry and if you have no till and depending on what your herbicide regime is, you just can't say two years volunteer monitoring is going to be enough.

We can also require additional reports. We can say things about, well, here's how you need to get rid of it once you're done with it. And only under permit can we require cleaning of equipment.

One of the situations that I described, on an inspection, the cavalier attitude, we were

on-site and they wanted to move equipment from a regulated area to a non-regulated area. Should we clean the equipment? And we're like, yes, you should clean your equipment. So they went away and cleaned the equipment and we inspected it, we found not only seeds, we found whole seed heads. We went through four rounds before the inspector said, okay, this piece of equipment looks clean of genetically-engineered wheat seeds, go ahead and move it.

So, again, benefits of permitting provide for better collaboration between APHIS and the responsible person. It helps everybody collect data. It helps us do more risk-based management in the future. That's my last one on this issue.

So the decision on our proposal is forthcoming this week, maybe next week. And when that decision is promulgated, we will provide more detail on the talk that I give you here today, explaining why wheat, why now, and a number of other things.

Okay. Let's get to the petitions for non-regulated status. We completed eight petitions in fiscal year 2015. It brings our total to 118. When we started our new process in 2012, we had 23 in-house. Only a single one of those 23 is still in-house. It's eucalyptus. We're doing an environmental impact statement on that. It's currently in review at Fish and Wildlife Service for endangered species issues. That one is no longer on our list of pending petitions because the petition was withdrawn earlier this year. What that means is that glyphosate-resistant remains a regulated article, and it is no longer on the list of pending petitions. If any of you track our web page on pending petitions, that's why this one disappeared.

We also received in the 2000s a request to list this particular genetically-engineered grass. We answered that this year. APHIS, Plant Protection and Quarantine, who does the noxious weed petitions answered that, and APHIS will not list this genetically-engineered grass.

So currently in-house, we have six. Three of these are petitions. There's the eucalyptus that I mentioned from 2011. One of the others came in last year, and one of the others came in this year. And then we had three extensions that are all 2015. One of them is currently out for public review. The other two are not out for public review because we're still working through the initial stage to get to the final where we put it out for public review.

So in-house, we've got the whole six right now. And except for that 2011 one, they all came in this year or last. But keep your ears perked for action on biomass.

So this is a table that just shows all of the different things that have been granted non-regulated status. It's a really busy slide, but I'd just call your attention to the left side with the green. Those are in major commercial production. The bottom yellow, a little bit, not so much. And then on the right side, even though USDA has granted non-regulated status to those, for

whatever reason, and, again, this is a business reason. People, companies decide whether or not they're going to market it. In the case of tomato, that was on the market for a while. Now it's off for business reasons. It had nothing to do with getting authorization from the USDA. And if they wanted to put that back on the market today, the non-regulated status would still apply, but it's just not in commercial production.

And then all the others, apple was recent, they're not in commercial production because they're gearing up for operation. I expect potatoes will be moving over to the green or yellow side pretty soon. There have been a number of potatoes authorized over the years.

Looking forward to 2016, we've pretty much completed the design phase of the signature process improvement that the Secretary is tracking. Now we have to walk the walk, and we've started walking the walk but we're not done.

We're going to continue to improve condition development for clarity and

enforceability. We're going to enhance inspection and oversight, as I explained partly. We're going to continue hiring for risk assessment and regulatory oversight, both on the BRAP side, John Turner's side, reviewing authorizations. I hope to hire four to six people this year for that group. And on the compliance side, we hired seven last year and will hire two or three more this year.

We do plan on delivering a compliance incident response plan. I mentioned that we continue to move towards BRS, people in my chain of command, doing a higher percentage of the inspections. We'll be there in 2017 or 2018, we'll reach the asymptote.

This year we'd like to finish five petitions. We've only got -- when I say petitions, I'm including extensions. We've only got six in-house right now, so having these measures is getting more and more difficult as we crank these out.

And rulemaking. I have a little session to talk about that a little bit later.

Questions?

MR. ANDERSON: Chris Anderson from Ames, Iowa. So these new inspections where you have regulatory analysts doing them, that's for all crops, not just the sensitive crops or crops in the limelight like wheat, but it will be with corn.

MR. FIRKO: Let me expand on that a little bit. If our hiring pool turns out to be primarily people who have done 20, 30, 40 of these a year, we're hiring them away from PPQ. They're the most competitive.

MR. ANDERSON: So they'll be out in the rural hinterland and not in Washington, D.C.?

MR. FIRKO: Absolutely.

MR. ANDERSON: Okay. Sometimes it's travel.

MR. FIRKO: None of these people are going to be in Maryland or D.C. There will be one or two in each of our hubs, Raleigh and Fort Collins. We have someone in Hawaii. We have someone in Puerto Rico. We have someone in Iowa. I might be missing one or two others, but we're

staggering them around, yes. And in many cases, they'll be the same people who have been doing it in the past. Instead of having a pool of 100 people doing them, we're going to have a smaller pool of people doing it as a much larger proportion of their overall workload.

MR. MEDLEY: Hello. Terry Medley from DuPont. I guess the question that I have for you goes back to the notice for request for comments on the change in the status, and our situation, in terms of putting our explanative mark on the process. My question is, is there a reason that this is a notice for request for comment, as opposed to a proposed rule seeking the same end goals?

MR. FIRKO: APHIS and MRP and the Office of the Secretary all agree that this was completely within the discretion of the administrator to do this without doing a rule change. This is not a rule change. This has happened many times over the years. That's why I handed out this sheet because a number of these moved from notification to permit as a policy

change as opposed to a regulation change. And you'll see this in the regulation change.

MR. IREY: Mike Irey, Southern Gardens. As part of the inspection process, do you anticipate having any feedback mechanisms for the permit holder, instead of just getting a note of compliance or non-compliance of, you know, you could have done this better but it meets the standards?

MR. FIRKO: I hope that gets better, absolutely. And that's one of the reasons why I feel more comfortable with having most of the inspections done by members in my chain of command because then we can make sure that that is a top priority for them and not one of 20 or 30 other duties that they got to deal with.

Biotech's their business, and that's all they have to deal with. Absolutely, we can give feedback. I mean, as I explained with the permits --

MR. IREY: But feedback to us.

MR. FIRKO: Yes, yes. One of the things about permits is that that dialogue happens

much more frequently and completely. I should tell the group that you and I meet twice a year.

MR. IREY: Or more.

MR. FIRKO: Or more. So, yes, I hope to increase a two-way exchange of information. That's the collaboration piece I was talking about on that last section, yes. Thank you.

OPERATOR: All participants are now in listen-only mode.

MODERATOR GEORGE: In the U.S., biotechnology is regulated by not one but three agencies in what's called the coordinated framework for the regulation of biotechnology, and here to talk about that coordination are representatives from each of the three agencies. From the Environmental Protection Agency, we have Michael Mendelsohn, Senior Regulatory Specialist, Microbial Pesticides; from the Food and Drug Administration is Bob Merker, Supervisor in the Division of Biotechnology; and from our own APHIS BRS is Assistant Deputy Administrator Sid Abel. And here's Sid.

MR. ABEL: Thank you, Dick. Good morning, everyone. We think this is a pretty timely topic for this group. Last year, as many of you may be aware if you were here last year at our Stakeholder in 2014, we began a conversation about how the three agencies interact during the conduct of the review of a product of biotechnology, whether we make a registration decision or a deregulation decision or the consultation with FDA on the food safety side.

So we believe this was a pretty timely topic also because, you know, back in July, the White House initiated an effort to do an update of the coordinated framework. So those two things are kind of connected together because they have to do with the way the three programs, the three lead agencies in the coordinated framework interact with the safety of biotechnology products.

The Office of Science and Technology Policy is leading this process to modernize the federal regulatory system for these products in

biotechnology. And we're doing this in order to increase the confidence in our regulatory system and to prevent barriers to future innovation and competitiveness.

This effort aims to improve our transparency, the coordination among the agencies, the predictability and efficiency of this system, and the regulation of biotechnology products while continuing to protect the public health and the environment.

I'm going to come back in a few minutes and kind of give you a landscape of where this process is, give a little background, where we are now, and where we're going in the next few months as we try to achieve our objective of completing this process by sometime in the summer of 2016. But before I do that, I want to let Mike Mendelsohn and Bob Merker give a little bit of an overview of that coordination activity and some of their roles and responsibilities among the three agencies, and then I'll come back after that. So next will be Mike Mendelsohn from EPA. Thank you.

MR. MENDELSOHN: Well, good morning. It's good to be here. I just want to share a little bit of some of our coordination activities. We work closely together with our colleagues here at USDA and with folks at FDA, as well.

So I think you're all familiar with this diagram here showing how the agencies work together under the coordinated framework, looking primarily at plants here. USDA, looking at what's safe for agriculture and the environment; FDA with what's safe for use in food and feed; and at EPA, our focus is pesticides.

So I just want to go down the list here and talk a little bit about how we currently work together and coordinate in the area of biotechnology. The first item here, we keep each other informed on specific actions and have monthly interagency teleconferences. So we talk about the different applications that are coming in. And many of these are sent to all three agencies, some to just one, some to two. But we keep each other informed of what's coming in the pipeline and the

status of those. We also have an interagency information-sharing memorandum of understanding, so we can share and talk about confidential information freely between the agencies.

We coordinate on international outreach at FAO and OACD. We also coordinate with incidents, as I mentioned earlier where they reach across the agencies.

With regard to small-scale testing of biotech microorganisms, we have a memorandum of understanding and USDA and EPA inform each other when we each see those. We share risk assessments, particularly with USDA. They make use of our bio-pesticide and chemical herbicide risk assessments to support their plant pest risk assessments and NEPA compliance. And, of course, we coordinate with weed-resistance management with herbicides.

And I just want to leave you with a little bit of contact. We've renewed our website within the last about month - month and a half at EPA. Many of the URLs are all different, so if you

notice that it's not www.epa, it's www2.epa. But we've updated the website, as well, I think for PIPs. We have an updated list of all PIPs that have been registered and linking to various databases, so that should be a good tool. Also listed here is the TSCA information, as well.

But I think the message is that we work together closely between the three agencies and coordinate on various things. Thanks.

MR. MERKER: Good morning. I'd like to thank the organizers for having me. As Mike just said, we actually do a fair amount of communicating between three agencies. We do have a monthly phone meeting. That's a regular activity. We also have what I would characterize as irregular activities. We've had joint meetings on scientific issues. We've had joint meetings to talk to certain small developers. So it's something that we do as a matter of routine. And for me, meeting with the people over here at APHIS is very easy. I just needed to walk down the street.

As far as FDA's programs, our model is we have a voluntary consultation program and we suggest that you consult with us early and often. Tell us the story about the new plant variety and why it's safe for food and animal feed. Consult early, and that way we'll avoid surprises that might delay us later in the process.

There are many different ways to interact with FDA when you're ready to interact with us. You can do it in person. We're happy to receive you at our spacious College Park offices. We're also happy to organize a teleconference. Words work pretty well.

We also have computer-assisted meetings so that you can actually show us your slides from your office in Honolulu and we can see them at our offices in College Park. That's via WebEx. So we can organize any of those types of meetings.

And we do regulate all food and feed, so even if BRS doesn't regulate your product, please talk to us. Food from the plant is still

regulated by FDA.

I've got some contact information, and, of course, I misspelled contact, so that's minus one for me. I'm the consultation lead. I've got a pretty easy email up there, robert.merker@fda.hs.gov.

For general questions, you can visit our website at www.fda.gov/geplantfoods, and that's not General Electric. And also any questions you have, you can send them to pre-market without a second "e" at fda.hhs.gov. If you have any questions about our early food safety evaluations, you can contact my colleague, Carrie McMahon, and her email address is there. And I thank you for your attention.

MR. ABEL: Thank you, Bob and Mike. Okay. So I want to continue on and talk a little bit about the effort by the White House to update the coordinated framework. As you all know, it's coming up on 30 years since the original release of the coordinated framework, which described a comprehensive policy for the safety of

biotechnology products. The three primary agencies being USDA, FDA, and EPA.

In that coordinated framework original announcement, it set up a series of principles, and among them were things like use existing authorities wherever possible to regulate the products of biotechnology, cover a range of products from plants to animals to microorganisms where possible and to the extent possible and where possible, have just one of the three agencies regulate those products. But when it's not possible and multiple agencies will regulate those products, do so in a very coordinated fashion, which is what I believe we are doing today. And then among them also is using a risk-based approach to the regulation of these products.

As we all know, advances in the science and technology have dramatically altered the landscape of biotechnology over the last 30 years. Such advances have enabled the development of products that may not have been previously thought of or even possible back even 30 years ago when we

first released the coordinated framework.

While we believe the current regulatory system effectively protects health and the environment, it is important that we continue to strive and improve the system that we established back in 1986. So updating the coordinated framework will help ensure appropriate oversight of the regulatory system while continuing to provide a framework for advancing innovation to address some of society's most pressing needs.

The Executive Office of the President, along with EPA, FDA, and USDA, are leading this implementation effort under a new workgroup that's been formed, referred to as a biotechnology working group, under the auspices of the Emerging Technologies Interagency Policy Coordinating Committee, ETIPCC for short.

Other agencies have also been involved, and so it's just not these four groups, but we have other agencies involved: U.S. Trade Representative is involved, OMB is involved, the State Department is involved. And then we've also invited others

into this program to provide some advice and counsel as we move forward, such as some of the funding agencies. Department of Energy, National Science Foundation, NIH are also at the table periodically during the course of these meetings. We conduct these meetings on basically a weekly basis, and then sometimes more frequently, as we have formed a couple of subgroups underneath this biotechnology working group.

The BWG for short will address three key principles during the course of this year-long process. The first thing is update the coordinated framework to clarify the roles and responsibilities of the three agencies, and that's where most of our focus is right now.

We'll also develop a long-term strategy for the future products of biotechnology, and then we've also commissioned an external independent analysis of the future landscape of biotechnology.

In updating the coordinated framework, each agency will retain its statutory authority and its regulatory authority, as well. However, we

will do a better job of clarifying to the public which agencies have lead regulatory role on particular products that are subject to overlapping jurisdictions.

We will clarify the standard mechanism for communication and coordination among the three agencies. We will also identify designated responsible people within those three agencies for the communication and coordination of these activities. And then, finally, we'll also clarify the mechanism for regularly reviewing and updating the coordinated framework to support innovation, protect the environment, and protect public health, and also to promote public trust. We believe that's very important. We don't want to wait 30 years before we take another look at the coordinated framework and update that.

And the long-term strategy will focus on predictability and efficiency in identifying the authorities, the regulations, the policies, if any, to improve our ability to efficiently assess impacts and risk from future products and to ensure

that these risks are grounded in the best available science. Develop a plan for periodic horizon scanning. Transparency. Working with stakeholders to identify impediments to innovation and develop tools and mechanisms for assisting small businesses.

We will also develop a user friendly sets of tools for communicating the agencies' authorities, practices, decision-making, and outcomes for regulating these products. And then, finally, the long-term strategy will engage the public to discuss how we can use a risk-based scientifically-sound approaches to regulating products of biotechnology.

The biotechnology working group will also then commission an independent analysis of a future landscape of biotechnology products that will identify potential new products and frameworks for risk assessments and areas in which the risk or lack of risk relating to products of biotechnology are well understood.

This effort is nearing start-up. We

got a tentative agreement in place now with the national academies, and we're kind of finalizing that scope of that particular project now and are putting agreements in place and getting the funding mechanism in place so we can begin that horizon scanning.

The independent review will help us inform our future policy and decision-making. Due to the rapid pace and the change in this area, the analysis will be completed at least every five years. So this will be the first of a recurring five-year cycle in doing these horizon scans.

So where are we now? As you all know, back on October 30th, we had our first public meeting on the coordinated framework held at the White Oak facility for FDA. That also included a comment period that was open on the request for information related to that White House memo. We received 903 submissions and, to date, 556 have been posted on the website. FDA will be managing those comments as they continue to review them and get most of them posted up on the website. We'll

then take those down, review them, put them into various buckets so we can begin to use that information to help guide us on how we will change the content of the coordinated framework.

Following that meeting the analysis of that information, we're going to update that coordinated framework based on that advice that we've gotten from the public comment period. And then sometime in the first quarter of next year, we're going to run two additional public meetings. Both of them are going to be focused on the coordinated framework and how we are proposing to change the coordinated framework, roles, responsibilities, etcetera, of the three agencies, and we're going to place those out in public comment, as well. We'll open up a docket for those, and it will be occurring somewhere west of the Washington, D.C. area sometime in that first quarter. We're still working on the logistics of where those two meetings will occur, getting them set up, getting the content and the nature of those presentations, if there will be any, for those two

public meetings. And you should probably be hearing more information about that over the next couple of months, at least we hope the next couple of months.

So APHIS, as well as USDA and, in general, FDA and EPA are looking forward to working with our other federal partners, with our stakeholders and the public at large to improve the coordinated framework and provide for a better, more reliable system of regulating biotechnology and certainly more transparent than it apparently is. And we've heard a number of the comments so far that we've reviewed from the RFI.

With that, I can take a couple of comments, if there are any, or questions. And then --

MR. MEDLEY: Sir, moving on, I just have two questions really. One, with regard to the group, can you speak at all about, you said the agencies, but who have you got sitting on that group? And, secondly, with regard to the independent assessment with the National Academy,

do you have any idea what a time frame might have for that to occur?

MR. ABEL: So to answer the first one, the representatives from the three agencies, FDA, EPA, and EPA are the sitting members of this group, along with OSTP, the Office of the Science, Technology and Policy are also on this group. We have probably 15 to 20 people represented across those three agencies in OSTP that sit on this working group. Many of them are here today. Mike is on the group. Bob is also on the group. I am also on the group representing APHIS and USDA at large. The Office of the Secretary is also represented on this group.

So we've got a pretty diverse group of people. Veterinary Services is on the group, the Center for Veterinary Medicine is also on the group. EPA's Office of Toxic Substances is also on this group. So it represents the three agencies broadly with a number of people on that group.

And then the second one, we were hoping that we'd be able to get this horizon-scanning

done. We have a time frame that we hope to achieve getting the coordinated framework updated, which is July of next year. We wanted to set up a year's process. It's taking us a little bit of time to get that contract or agreement into place, so it may be a little behind the actual coordinated framework. But I would expect it sometime in late summer or early fall next year, somewhere in that time frame. We'll have more information on that as we move forward to get this agreement in place.

MR. JENKINS: Dan Jenkins with Monsanto. Sid, your comment once again on your comment around identifying a lead agency and how the agencies need to work together in that respect. Obviously, the agencies have to work independently. EPA, for example has to be on its own time line to some degree. I would imagine that a lead agency, despite having the title of lead agency, would still run independent time lines. Can you comment on that?

MR. ABEL: The concept of the lead agency is the coordinated framework from the

original 1986 release. It is open for discussion. It's suggested that, when you have multiple agencies involved, that, if there is a lead agency, if there can be agreement on the lead agency there should be one. That way, the public, the stakeholders, and the company itself has one conduit into the system. It's open for discussion whether or not that is even possible as we move forward with the updated coordinated framework.

I think the timing issue that you raised there in terms of how long it takes EPA or FDA or USDA to complete their activities, we've become a lot more, I would say, coordinated there or at least synchronous there than we have been in the past. Our attempts, our success at improving our processes for running a petition through the deregulation process has narrowed down much, you know, greatly. We're down to pretty much meeting our time frames and we will this year for anything that came in in 2015, the 13 and 15-month deregulation decision periods. Those pretty much line up with EPA's dates, for the most part, for

many of the new uses that may be used on these products of biotechnology and specifically things like herbicide-resistant crops.

And we have found it's pretty close to the same timing that the FDA completes its consultations, so we're within a pretty synchronous there, within a couple of months of each other most of the time. So I don't think the concept of lead agency will cause any problems there, but that's still, again, open for discussion between the three agencies as we move forward.

MODERATOR GEORGE: Thank you, Sid, Bob, and Mike. At least year's meeting, we told you about a major initiative to update our systems in significant ways. We call that project CARPOL, which stands for Certification, Accreditation, Registration, Permits, and Other Licensing. For us, it applies mostly to our permitting process.

Here to talk about the progress so far and what to expect in the future is Janet Bucknall, APHIS Associate Deputy Administrator for BRS.

MS. BUCKNALL: Hi, everyone. So I'm going to talk about the most exciting topic on the agenda, our IT system. And I just, I actually have very short comments, just five or six slides.

So the title slide noted E-File, which is actually going to be our electronic system that's going to replace, among other things, the ePermit system that many of you are familiar with. But the overall agency effort, just to kind of organize the lingo, the overall effort so what we call CARPOL, which really just stands for, as Dick had said, Certification, Accreditation, Registration, Permits, and Other Licenses. So the part where BRS fits and where all of us fit together is in the permitting module, which, happy for us, was the first one that we started developing. So I'll just give you a very brief summary on what our progress is to date and then a little bit what it looks like moving forward for all of us.

So in general, the effort here was to really streamline both for all of you but also for employees, for APHIS employees, to streamline a

bunch of different systems that are already in place. We have eight legacy systems that result in the creation of authorizations for the public, basically, from APHIS and also 12 feeder systems which are sort of the off-to-the-side databases and systems that we use to sort of inform and enable to the eight legacy systems. So the overall goal with this CARPOL effort and the E-File system that will be created is to combine those into one system so that an applicant, any one of our companies here today, you may not only get a permit from BRS but you may also have permits or other authorities from some of our sister programs in APHIS, PPQ for example.

So the end result of this system, the hopeful end result, is that, as you apply for, say, your BRS permit, you won't have to, for example, re-do the whole thing from soup to nuts when you pursue your PPQ authorizations. So that's one of the benefits that we see but also the collection of benefits for all of us as we go through this.

I did just want to note that APHIS

issues -- and I did not know this -- just under a million authorizations a year in all of those sort of six buckets of the CARPOL overall effort, so it's a substantial body of work. And when we consider the applicants, the APHIS employees involved, it was about 30,000 global users of our systems collectively. So it's really quite an effort.

So this APHIS E-File effort or system that we're creating is going to be a single electronic system. It's going to be cloud-based and based on the Salesforce platform, which some of you may be familiar with.

So in terms of the BRS permitting part, I was thinking this morning we may be around 40 percent done with the development of the part that you all will be working on with us, in terms of BRS notifications and permits. We're working on the first two parts of the application process that you'll be involved in, the authorization part of it which is us issuing a permit or acknowledging notification. Then other components would involve our inspection compliance, incorporation

of reporting, and things like that that have yet to be developed.

But our overall approach this fiscal year or our sort of expected time line is that we'll look forward to either having user acceptance testing which will involve some of you sort of early summer-ish, maybe late spring. And then we're hoping that the system could be implemented by the end of the year.

And I know we discussed a little bit about this last year when Mimi presented to the group and some follow-up conversations we had. We are still interested in knowing who of you would like to be involved in the user acceptance testing, and I know we did get some names about a year ago and we just would like to refresh that list. You can talk to me either at the break or any time today or this week or next if you'd like to be involved in that, if you have a very particular interest in being involved in that part of the process. And, again, that will be sort of early summer.

I guess that was it. I think I had one

more slide. I think I pressed the wrong button. Yes, there we go.

So I'll just finish up from that. And, again, I am available to answer any questions. And Mike did mention that we do expect to accomplish sort of a bunch of things with this developing system, and not the least of which is to help us bring to life the recommendations that we heard from OIG and also some of the other things that we see. Certainly, included among those are the recommendations and our own sort of improvements that we seek to better incorporate the information that you guys give us in your reports into our process to develop permit conditions and to conduct our inspection compliance program.

So, hopefully, we'll keep that all on track. And like I said, I'll be here for questions or any requests that you guys have about this. So thank you.

Are there any questions now? Yes.

MR. GIDDINGS: I'm Val Giddings with the Information Technology and Innovation

Foundation. You mentioned that you issue 900,000 some odd notifications every year, 30,000 total users. Could you please explain how you define your total users?

MS. BUCKNALL: I think what those numbers were, I think, a conglomeration of applicants and APHIS personnel and people who have received authorizations from the program and combined not only the permits but any of the other forms of authorizations, like accreditations. So it can range from, you know, facilities to other permitees, people that get permits.

MR. GIDDINGS: So those are the people who are actively engaged with you securing regulatory approval or permissions, not just folks who log onto the website?

MS. BUCKNALL: Yes, right, right.

MR. GIDDINGS: Thank you.

MS. BUCKNALL: Sure. All right, thank you.

MODERATOR GEORGE: Thank you, Janet. Great presentation, plus you got us almost back on

time. So thanks so much.

We're going to take a ten-minute break. If you'd like to sign up for an individual meeting with BRS leadership this afternoon, please do so during the break at the registration desk. If you're on the phone and you'd like to sign up, send us an email with your contact information. We'll get back to you to set it up. Send your email to brs.stakeholders@aphis.usda.gov.

Thank you, and we'll see you back at 10:45.

(Whereupon, the above-referred to matter went off the record at 10:35 a.m. and resumed at 10:50 a.m.)

MODERATOR GEORGE: If you could take your seats, please, we could get started. We're almost on time. Hello, folks. If you could just -- it's nice to see people having a great time. Please take your seats, and we can get started again. Thank you.

Our next segment is about the extensions provision for deregulation at 7 CFR part

340. Here to cover that subject is John Turner, Director of the BRS Biotechnology Risk Analysis Program. John?

MR. TURNER: Okay. Listen up, everyone. I've got a question for you, a game of sorts, and you guys are experts and should have some great ideas. What do you think is the most frequently-reviewed trait in the 115 petitions that we have deregulated? So were his hypotheses good? That's the thing: you've got to think in categories. And I'm thinking large: glufosinate, fruit ripening, coleopteran resistance, so phenotype, not phenotype category.

So we'll go ahead. I heard some people say glyphosate resistance and, of course, that's a great guess. It's wrong, but it's a really good guess. I would have guessed that until I did the math.

The big winner, glufosinate resistance in 26 petitions. That's nearly a quarter of all petitions. Now, I didn't know there are many more that use this than all the rest, and all use the

same mechanism of action, phosphinothricin acetyl transferase, the PAT protein, two different genes linked to the PAT protein.

Next, lepidopteran resistance. Of course, controlling important pest solubility in both corn and pests in cotton. 25 petitions, nearly as many. Next is glyphosate, also very high, 22 petitions.

If you kept going and adding all these up, it would equal more than 115. Of course, many of them are stacked. Lepidopteran resistance, that's the Colorado Potato Beetle and more recently, the Corn Rootworm petitions get a lot of petitions. And, again, very similar mode of action. You've got that cry-1 family and that cry-3 family, in most cases providing resistance. Fruit ripening altered goes back to the flavor of tomato. Nine petitions. And, finally, I clumped all the viruses. Eight petitions. After that, I think two was the highest of the numbers.

Okay. Let's do the same thing with crops. What's the biggest crop? Corn is the big,

34 petitions, nearly a third. Next is soybeans. Yes, you would have guessed that. How about three? Cotton, 17. You guys are good at this. Next? Tomatoes, all kinds, rape/canola, nine petitions. Finally, seven -- I mean, potato, seven petitions.

So the point of this exercise is we spent a lot of time reviewing some of the same things over and over, very familiar traits and very familiar crops. And then you pose the question, is there a way to leverage all of this previous work so that we can expedite the review of similar things when they come in, align with the previous work that's been done? And, of course, Mike will be talking about this in the afternoon, but is there a way to do it without a rule change? And, yes, of course, there is. You know, Mike calls them extensions today, so this is something that's already on the books.

So at the risk of losing you, I'm going to go directly to reg. text. It's interesting. It's very important to understand. It says the administrator may determine the regulated article

does not pose a potential for a plant pest risk and, therefore, should not be regulated under this part based on similarity of that organism to an antecedent organism. In other words, they're not establishing plant pest risk de novo; you can make the determination that it does pose a plant pest risk based on similarity. And developers can ask us to do an extension of regulated status.

And the second sentence is very interesting, also. This is all regulations say in terms of data or information requirements. Such requests shall include information to establish the similarity of the antecedent organism and the regulated article in question.

So, again, not to show de novo that the new thing is not a plant pest but to show that it's similar to something else. So, in its essence, this is a bridging concept.

So last year, we announced an extension process. We were going to look at this and see if we could use it more broadly, what we could do with the extension. We talked about that a little last

year, and we've been doing it for a year. We have some draft guidance. It's not on our website yet, but we're hoping to have it up there very soon, by the end of the year, and then some new information requirements.

And, again, we're starting to think about, you know, this is something that's on the records that's maybe not being utilized as much as it can. Is there a way to use this to work more efficiently without compromising plant health at all? That's the idea.

So under our new system that we've been working on, to be eligible for an extension, we must approve the same crop with the same mechanism of action. So what do we mean by mechanism of action? The EPSPS gene for giving glyphosate to corn, that would be a mechanism of action. There are other ways to do it, glyphosate oxidase, which would be a different mechanism of action. But as long as something shared the same mechanism of action, we think that's what's important.

Now, it could be different genes.

There are different sources for these EPSPS genes. As long as they encoded protein which did the same thing, we would consider that the same mode of action, or we'd be willing to think even more broadly: as long as you've seen the crop before, and you've seen that same phenotype category, herbicide tolerance say, we would consider the extension if we've seen the mechanism of action in something.

So, basically, we have to have seen the crop before. We would have had to have seen the phenotype category that they're asking about in that crop, and we would have had to have seen the same mechanism of action in something.

So there's three scenarios that would fall out if you go down this path. The first one is the easiest. So, we're going to have a previously-introduced trait, and you're just putting it into a different variety. Same gene, same trait, different variety. Our example here is an arctic apple that was recently deregulated in two varieties. If someone came with the same

trait in another variety, that obviously would qualify for an extension. And that's sort of the extension classic. That's the way we tell it for the future.

The second example, where traits previously were reviewed separately in a particular crop are stacked together in the same crop, introducing them as a molecular stack. For example, a stack corn line is created introducing both an EPSPS gene which was previously reviewed in corn and a cry gene which has been previously reviewed in corn. Put them both together. Do you think that should qualify for an extension? And in this case, in the case I mentioned, there would be two antecedents. If it was a stack of three, there could be three antecedents. So there can be multiple antecedents.

The last example I have is where phenotype categories have been reviewed previously with the crop, but a mechanism of action is new to the crop, but it's been reviewed in another crop. For example, if the hppd gene, which confers

resistance to at least a kind of herbicide, is introduced in corn, so we've had herbicide within the same type of category. Herbicide is obviously in corn but not that particular mechanism of action. However, it had previously been reviewed in soybean, so this also would qualify, and this would be another example where there could be two or more antecedents.

Data requirements. We think we need a complete description of the genotype and phenotype, and this includes the genetic modifications of the regulated article under consideration. Function and other organisms for any inserted genetic material, transformation factor, the mechanism of action of the genetic modification.

We think molecular characterization to show that what is in there is what you intended to put in there and it's intact. A concise written narrative comparison summary table of the regulated article and the antecedents. Again, the important thing is that we see similarity, how it's

similar.

Information with phenotypic expression describing differences between the regulated article and an antecedent organism. And you need to identify the petition numbers and actually probably the events from which the extension is requested.

In terms of time line, time lines for review would change depending on the complexity. In the three examples I gave earlier, they get less similar when you go from example one to example three. So there could be a difference in time.

NEPA is NEPA, and it's sort of a separate consideration. So in many cases, we think the previous NEPA analysis could be sufficient. Just write a new policy and other cases that may be new to NEPA. So depending on the NEPA analysis, that can change the time line.

And, finally, APHIS believes that, in most cases meeting one of the three criteria, we can do this in eight months or less. And our hope is to do it in much less than eight months, but this

allows for a case where you had to do a lot of de novo paperwork.

So this is sort of my summary slide pulling together a lot of things. There may be one or more antecedents. Developers requesting extensions may rely on antecedents in petitions from other developers. NEPA considerations are separate and, in some cases, it will involve a new policy, and in other cases a new environmental assessment will need to be prepared.

Field data is not necessarily required, so, again, you're showing similarity, you're talking about what's in there, making sure you have the intent and phenotype. And we encourage developers who are considering extensions to come talk to us.

So the extension project, people working on it in the past year, certainly not just me. Ginny was our chair. Donna Lalli, our chief of staff, was on the committee. Neil Hoffman contributed big time, as did Chessa Huff-Woodard, keeping us on the legal straight and narrow. And

then there's me, and our executive champion for this project is Janet Bucknall.

Thank you. We are going to do questions now.

MR. COKER: A gentleman online would like to know is there a way to challenge the extension qualification? Is there a way to challenge the extension qualification?

MR. TURNER: You can ask us anything you want, and we encourage people to consult with us ahead of time. But the intent of any guidance is to let people know and to be as transparent as possible as to how we're going to make our decisions. So that's what the guidance is for, and we think the new guidance will give us a lot of leeway to use the extension process.

So Mike is asking what sort of public participation there is for the extension process. And the extension process, as described in the regulations, is a little different than a normal petition. The normal petition has to be published, and it goes out for 60 days. You have

to take comment on the petition. Then we make our decision, and that can either require a draft EA, draft documents which go out for comment, or sort of a preliminary decision.

So under the extensions, there is no 60-day comment period on the extension requests. That's not described. And, of course, the relevant petition has already been out, so, essentially, we have to put the preliminary decision out for a 30-day review period before it can become final. That's the comment period and then the public review period.

MR. MEDLEY: Thanks, John. I have two questions. One, in the extension provision, there's nothing that would prevent the agency from identifying something that's entitled to that, correct?

MR. TURNER: That's correct.

MR. MEDLEY: And, secondly, looking at the time line, it said eight months. Would it be possible to look at six months?

MR. TURNER: Would it be possible to do

what?

MR. MEDLEY: The time line.

MR. TURNER: Again, I think the eight months we were envisioning would be the worst-case scenario. I think certainly six months or much less is very possible, if I understood the question. And we've noticed, that's a very astute observation that the administrator could do an extension without a request coming in, and we've spoke about that a great deal as to when we might want to do that. But one of the issues is you've got all these permits and notifications. You don't ever know exactly which ones would be your bang for a buck in terms of getting something approved where you wouldn't have to again. We don't exactly know where to start, but we're very open to ideas on that.

PARTICIPANT: My question is around the data conversation, and the way I understand this is you're prolonging a previous non-regulation petition, and there may be data associated with that that this new person doesn't

have to do. Is there anything in here to compensate, or people can just use data for a different application, even if it's a different company, without compensation? I mean, how does that work in this?

MR. TURNER: So we have no mechanisms for compensation, and most of the data that's in a petition is non-CPI and it's open to the public. So there's not, there's nothing, you know, on our part to prevent someone from utilizing that data. It's an interesting question, but we don't have that at this time.

MS. SCHMIDT: Daria Schmidt, Pioneer. Did you mention when this posts to the website?

MR. TURNER: We're hoping to have the guidance which covers what's not covered today and expounds upon that, you know, soon, maybe by the end of the year. And in the meantime, if people think they're interested in extensions, you can talk to us at any time.

MR. JENKINS: Dan Jenkins with Monsanto. How would you distinguish under the

approved petition process, path 1, which we earlier traced, this seems like a pecuniary path, right? So what we've done here is path 1, right, for a petition process, which is really for traits more familiar. Extensions are very similar to that. You're talking about traits, familiarity with cross --- with phenotypes. How do you distinguish those two processes?

MR. TURNER: Those are very closely-related concepts, and I do, in fact, anticipate that a lot of things maybe that were previously path one, familiar crops and familiar traits that developers might come and ask us about a petition. But I'd have to think about it, so I'm not convinced every path one would meet the criteria. It can be a familiar crop and a familiar trait, but a phenotype category we haven't seen in a crop.

Thanks for your attention, everyone.

MODERATOR GEORGE: Okay. So while they're transferring the microphone, as most of you know, back in February we announced the withdrawal

of our 2008 proposed rule. Since then, we had three webinars in May and an open docket on regulations.gov through June 22nd where we received public comments in response to our request for initial feedback on how our regulations should work.

Here now to describe our current thinking about a new proposed rule, once again is Mike Firko.

MR. FIRKO: Hello again. So we're in a unique period of time right now with respect to thinking about where we will go with these regulations. We can have lots of conversation about this. This is why we opened up the opportunity this afternoon for one-on-one meetings because, once we publish the proposed rule, those conversations are not going to be as easy to happen. So this is a good time to be talking about ideas.

The reason you'll see the terms "current thinking" multiple times on my slides is because that's what that means: this is where our current thinking is. There will be things in the

proposed rule that you're not going to see here today, and you may not see some of the things you're going to see today in the proposed rule. But this is where we are right now.

So I want to remind folks, and I have, in the spirit of updating the coordinated framework, you might notice that under USDA it says we're plant health. That's really our authority. The previous slide is a version of the slide that's going to be used for many years. It says safe for agriculture and the environment. But our statutory authority is really about plant health, as the name of our agency is the Animal and Plant Health Inspection Service.

I wanted to remind folks of basic tenets of the coordinated framework. These were published in 1986, and they have proven to be true over these past 28 years of regulating the products of genetic engineering. The risks of GE organisms are not fundamentally different from risks imposed by non-GE organisms with similar traits.

The coordinated framework was clear

that regulation should be science-based and to be done case-by-case and that existing laws provide sufficient authority. If you look at the, I could have shown you a slide that looks at all the statutory authorities that the three agencies use. I decided not to, but it's things like FIFRA. For us, it started out to be in federal acts, like the Plant Protection Act. But there is sufficient authority to protect all of those things: plant health, food and feed use, and use as a pesticide.

And, lastly, this is the new one that I added. Agencies should stick to their statutory authority, and that's going to be one of my themes over my next several slides.

So new regulations. So we've been in discussion within USDA on these ideas for a while. And not too long ago, the Secretary's office came out with what they call their topline messaging, and so I'll give you those and then I'll expand on those.

First of all, it's USDA's position that the biotech regs across the federal government,

USDA in particular, have been successful at protecting plant health. We have no reason to believe that anything that we have authorized for field trials or non-regulated status has represented any risk to plant health, so we have successfully protected plant health.

But the science is changing. The regulations in 1987 were based on science at that time. At that time, if you were genetically engineering a plant, you were using a plant to transform. That is no longer true. Science has changed.

The regulations have stayed essentially the same since 1987 with a few tweaks that I referred to earlier on. We have a new statute.

Now, neither in the Federal Plant Pest Act nor in the Plant Protection Act will you find the term biotechnology or genetic engineering. That's because our authority is plant health. It's for plant pests and noxious weeds. But we don't have new regulations since the new statutory

authority was created.

The language that we adhere to in our regulations, the language in the Plant Protection Act is the same as was in the Federal Plant Pest Act. That didn't change. The main thing that the Plant Protection Act did was it incorporated the noxious weed authority into one statute.

We want to do a much better job moving forward focusing on risk, and by that I mean not worrying so much about things that we're pretty sure don't represent a risk and capturing the very small number of things that we think do represent a risk but are not subject to the current regs because of the way they're written.

Our current system is regulate first and analyze later. We get, like I said, we issue 2,000 authorizations a year for regulated activities, rotation, interstate movement, outdoor use. When someone asks us to be regulated by submitting a permit application or notification, we give it to them. We specify conditions when we can, but we don't analyze the

risks, the plant pest risks, at that time. We want to move from a regulate first, analyze later, to a situation where we're analyzing first to determine whether or not we have the statutory authority to regulate the product, organism, whatever it happens to be, and then only regulate it if it represents a risk.

This is going to amount to regulatory relief for many people. I believe it will dramatically stimulate innovation in new plant varieties. When we speak to universities, they're very clear. They say, look, we can do field trials, but we simply can't afford an efficient process, so we could never get a product on the market. This will make it possible for folks who are creating products in biotechnology that do not represent a risk to American agriculture, don't represent a risk as a plant pest or a noxious weed, to go ahead and do the development of their product.

So current thinking, there it is. So when it came down to a proposed rule earlier this year, we also opened up a public comment period.

We had 40 or 50 comments that were received during a series of three webinars that we did, but, overall, we received comments from 221,000 individuals. Now, like the previous situation, many of those were group comments. They take a variety of different forms. There's one statement, and then it's signed by a number of people, or a statement is shared with a variety of people and they each sign it and it comes in as a package. But we received comment from 221,000 individuals.

Next month, it's our intention to publish a notice of intent to conduct an environmental impact statement. This is what's called a programmatic environmental impact statement, programmatic because we're talking about changing our program. So you do an environmental impact statement that reviews a variety of different approaches.

Now, again, our current thinking is that we're going to have four alternatives that will be discussed in the NOI. We're required to

have what's called a no-action alternative, which means don't do anything, just keep the regulations as they are. So that will be analyzed in the environmental impact statement.

We will analyze an alternative that looks like what I'm going to show you over the next couple of slides. Of those 221,000 comments that we received, the vast, vast, vast majority of them were, first of all, they'll never allow any of this to be planted anywhere; and, secondly, if you do, it has to remain under regulation forever, don't ever grant non-regulated status. So that will be one of the alternatives in the EIS. You can't ignore 200,000 comments.

We have created, because it's our intention to implement the noxious weed, we have created a weed risk assessment tool. It has not been used for an operational decision to this point. We've been working on it for a couple of years. We have a very talented and diverse staff of scientists not only in BRS but through APHIS people who have been doing weed risk assessments

for decades. APHIS has an outstanding weed risk assessment tool in Plant Protection and Quarantine at the Center for Science, Center for Medical Science and Technology. And our model is based primarily on their model, but it also has elements from models from around the world: Australia, New Zealand, and other places.

What you'll see when you look at our model and these other models is that there's a lot of similarity among the models. I mean, people pretty much agree on what are the things that make a plant a weed.

We have currently entered into an external peer review of our model. This is being conducted through USDA's Office of Risk Assessment and Cost Benefit Analysis, and it's consistent with the OMB process for external peer review. And then it's our intention to, as soon as possible after that peer review process and revisions to the model, we expect to submit the model to a peer review journal, scientific journal publication.

So we have run several risk assessments

in-house to see how it's working, see if it's getting reasonable results. We're very happy with the way it's working. It's not an operational tool at this point. But when we publish the proposed rule, there will be much more information available at that time about some of these results.

We're developing the proposed rule now, and it's our intention to publish the proposed rule this coming summer. Like I said, we briefed the Secretary numerous times on this, and he said to us about six months ago or so, okay, go ahead and publish your proposed rule, but you've got to do it no later than September. Does anybody know what's happening around here in November next year? Elections. I hope that we're able to publish in August. I'd love to do it in July, if possible.

But, you know, we learned a lot of lessons with the 2008 proposed rule. We're trying to avoid some of the things that we did that caused enough problems.

Again, you know, one of the things that comes from that first piece is that we've been

learning for 28 years about the risks associated with these products, where they are and where they are not. We need to take advantage of that. We need to stick to our statutory authority, and the reason I said that a couple of times is that our current regs, and I'll show you this slide in a minute, are based on a particular way to transform plants, in particular use of the plant pest. And history has shown over the last 28 years that that doesn't necessarily mean that the plant becomes a plant pest, but we just keep asking that question over and over again. We need to take advantage of the learning that we've done in that area and stick to our statutory authority to only regulate things that represent a documented risk as a plant pest or a noxious weed.

We're talking definitely about a new trigger or definition. I'll show what the trigger is now in a few minutes. And it's basically moving from this situation where mere involvement of a plant pest in the transformation process means we're automatically a regulated article.

So here are our current regs. It's the two-tiered -- here are the two hurdles that have to be met in order for you to be a regulated article, and if these two things are true you are a regulated article. Your organism has been altered using recombinant DNA techniques. It depends on who you ask. You'll get different answers about what that word rDNA means. Some people take a very narrow view and think that only means if you're moving genetic material from one species to another all the way to the other end of the continuum where any time you've done anything to cleave a string of nucleotides in the DNA and it reassembles, that's rDNA. And I think you'll get any number of different answers between those about what rDNA means. But if you use rDNA, concepts and there's a possibility the organism is a plant pest, so how can, for example, a corn plant become a plant pest? Well, according to our current regs, it's either because you used plant pests to donate genetic material. Maybe you found a bacterium that's considered a plant pest that has an

herbicide-resistance gene, and you put that herbicide-resistance gene in corn, so it's automatically regulated, or the recipient is a plant pest. You know, most of those are plant pests. I mean, if the thing you're transforming is a plant pest, then it does meet the plant pest criteria. That was pretty clear.

The reason that we regulate the vast, vast majority of everything we regulate is because the way that the plant was transformed was with the use of plant pests to show DNA from here to there or something else like that. It's done in a variety of different ways. And, again, if there's anything we've learned in 28 years, simply using disarmed agrobacterium tumefaciens, just using it to show genetic material from one place to another, that doesn't necessarily make the plant a plant pest. I see lots of heads nodding, you know. We'd like a new trigger. There's a list in our regs that needs to be met.

Again, current thinking. In our future world that I always smile when I think of,

when we're regulating only those things that represent a risk, we would not be regulating products, plants, whatever, until such time that we have completed either a plant pest risk assessment for plant pests or a weed risk assessment for plants and be able to document a reasonable risk hypothesis with scientific support about why we think this needs to be regulated. So regulate only with documented risk. This is the analyze first and regulate only when needed.

Obviously, this takes us to a place where regulation is risk-based. When I say regulation, you know, I'm talking about regulated field trials, move it to interstate. All that is regulated now. And it's not analyzed. It's just regulated now until such time when someone submits a petition for non-regulated status.

We joke with ourselves consistently over the last several years about what comes in and what does "in" mean. So there's two tiers here. The first is that we have a pretty good idea what we think should be regulated because it represents

a risk as a plant pest or a noxious weed. I don't think that's a very fun question to answer. I think we've got 28 years of experience dealing with plant pests and we developed a new weed risk assessment tool to look at noxious weed risk and, to me, that's not going to be that hard.

The first year or two under new regs is going to be a struggle. It's going to completely change our operations and go to a different way of doing business.

The harder thing, though, is how do we say in the regulations that you have to come ask us if? And I'll ask this group, just like I've asked many other groups over the last several weeks, how should that be phrased in the regulations? I guarantee you, no matter how we phrase it, there's going to be screaming and yelling and everything else. But as regulators, we're used to getting screamed at from all different directions. No matter how we phrase it, there will be people saying, you idiots, you're killing us with this over-regulation; and there

will be people saying, you idiots, you need to regulate all this this way.

So we're trying now during this time period when we actually have it for conversations to come up with how should that be phrased in the regulations about when you have to come ask us. So a big picture idea of what we're looking at now is a larger umbrella simply because now we're talking about a new authority, noxious weed authority. So the things that should get our attention might be greater for a very short period of time, but then the stuff that fits through the filter and actually gets regulated is much smaller. Much smaller.

I couldn't talk today without talking a little bit about precision breeding. Let me give you, think about an advantage of engaging in these conversations. I gave a presentation sort of like this one not too long ago to a group, and I read our working definition of genetic engineering. Wow. It was not received well. It was viewed as an overreach. One of the things it said is, look, if you use any techniques of modern biotechnology,

we're calling that genetic engineering and you need to ask us if it's regulated. And that was, like I said, that was viewed as a dramatic overreach.

So we got that input. It was great input. That definition of genetic engineering is gone from our framework document now. So we responded already when we received input, as opposed to questions. And one of the main things that we're talking about now is how do we characterize some of these precision breeding techniques?

I'll give you an example. Look around the world at what's happening in other countries. Some countries are saying simply, look, if there has not been any genetic information put into the product, that doesn't need to be regulated and we're not going to regulate that. And there's also some techniques that are used in precision breeding that either knock out a nucleotide or knock out several nucleotides, disable a gene, whatever. There's several things like that that don't involve moving any genetic information into the process.

That's a possible direction we could go and say anything like that is exempted, but it's a long way from here to next summer, and we're trying to figure out the best way to characterize that in our regs.

What comes in, I already mentioned this, this is our number-one issue that we're talking about internally. When I have a meeting like this, and I ask people for input on that.

So now, under our current regulatory system, if, after we've been regulating something for two, four, five, ten, twelve years under controlled field trials, if someone comes to us and says, you know, I don't think my plant is a plant pest. We do a plant pest risk assessment. We do our NEPA documentation. And then I sign a determination that says we did the PPRA, plant pest risk assessment, we did the NEPA documentation, and guess what? This thing is not a plant pest.

In the future, we see someone coming in where we analyze first part, and then we write a letter to that person that says we reviewed this thing completely and guess what? This is not a

plant pest, and it's not a noxious weed. Go forth and prosper.

So from day one, I challenge folks on my staff to design the letter that's going to go out under our new system to look strikingly similar to the letter that goes out now in public cases. We're reviewing the product. We're making a determination does it represent a risk to plant health, and we may need appropriate environmental considerations.

We have in our regulations for NEPA currently that under our current system, a petition for non-regulated status requires this many days. We want to move to a new system.

So I think now we have time for questions. Dan?

MR. JENKINS: So, if you were to determine that something was not in --- that something needed a major federal action to get in, are you saying that there would not be any methods to consider it or that there might be?

MR. FIRKO: So, originally, we were

thinking that the way to do this would be to have it all be done under a permit application because, you know, in our NEPA regulations it says permitting activities are a category that are excluded under the requirements of the NEPA. So for a variety of different reasons, it looks like that's not going to work very well.

In our current framework, we see a two-tiered system where people would engage with us in a regulatory status inquiry, simply asking the question is this a regulated article or not? Now, I'm not an attorney, but if someone asks you is my product a regulated article, and if our answer is no, I'm not sure what the federal action is to trigger a need for an environmental assessment or EIS.

Does that mean that we're exempt from NEPA? Of course not. We do all sorts of NEPA stuff that most of you aren't aware of. For every permit that we issue, authorizations, we do a lot of NEPA stuff behind the scenes. But it's not EAs. And we would continue to do that due diligence

according to a law that we are required to follow. We continue to do that. But I don't see telling somebody, no, your product is not a regulated article that's requiring an EA.

An example, our Am I Regulated process. We don't do EAs for those. That's the version of regulatory status inquiry that we have now, but it's based on the Am I Regulated process we have now. It's based on our current regs.

MR. JAFFE: So, just a follow-up on that. So, you talked about that definition as being, you know, what comes in, as being critical, so if in fact, so -- and you said that it's focused on risk. So you have to have a definition that would be a risk-based definition, if I'm hearing you correct.

MR. FIRKO: Our answer to that doesn't represent a risk would be in the risk assessments that we produce and the associated overall risk analysis because a risk assessment, whether it be a plant pest risk assessment or a noxious weed risk assessment is just part of the risk analysis

process. The other part is our other considerations and other factors that are not covered in your risk assessments. But like I said before, we would not be regulating anything if we did not offer a document that says here's why.

MR. MUNDELL: Hi, Scott Mundell, DuPont Pioneer. So earlier today, you talked about the numbers of authorizations and imports and all those kinds of things that the agency authorizes every year. That earlier research under this new framework, how do you envision that occurring?

MR. FIRKO: So we would be happy to receive regulatory overlooking. You know, part of this whole question about what comes in is how much of a volunteer system is this going to be, you know? When you phrase in your regulations, you know, when do you have to come and ask us the question whether or not you're regulated, that's the same thing as establishing how much of a volunteer program that you have.

I would expect lots of people to come and ask us so that they can get an answer about

either, no, you are not regulated or, yes, you are.

One of the things that we plan on publishing when we publish the proposed rule is our initial lists of here are the things that we would not be regulating under the new rules and here are the things that we would be regulating under the new rule. And I see that as -- and that would be the regulatory status registry. I see that as being contained on our web page, not the regulations. I mean, it's tough to get regulations done in four years now. It's tough to get it done in one administration. So I see that being maintained on our web pages so that anyone who's interested can look at that list of whatever you want to call it. If you want to call it exemptions or previously reviewed, or there's a lot of different things that you could call that. But if your product is like one of these things, you're done. If you want to come and ask us so that you have a letter from us, we're happy to do that. Does that answer your question?

MR. MUNDELL: Partially. Well, I

think it's, about also the weeds the volume. So I understand the up-front nature of the process, but when you think about many of the large multinationals that are engaged in broad swaths of research into what I understand, for coming up with a new glufosinate and new glyphosate, those may be categorically exempted from the start, it sounds like to me. But when we think about, you know, a multitude of other things that -- the degree of technology that each level has, just the science that is available to us right now, I have a concern about the agency having the staff to address all of the questions that you will receive, especially upfront.

MR. FIRKO: Thank you for your concerns. Realistically, though, like I said, when we publish the proposed rule in about nine months from now, eight or nine months, we expect to have a significant start on that list of things that, okay, we've analyzed these, and we're done.

Now, let's get real about when we can expect to find them. So if we publish a proposed

rule in August, then the elections happen. Nothing is going to happen until the new administration comes in. Once a new administration gets here in January of '16, they're probably not going to want to talk about this for a while, six months a year. And then we move into creating a final rule and working it through clearance. It's going to be three or four years, I think, at best. Maybe two or three but, realistically, three or four before we see a new final rule.

We've got all that time from now until then to continue adding to this list of we reviewed it and you don't need to ask us about this. You can if you want, you can get a letter if you want, but you don't have to. And these things over here, you know, actual plant pests, like citrus tristeza virus or diamondback moth or pink bollworm, you know, there's lots of genetically-engineered plant pests that we work with, which will probably all be on the okay list, unless there's some compelling reason for them not to be on the okay list. But

by the time we publish a final rule, I expect that list to be very well populated.

Now, I'm not saying that the first year is going to be easy. It's going to be hard because any time you completely change operations in your group -- I mean, right now, our group is -- our BRAP group, the group that John Turner leads, is spending a significant amount of his time reviewing all of these authorization requests that come in, regardless of whether they're permits or notifications, doing NEPA checks on all these things. When they're not doing those sorts of things, they're working on petitions for non-regulated status. I expect those two pieces of work to go away to a large degree because I see us focusing on things that we've said, okay, this represents an actual risk and this is something that does need to be regulated for whatever reason. I expect that list to be small. I expect us to be paying closer attention to things that are on that list. Instead of having 11,938 planting sites

that are under regulation, I expect that list to be substantially smaller. So instead of inspecting 10 percent of field trials, the same staff can expect maybe 50, 60, 70 percent of field trials. And with that communication, you know, I think everybody is getting benefits out of that. Incidences should go down, episodes of non-compliance should go down, understanding about making sure that there's no persistence in the environment should go down.

I mean, let's get real. Our business in APHIS is about protecting plant health. That's our laser focus. A lot of people doing field trials for whatever reason, whether they're regulated by us or not, they're focused on different things for the most part. Do I have a product? Does this plant do what I want it to do? And they're not as laser-focused on preventing persistence in the environment as we are.

I think it helps, to the extent that we're having conversations about what are the good ways to make this happen, you know, one of the

things about the GE wheat, I've spent a long time talking about GE wheat, I doubt there are any that we're aware of that would be regulated in the future. So I see this requirement of having permits right now as kind of a temporary solution until we can have new regs. I mean, you've seen the traits for a lot of GE wheat. It's on our website. I mean, is herbicide-resistant wheat a plant pest because agriculture was used to transform it? Is it a weed?

MR. SAYRE: Okay. I'm Phil Sayre, Keller and Heckman. Really, there's just a sort of assumption that I want clarified. So it sounds like we're looking from more, what's the term -- process-based systems to risk-based systems, and I'd like some background, some clarifications about what triggers the risk that results in inaction. So you've already mentioned very specifically a couple of different items that are under consideration as posing risks, with higher warnings needed by the USDA. So I'm sort of assuming that between now and the summertime more

of these risk issues are going to be considered by the USDA. There will be, presumably, a continuing dialogue up through the summer, so that a rule could come out of it that bears some validity. So that's my assumption, and then my question is what is a process between today and this summer to talk about some of these issues? Is there a particular process or a particular way all these things should be done?

MR. FIRKO: Yes, and I have to ask you, on that last piece, let me be real. I keep saying next summer. Well, no, no, I'm not saying it's going to be longer, but, in order for the federal government writ large -- because this is not just about BRS, everybody's interested in this stuff. In order for there to be a proposed rule published next summer, we in BRS have to pretty much finish our work next month and send a draft proposed rule forward for clearance throughout the Executive Branch in the government. So the next six weeks is important for us.

Can we continue to talk with you up

until next summer? Absolutely. We'll continue to take input. But our ability to continue holding that draft back from the Office of Management and Budget and the U.S. Trade Representative's office and the White House, you know, you just can't keep pulling it back and saying, oh, oh, oh, we need to make some changes here, you know.

So we've got to do that in the next several weeks. By the end of the calendar year pretty much.

MR. SAYRE: So I assume that we're all --

MR. FIRKO: Risk factors.

MR. SAYRE: Yes, that's okay. So the process then for, say, the next month or six weeks is, in fact, with APHIS.

MR. FIRKO: Dick is our communication branch chief. I think there's still a slot or two open this afternoon. You know, we started with eight 30 minutes. We had more requests, so we went to the current sessions. You know, we're going to try to accommodate, anybody who's here today, we're

going to try to accommodate to have some time with BRS management, whether it's me or Janet or Sid or John Turner or Neil Hoffman, you know, any of our senior BRS management.

MR. SCORZA: Ralph Scorza, USDA ARS. I'm wondering how you see this, I would say, updated thinking on risk based, how do you see that affecting the coordinated framework in terms of is this in discussion or is EPA going through a similar kind of process, FDA? How do you see that affecting that relationship that we have?

MR. FIRKO: I love these question and answer sessions because it reminds me to say things that I wanted to say but forgot, so thanks for that. We have had a lot of questions about the relationship between the effort in the Executive Office of the President to review and update the coordinated framework and what we are doing. So I like to think of this as a diagram with just a little bit of overlap, and the reason the overlap is only a little bit is the coordinated framework is all about, okay, you've got your statutory

authority, here's how the agencies coordinate.

You won't see anything in that July memo from the Executive Office of the President that either says change your regs or here's what the new regs should do. You won't see any of that, and that's because that's the agency authority. We have authority granted to us by the President and Congress to regulate based on certain factors and it's within our discretion to write those regulations. And I've only worked with a couple of administrations, and I've never really encountered a situation where they've had to drive the regulatory approaches. I've never seen that.

Now, the overlap piece is that our lead on the updated coordinated framework is Sid Abel who talked to you earlier. He is one of our small, we have a small group on the 340 steering committee where we're meeting two to four times a week and we're hammering out what this proposed rule is going to look like. He's in the office of the Deputy Administrator, so he is intimately involved in both of those initiatives. So they are

absolutely moving in concert.

Now, with that said, I have briefed five different offices in the Executive Office of the President, and I would say that OSTP, who's driving this forward, is in complete support of what I told you. Their position is that maybe we're not in such good compliance with the coordinated framework because we're regulating things that the builder of will remain anonymous.

MS. PREUSS: So Daphne Preuss, Chromatin. We're a small seed company dealing with a lot of seed technologies. First of all, thanks for doing this today. It's great to hear your thoughts and views and really your approach to encourage streamlining. One of the things that's a little challenging for us and I think it's probably the case in small companies in general to be in a situation, anytime any regulations change, it creates uncertainty. And so the specter is changing. Unfortunately, for us, it's already caused us to shut down some programs while we're waiting because we just don't have the investment

to make if something is not going to work out for us or make those return on investment numbers work. Three to four years of uncertainty takes us well beyond, you know, a small company's ability to risk capital because of different rates of your approval. What can you do, if anything, to remove that uncertainty? And I know it may not be possible, but I think what one impact of this four years of uncertainty is certainly venture capital but also equity is backing away from these investments.

So, again, it's just a challenge that we have. But we'd hate to see the nation's innovations stall.

MR. FIRKO: Yes, I hear you. So let me give you a response to that. It may not seem like it's responding to your question, but I think it does. The vast, vast majority of what APHIS regulates is commercial activity. That's not so with BRS because the way our regs are written now, for the most part, 99 percent, something like that, whatever, there is no commercial activity while

something is regulated, and commercial activity, quote/unquote, cannot happen until it's been granted non-regulated status.

So here's the scenario. If someone comes to us and they've got a plant that they're interested in transforming with some trait, and we do a risk assessment and it gives us pause, and we say, oh, we're concerned about some noxious weed risk here. Does that mean that you can't go forward in commercializing? Absolutely not. The vast majority of what APHIS regulates is commercial activity. Instead of having people going through, you know, thousands and thousands of genetic constructs simply because agro was used to transform the plant, if we use those people instead to work with folks who want to plant something that has a documented risk associated with it so that that work can be done in such a way that the business can go forward as it needs to go forward and we can do our due diligence and earn our taxpayer money by making sure that we're protecting plant health.

And that's a very different operational

model than what we're doing now, but I think that there will be problems. I mean, we've had this conversation with people in the room, people who are here today. You know, APHIS regulates bio-control agents that eat plants. That's a plant pest, right? Weed bio-control agents, those are regulated. But it's commercial activity. There are hundreds of companies around the world that mass produce plant feeding weed control agents, and we regulate that by issuing the permits to go ahead and make those releases. That's commercial activity.

That's not the way the BRS model has been working. I see us moving to that in the future. I think that's a very small number of things, though.

MR. GIDDINGS: Thanks. I appreciate your comments. Val Giddings with ITIF. I like a lot of what I've heard here in theory, and I'm the last person who would discourage a regulator from thinking boldly about how to try to bring regulation back into a closer state of matching the

degree of oversight for a passionately presented product. But where I have trouble with what I've heard you say is in envisioning how you're going from where we are to where you say you want us to be in four or five years because, as Dr. Preuss has pointed out, that four or five years can be the valley of the shadow of death for small companies and academic researchers working in this area.

What you're talking about, if I understand it, is supplanting the current plant pest DNA risk trigger with something else, but I haven't heard any articulation of what the something else in terms of a trigger that would bring something in to be reviewed. But what it sounds like you're doing, and I'm hoping that I'm wrong, but what it sounds like you're doing is something that would be accomplished by a de facto process-based trigger that would capture everything until you have a conversation with somebody who may or may not be regulated to assure them that, in fact, they fall into one of the areas that you think does not present a risk under your

newly-construed authorities with regards to plant pests or noxious weeds.

It sounds like what you're trying to do in you articulating a new risk-based or hazard-based trigger is to build up what you describe as a regulatory status registry, build up a collection of case studies of stuff that falls outside the regulatory purview of the new system you're trying to design. Four or five years of building something like that up, you'll see a whole lot of stuff die. And I'm wondering if it might not be a shorter path to your desired endpoint simply by working more incrementally and, forgive me, less boldly within the existing system and working to develop categorical solutions that you said vast quantities of stuff you're now reviewing, which no one who has any allegiance to evidence-based decision-making could defend.

So I'm really curious as to how you produce uncertainty when a crowd is articulating a less ambiguous and more clear trigger for stuff to be brought in for review in a way that allows

small companies, like Preuss and others, to be able to look down the road to a horizon four years from now without having the uncertainty kill their fundraising opportunities or whatever.

MR. FIRKO: In the minute or two that I have, I mean, we can go a couple of different directions. One is please submit something in writing for this about how you see that working. One of the downsides I see with that is that we would continue to have a regulatory trigger that the scientific community seems to be unanimous isn't realistic. And to the extent that we have a regulatory trigger that doesn't make sense either with respect to statutory authority or with respect to risk, you know, I'm not sure I think of that as good governance.

There's no doubt that there are challenges associated with changing. USDA is not afraid, we're not afraid of change. I would assert that the reason I'm in BRS is to make changes, and the change is not going to be easy for anybody. But I believe that we can get to a better place with

having a more science and risk-based trigger and by regulating only those things that represent a documented risk. Your question is a longer conversation.

MR. FREDERICK: Real quick, Bobby Frederick with the National Grain and Feed Association. You mentioned trade --

MODERATOR GEORGE: I'm sorry to say that we're out of time.

MR. FREDERICK: Oh, I was just about to get to it, too.

MODERATOR GEORGE: We have to cut it off at some point. I'm sorry to say it, but that point is coming. So if you have a session set up this afternoon, perhaps you could pursue that, or if you don't have a session set up this afternoon and you would like one, go to the registration desk and we still have a few slots left and we will try to accommodate you as best we can.

If you are on the phone and you have not signed up for an individual session and you would like to, just send us an email at

brs.stakeholders@aphis.usda.gov. We will try to set up a phone conversation either today or sometime in the very near future.

If you have a meeting set up this afternoon, please report to the registration desk right outside here about five minutes before that meeting is scheduled and we will see that you get to the right place, to the meeting room, on time.

I'm very sorry to have to cut this off, but the problem is we need to try to get some food into some of these guys before they start meeting with folks. So thank you so much. This concludes our meeting. Please answer our email survey that you will receive, and there's a comment box in the back, as well.

Thank you all for being here. I'm very sorry for the folks on the phone who had questions, but we've just run out of time. Thank you also for being here, and this concludes our 2015 BRS Stakeholders Meeting. Thank you.

(Whereupon, the above-referred to matter went off the record at 12:04 p.m.)