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Public Stakeholder Meeting 12-05-2012

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U.S. DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

Biotechnology Regulatory Services

Public Stakeholder Meeting

Wednesday, December 5, 2012

USDA Center at Riverside

4700 River Road

Riverdale, MD 20737

Reported by: Erick McNair, RPR/CSR,  
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1 P R O C E E D I N G S

2 MR. GEORGE: Good morning, all. If you could  
3 please take your seats, we'll get started. Thank you.  
4 First things first. If you have a white Infiniti with  
5 North Carolina plates XPB-1933, your lights are on.  
6 We'll take care of the important business first. Good  
7 morning, and welcome to the 2012 BRS stakeholders'  
8 meeting. I'm Dick George, Communications Branch Chief  
9 here at BRS. This is our annual opportunity to look at  
10 where we've been in the past year and where we're  
11 headed in the next and to answer your questions. We  
12 have a full schedule, so we'll get right to it.

13 First a few housekeeping items. Please  
14 silence your cell phones so they don't chirp or whistle  
15 or chime or play the theme to your favorite TV show. We  
16 do have coffee and water on the table in the back of  
17 the room. Down the hall, out this door to the right,  
18 past the elevators, and your first left, is the  
19 cafeteria, if you prefer Dunkin' Donuts, coffee, or  
20 would like something to eat during the breaks.

21 Also, during the breaks and at lunch, our  
22 Permits Branch Chief Steve Bennett is here to help

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1 anyone who may need help to get eAuthenticated in order  
2 to access our ePermits system. And there's Steve in  
3 the back. Give a wave. If you need help with  
4 eAuthentication, Steve is your guy.

5 Today's presentations are available as  
6 printed handouts that are on the sign-in table, so if  
7 you'd like to follow along, take notes on the handouts,  
8 be sure to pick one up if you haven't already. If you  
9 need one, just give us a wave, and we'll get -- we'll  
10 get a set to you. Also, all of the PowerPoint  
11 presentations today will be on our website within the  
12 next day or two.

13 Today for the first time we're webcasting our  
14 meeting, so I'd like to extend a special welcome to  
15 those who are joining us online. Our hope is that  
16 webcasting will make it easier for more people to  
17 attend our meeting, so welcome all attendees, whether  
18 you're in the hall or online. Those of you online  
19 should be able to see the presentations and to ask  
20 questions by way of a textbox. This is the first time  
21 we've tried this, so there will no doubt be a learning  
22 curve, and thanks in advance for your patience.

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1           Also, a note to our presenters. You're on  
2 camera, and the camera is locked down, so please speak  
3 from the podium (indiscernible). We have a court  
4 reporter here today, Erick McNair, over here in the  
5 corner, who will produce a complete transcript of the  
6 meeting, which will be posted to our website within the  
7 next few weeks. So if you want to go back later,  
8 double-check something you heard today, it'll be in the  
9 transcript on the site.

10           Today's meeting starts with a very broad  
11 perspective and then gets into more and more detail as  
12 the day progresses. We'll begin with an APHIS-wide  
13 perspective, then we'll talk about the Advisory  
14 Committee for Biotechnology and 21st Century  
15 Agriculture, which just recently published its final  
16 report on issues related to coexistence. Then we'll  
17 have a BRS perspective on the year past and the year to  
18 come, a quick look at biotechnology on an international  
19 level, and then we'll get into the details of the new  
20 petition process and our NEPA pilot project, all before  
21 lunch.

22           After lunch, we'll cover some of the most

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1 frequently asked questions regarding ePermits,  
2 including whether and how it might be replaced. Then  
3 we'll talk about compliance and inspections and end the  
4 day with a look at notifications, permits, and design  
5 protocols, with an emphasis on common mistakes and most  
6 frequently asked questions.

7           We request that you hold your questions until  
8 each speaker has completed their presentation, as we  
9 provide a time for questions at the end of each  
10 presentation. Then, for those of you in the room,  
11 please wait until we get a hand microphone to you  
12 before you ask your questions so that all can hear, and  
13 also, please identify yourself and your organization  
14 when you ask your questions. For those of you online,  
15 just type your question in the textbox on your screen.  
16 If you would please indicate your name and  
17 organization, that would be helpful.

18           For our speakers, I will begin waving at you  
19 when there are five minutes left in your allotted time,  
20 so let's be sure to keep our eyes on the clock and stop  
21 in time to take questions. Also, after our last  
22 presentation this afternoon, around three o'clock, BRS

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1 staff will stick around to answer any questions that we  
2 may not have gotten to.

3           At this time, we'd like to have everyone  
4 introduce themselves, so we'll pass around a  
5 microphone. Please just give us your name and your  
6 organization, and please speak clearly and slowly  
7 enough that our court reporter has a shot at spelling  
8 your name right. We start right over here.

9           MS. COLLINS: I'm Susan Collins from the J.R.  
10 Simplot Company.

11           MR. CLARK: Pete Clark with the J.R. Simplot  
12 Company.

13           MS. BOHMERT-TATAREV: I'm Karen Bohmert-  
14 Tatarev, and I'm here on my own. I used to work for  
15 Metabolix in Cambridge.

16           MS. GRUSWITZ: Ariel Gruswitz, DuPont  
17 Pioneer.

18           MR. SHEA: And I'm Kevin Shea, the Acting  
19 Administrator.

20           MR. SCHECHTMAN: Michael Schechtman with the  
21 Agricultural Research Service and Executive Secretary  
22 of the Advisory Committee on Biotech and 21st Century

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1 Agriculture.

2 MR. GREGOIRE: I'm Mike Gregoire, Deputy  
3 Administrator of Biotechnology Regulatory Services,  
4 APHIS.

5 MS. MASSEY: Adrienne Massey, BIO.

6 MS. SPURGAT: Jennifer Spurgat with Bayer  
7 CropScience.

8 MR. KENDRICK: Dan Kendrick from Monsanto  
9 Company.

10 MALE SPEAKER: (Indiscernible), Monsanto.

11 MR. DOHRMANN: Todd Dohrmann, Monsanto.

12 MS. HOOD: Aimee Hood, Monsanto.

13 FEMALE SPEAKER: I'm (indiscernible) from  
14 DuPont Pioneer.

15 MS. GUTSCHE: Annie Gutsche, DuPont Pioneer.

16 MR. HARRON: Bob Harron, Scotts Company.

17 MR. MCCLUER: Jess McCluer, National Grain  
18 and Feed Association.

19 MR. CLAPP: Steve Clapp, Food and Chemical  
20 News.

21 MS. RECORDS: I'm Angela Records with  
22 Eversole Associates and the American Phytopathological

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1 Society.

2 DR. FIRKO: Good morning. Mike Firko with  
3 Biotechnology Regulatory Services.

4 MR. SCORZA: Ralph Scorza, Agriculture and  
5 Research Service.

6 MS. KOEHLER: Susan Koehler, Biotechnology  
7 Regulatory Services.

8 MS. STANKIEWICZ GABEL: Rebecca Stankiewicz  
9 Gabel, Biotechnology Regulatory Services.

10 MR. HOWIE: William Howie, BASF Plant  
11 Science.

12 MS. MCKEAN: Angela McKean, BASF Plant  
13 Science.

14 MS. ROOD: Tracy Rood, DuPont Pioneer.

15 MR. GRANT: Doug Grant, Biotechnology  
16 Regulatory Services.

17 MS. DANIEL: Renee Daniel, Perspective  
18 Consulting.

19 MR. LOWE: Jeff Lowe with Scotts Company.

20 MR. THIES: Greg Thies, Syngenta.

21 MR. WHALEN: David Whalen, Forage Genetics.

22 MR. REDDY: Srinu Reddy, Forage Genetics.

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1 MR. BRYANT: Matt Bryant, D.C. Legislative  
2 and Regulatory Services.

3 MR. JAFFEE: Greg Jaffee, Center for Science  
4 and Public Interest.

5 MR. TURNER: John Turner, Biotechnology  
6 Regulatory Services.

7 MR. MAYER: Mike Mayer, Louis Berger Group.

8 MS. EITNER: Julie Eitner, The Louis Berger  
9 Group.

10 MS. BYER: Rudie Byer, The Louis Berger  
11 Group.

12 MR. PORTER: Ed Porter, Foreign Agricultural  
13 Service, U.S. Department of Agriculture.

14 MR. JOHNSON: Jay Johnson, Dorsey & Whitney.

15 MS. SPENCER: Erin Spencer, DuPont Pioneer.

16 MS. JONES: Wendelyn Jones, DuPont Pioneer.

17 MS. HYTEN: Aimee Hyten, DuPont Pioneer.

18 MR. MILES: Paul Miles, Syngenta.

19 MS. JARRETT: Sydney Jarrett, Syngenta.

20 MR. YORK: Ed York (ph), Office of Budget and  
21 Program Analysis within USDA.

22 MS. BOWEN: Tracey Bowen, Biotech Regulatory

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1 Services.

2 MS. BARRON: Joy Barron, Policy and Program  
3 Development.

4 MS. SIMON: Samantha Simon, Biotechnology  
5 Regulatory Services.

6 MALE SPEAKER: (Indiscernible), Biotechnology  
7 Regulatory Services.

8 MR. GEORGE: We can abbreviate the BRS, guys.

9 MR. GENE: Edward Gene, BRS.

10 MS. SINKOWSKI: Dee Sinkowski (ph), BRS.

11 MALE SPEAKER: (Indiscernible), BRS.

12 MR. GUPTA: Subhash Gupta, BRS.

13 MR. MCGOWN: Paul McGown, BRS.

14 FEMALE SPEAKER: Sheila (indiscernible), BRS.

15 MS. FLEMING: Mary Fleming, BRS.

16 MS. BURNETT: Gwendolyn Burnett, BRS.

17 MR. HANDLEY: Lee Handley, BRS.

18 MR. HERON: Dave Heron, BRS.

19 FEMALE SPEAKER: Good morning,

20 (indiscernible), BRS.

21 MS. DUKES: Good morning, Tracy Dukes, BRS.

22 MS. ECK: Cindy Eck, BRS.

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1 MR. NESBITT: Clint Nesbitt, BRS.  
2 FEMALE SPEAKER: (Indiscernible), BRS.  
3 MS. MANE: Allison Mane, BRS.  
4 MR. BLANCO: Carlos Blanco (ph), BRS.  
5 FEMALE SPEAKER: (Indiscernible), BRS.  
6 MS. LALLI: Donna Lalli, BRS.  
7 MS. JONES: Jennifer Jones, BRS.  
8 MS. BOULAY: Virginia Boulay (ph), BRS.  
9 MS. RAPPAPORT: Kate Rappaport with BRS.  
10 MS. BARDO: Linda Bardo, BRS.  
11 MR. ROSA: Craig Rosa, BRS.  
12 MR. HOFFMAN: Neil Hoffman, BRS.  
13 MR. BENNETT: Steve Bennett, BRS.  
14 MR. GEORGE: Okay. Thank you very much. We  
15 have a great -- oh, we have some late arrivals.  
16 Colleen, if you could get a mic over to our two who  
17 just entered. Thanks, Mike.  
18 MR. WEEKS: Michael Weeks, Bayer CropScience.  
19 MR. WEGENER: I'm Randy Wegener with Bayer  
20 CropScience.  
21 MR. GEORGE: Thank you. Well, we have great  
22 attendance today. One more. I'm so sorry.

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1 MS. ASANUMA: Yoko Asanuma. I'm from Bayer  
2 CropScience.

3 MR. GEORGE: Great. Thank you. Thank you  
4 all for being here today. At this time, I would like  
5 to introduce the Deputy Administrator for Biotechnology  
6 Regulatory Services, Mike Gregoire.

7 MR. GREGOIRE: Thank you, Dick. Good  
8 morning, everybody. Welcome to our annual stakeholder  
9 meeting. It's my pleasure today to introduce the Acting  
10 Administrator of APHIS, Kevin Shea. Kevin Shea and I  
11 have worked together a long, long, long time in APHIS.  
12 Actually, Jimmy Carter was President of the United  
13 States when we started in this agency. You can look up  
14 what year that was.

15 Kevin has been the Associate Administrator of  
16 APHIS since September of 2004, and in that position, he  
17 worked closely with Dr. Gregory Parham to ensure the  
18 smooth daily functioning of APHIS. In June of this  
19 year, Secretary Vilsack designated Kevin to act as the  
20 administrator of APHIS while Dr. Parham is serving as  
21 the Acting Assistant Secretary for Administration in  
22 USDA. In addition to his regular duties as Acting

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1 Administrator, Kevin serves on the Secretary's  
2 Executive Resources Board and the Secretary's  
3 Management Council.

4           Before becoming Associate (sic)  
5 Administrator, Kevin served four years as the Deputy  
6 Administrator for Policy and Program Development in  
7 APHIS, and in years prior to that, he was also the  
8 Agency Budget Officer. Kevin has been a real champion  
9 of process improvement and customer service and good  
10 management practice in APHIS. He has challenged  
11 several of the Deputy Administrators in APHIS to really  
12 look at ways to make their processes more efficient and  
13 predictable and is holding us accountable for the  
14 results on that.

15           Kevin is a graduate of the University of  
16 Maryland in College Park and has a law degree from the  
17 University of Baltimore School of Law. So, Kevin,  
18 welcome and thank you.

19           MR. SHEA: Thank you very much, Mike. Good  
20 morning to everyone. I want to assure all of our  
21 guests that there won't be any one person, one vote,  
22 votes here today. As you can see, our BRS contingent

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1 would probably outvote you, so we're not going to allow  
2 that to happen. Maybe they all get one vote if it  
3 comes to votes.

4 I want to, again, welcome you here on behalf  
5 of Dr. Parham. As Mike mentioned, Dr. Parham has been  
6 asked by the Secretary to do something else for a  
7 while, and I'm filling in for him. Mike mentioned he  
8 and I have worked together a long time, and the thing  
9 is, we've really exchanged many jobs over the years.  
10 We've pretty much held all the same jobs, but he has  
11 finally gotten to a job that I don't think I want, so I  
12 think he and I will be stuck in place for at least a  
13 while now. It certainly is one of the toughest jobs in  
14 APHIS, and he's done a great job with it and working  
15 with all of you, and I appreciate what Mike has done,  
16 but I understand just how tough that job is.

17 I want to talk to you just very briefly today  
18 about APHIS more in general, where we stand as things  
19 are changing and as the budget picture, of course, is  
20 so murky and difficult to figure out. You know, this  
21 is a big anniversary year. It's the 150th anniversary  
22 of USDA, the 40th anniversary of APHIS, and,

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1 technically, it's the 10th anniversary of BRS, but, of  
2 course, we've actually been in the biotechnology  
3 regulation business for over a quarter century, but  
4 this is the official 10th anniversary of BRS.

5           And we created BRS ten years ago under the  
6 direction of the then-administrator Bob Acord and, of  
7 course, our first deputy for Biotech, Cindy Smith, who  
8 went on to become the administrator because it was so  
9 important. We realized how important it is and  
10 required a fully dedicated staff working on just that  
11 topic, it is so important to us.

12           As we've been celebrating all these various  
13 anniversaries, it's probably a time to take stock of  
14 who you are and where you're going, and that's one of  
15 the things that we've done during this past year. And  
16 during the last decade or more, APHIS has been called  
17 upon to do lots of things, and lots of people defined  
18 us lots of ways. Some called us an emergency response  
19 agency. Some called us a one-health agency. Some  
20 called us merely a regulatory agency.

21           But when you cut through all of those things,  
22 those are really just techniques that we use to get to

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1 our core mission, which is to be a plant and animal  
2 health agency. That's our goal. Everything really  
3 works toward that to ensuring the health of plants and  
4 animals so that we have a profitable agriculture sector  
5 and many other things that go along with that.

6           So that's something that we've spent a lot of  
7 time over the last few months thinking about, and with  
8 regard to biotechnology, our job, under the Plant  
9 Protection Act, is real simple, and that's to ensure  
10 that the introduction of certain genetically engineered  
11 organisms don't pose a risk to plant health. That's  
12 our role, and that's what we carry out in  
13 biotechnology. Other agencies have other roles. Other  
14 agencies have other responsibilities. And as we all  
15 note, the courts sometimes muddle those together a  
16 little bit. But that's our role, to ensure plant  
17 health, and that's what we will continue to do.

18           But although our mission is real clear in our  
19 minds, the techniques have to change. We realize we  
20 can't do the things we did in the past. This is  
21 probably a little more applicable to some of our  
22 operating programs in animal health, in plant health,

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1 where we literally try to eradicate or at least control  
2 diseases or pests.

3           But a lot of the techniques available to us  
4 just aren't available anymore. They're either too  
5 costly societally, legally, as well as just financial.  
6 So we're looking to do things in better ways all the  
7 time, and, of course, one of the things that's of most  
8 interest to you is the petition process, and we realize  
9 that that has not always been fast, not always been  
10 clear, but we're dedicated to trying to change that.  
11 And that goes hand in hand with the Secretary's goal.

12           The Secretary asked me personally to make  
13 sure that we somehow improve the petition process,  
14 among other processes at APHIS. And, of course, his  
15 goal remains some kind of coexistence among GE,  
16 conventional, and organic growers. And our job is to  
17 try to make that happen as well, to the extent we  
18 possibly can.

19           As we look at the petition improvement  
20 process, we're looking at it from many perspectives.  
21 Obviously we have to think about the legal exposure.  
22 There are lots of folks who are more interested than

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1 ever in this subject, and there are advocates who  
2 advocate in lots of forms, both political, media, and  
3 the courts. So we have to run a petition process that  
4 stands up to all the scrutiny from all of those places,  
5 which means that it has to be fair, has to be  
6 transparent, and has to be aimed at the basic goal of  
7 protecting plant health. That is what we're doing  
8 there.

9 Mike and John Turner will talk to you a  
10 little bit more specifically about the process, and  
11 suffice it to say it's not perfect yet. We haven't  
12 rolled out as many things as some might have expected,  
13 but, in fact, we have made some big changes, and we've  
14 already seen progress, and already, on the things  
15 moving through the new process, we see that we've  
16 shaved 260 days off the time it takes to review a  
17 petition for completeness.

18 Now, everyone in this room knows there are so  
19 many complex factors that go in to the final decision,  
20 but the upfront part of the process that we can control  
21 the most, we're making great progress. Again, Mike and  
22 John will talk about that in a little more detail

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1 later. It's only when we looked at these improvement  
2 processes, probably some of the same things that you do  
3 in your companies, you look at a process at every step  
4 along the way and to see what makes it go faster or  
5 slower.

6           And we found some very simple things; for  
7 example, that there are ten steps in a process, and  
8 someone at step one and step ten, they have a great  
9 interest in bringing that to completion. But maybe  
10 someone in step seven, it's not quite their priority,  
11 and simply by assigning very specific deadlines at all  
12 the steps in the process, we find that we can really  
13 speed it up. Really simple stuff.

14           But there are far more complex things that  
15 might -- I'll leave to Mike and John to talk about in  
16 terms of when we seek public notice, when we go up for  
17 public comment, all those sorts of things that they  
18 will talk about. But we're doing everything we can to  
19 make it work better. And, of course, hanging over all  
20 of this, this budget picture. This has been going on  
21 for several years. Right now, well, this is the talk  
22 of the town with the fiscal cliff, but we've really

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1 been living through this for the last several years.

2           And over the past three years, from fiscal  
3 year '10 to fiscal year '13, our corporation's gone  
4 down by over 10 percent overall in APHIS. We have over  
5 500 fewer people in APHIS today than we did just two  
6 years ago. We can't sustain those kinds of budget  
7 reductions without having fewer people. So that's the  
8 context for APHIS as a whole, but for biotechnology,  
9 the story's been different, and the appropriations  
10 actually increased. And I think that reflects a couple  
11 of things. One, it reflects this administration's  
12 commitment to biotechnology and making this process  
13 work better, and I think it also speaks to a growing  
14 awareness in Congress, and, indeed, the entire  
15 interested groups, about how important this is on any  
16 side of the issue.

17           So I think that we are pleased to see that we  
18 are going to have at least stable resources through  
19 this particular part of the agency. Now, we can't  
20 predict what will happen with the fiscal cliff. I  
21 mean, a lot of people talk about sequestration. The  
22 numbers aren't exact, but from what I understand, if

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1 sequestration occurs on January 1st, our appropriation  
2 across the board will be reduced by somewhere between 8  
3 and 10 percent.

4           Of course, one of the downsides of the way  
5 that the Congress chose to go about the debt limit  
6 ceiling bill here a few years ago and came up with the  
7 fiscal cliff concept is that it's not very selective.  
8 Now, there are some things exempt from the cliff, from  
9 the sequestration part of the cliff, but APHIS is not,  
10 and our entire appropriation is subject to that across-  
11 the-board cut, and that means biotechnology work could  
12 be cut, just like Plant Protection work is cut, Animal  
13 Welfare work is cut, Wildlife Services, all the parts  
14 of APHIS will see that same across-the-board cut.

15           Now, I choose to be an optimist and think  
16 that this won't happen, that we won't see those kinds  
17 of cuts. My belief has been all along that, really,  
18 what the Congress did here a few years ago, August  
19 2011, I guess it was now, was sort of like the modern-  
20 day fiscal equivalent of the Cold War theory of  
21 mutually assured destruction.

22           Some of you are old enough in the room to

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1 remember that. Many of you are not. But, of course,  
2 the theory was that we had enough nuclear weapons to  
3 annihilate the Soviets, and they had enough to  
4 annihilate us, so neither of us would be crazy enough  
5 to shoot the first one off. And it worked, actually.  
6 Right? No one fired a nuclear weapon in anger during  
7 the Cold War.

8           Well, it's the same thing with this deal.  
9 Certainly there are interests in Capitol Hill that  
10 don't want certain taxes increased, and there are  
11 interests on Capitol Hill that don't want certain  
12 budgets cut. The Defense Department, I would say. And  
13 so I think they did set up mutually assured destruction  
14 in such a way that that wouldn't happen in the long  
15 run.

16           So I remain optimistic to that and also, of  
17 course, believe in the cliché that nothing happens  
18 until the deadline. The deadline is January 1st, but,  
19 of course, the deadline is malleable too, isn't it?  
20 They make the deadline, they can change the deadline.

21           So I hope that this won't happen, but as the  
22 Acting Administrator, and Mike as the acting -- or as

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1 the Deputy Administrator of Biotech, we have to be  
2 prudent about it, and so we're going to be conservative  
3 and prudent in our spending until it's clear for this  
4 year, if you take the whole sequestration and fiscal  
5 cliff discussion out, we still don't really have an  
6 appropriation for the year.

7           We have a continuing resolution that runs  
8 through late March. So regardless of the fiscal cliff  
9 discussions, they still have to potentially pass some  
10 sort of appropriation. So we're anxiously awaiting to  
11 see what that will be. But I think there's good news  
12 in that too in that both the House and the Senate  
13 (indiscernible) our appropriations bill, and the Senate  
14 was not going to cut APHIS at all, and the House was  
15 going to cut APHIS only by a small amount, far less  
16 than had been proposed.

17           So I think we may have turned the corner from  
18 people who make budget decisions about APHIS, whether  
19 it's within the Executive Branch or in the  
20 Congressional Branch. I think there is a good sense  
21 that the 10 percent reduction for APHIS may be as much  
22 as the market should bear, and I think that's the

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1 recognition of how important all this work is;  
2 biotechnology, of course, very much part of that. So  
3 we will be spending a little conservatively over the  
4 course of the next few months until we get the  
5 appropriation, and I hope that nothing really bad with  
6 that happens with sequestration.

7           As we look forward to biotechnology work in  
8 the future, I think it will continue, from our  
9 perspective, to be so much about process improvement. I  
10 mentioned earlier we, as the scientists, like the fine  
11 folks at BRS -- I'm not a scientist, as Mike made clear  
12 to you, but I'll be there's a lawyer or two in the room  
13 too as well as a scientist. But the key role for APHIS  
14 is indeed to look at the science and to make reasoned  
15 decisions on science, and then there are others who  
16 will make decisions throughout the process, and, of  
17 course, none less important than the courts.

18           But we want to make sure that we're doing  
19 everything we can in APHIS to make the process part  
20 that we control to be smooth, transparent, and faster  
21 than it has been. Our entire business process  
22 improvement solution is real simple. We're trying to

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1 do things faster and cheaper and make it easier for  
2 people to do business, while, of course, we carry out  
3 our role to protect plant health.

4           But we understand that business moves at the  
5 speed of business, and government has tended to move at  
6 the speed of government, and our goal in the process  
7 improvement working on biotechnology is to nudge up the  
8 speed of government a little bit and get it a little  
9 closer to the speed of business. That's our goal.  
10 That's what we're going to continue to try to do.

11           Dick hasn't given me the five-minute sign  
12 yet, but -- so I guess I'm allowed to ask you if there  
13 are any questions. Okay. Well, thank you very much,  
14 and I'll see my remaining time (indiscernible).

15           MR. GEORGE: Thank you, Kevin. As many of  
16 you know, the Advisory Committee on Biotechnology and  
17 21st Century Agriculture, also known as AC21, has been  
18 meeting over the past 18 months to address questions of  
19 coexistence among various sectors of the agricultural  
20 community. I had the opportunity to attend almost all  
21 of these meetings, and I have to say when there's so  
22 much partisanship in the news that it was reassuring to

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1 see that it's still possible for a group of smart and  
2 committed people to come together, express significant  
3 differences, and work toward a solution.

4           We're lucky to have with us today one of the  
5 people most responsible for making that happen. Michael  
6 Schechtman is the Executive Secretary and Designated  
7 Federal Official for AC21 in addition to being the  
8 Biotechnology Coordinator for the Office of the Deputy  
9 Secretary of Agriculture. I would say that his job on  
10 AC21 was like herding cats, but I think that would  
11 understate it. AC21 has now issued its final report,  
12 and here to tell us about it is Michael Schechtman.

13           MR. SCHECHTMAN: Well, good morning,  
14 everyone. I'm happy to be back at the stakeholders'  
15 meeting. As soon as the slides come up -- thank you.  
16 And I'm happy to have you here and give you an update  
17 on the work of the AC21. As Dick pointed out, it's  
18 timely for the update because the committee has  
19 completed a significant report. I have brought copies  
20 of the report.

21           I'm not sure I have -- well, in fact, I'm  
22 pretty sure I didn't bring quite enough copies for

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1 everyone that's in the room. It is, however, available  
2 on the Web, and I think they're outside the -- at the  
3 door. I have a lot to talk about, so first let me zip  
4 through some information on history and background of  
5 the committee.

6           So the committee has been in existence for a  
7 long time. There was even a predecessor of the  
8 committee. It was in existence -- this precise  
9 committee in existence since 2003. With the change in  
10 administration at the beginning of 2009, the committee  
11 was quiescent. There are a few years didn't meet. In  
12 January of 2011, the Secretary brought this committee  
13 back specifically as part of a package of measures to  
14 bolster coexistence that were announced at that time.

15           There was a process in March. Nominations  
16 were solicited. Members of the community were  
17 announced in June of 2011, and the first meeting took  
18 place at the end of August 2011. For those of you who  
19 have experience dealing with advisory committees,  
20 that's a breakneck speed. Process improvement. But  
21 the committee did, in fact, get going. What the charge  
22 of the committee -- the committee has a very broad

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1 overall charge, which is to examine the long-term  
2 impacts of biotechnology on agriculture and work with  
3 USDA and also to do anything else that the Secretary  
4 thinks is important, essentially, on biotechnology.

5           The specific charge that the Secretary gave  
6 the group in reconvening it was a three-part charge.  
7 First off, to address -- to address the question what  
8 types of compensation mechanisms, if any, would be  
9 appropriate to address economic losses by farmers in  
10 which the value of their crops is reduced by the  
11 unintended presence of genetically engineered  
12 materials? Secondly, what would be necessary to  
13 implement such mechanisms? What kind of eligibility  
14 standards would you need to verify such losses and  
15 determine if particular claims are compensable? And  
16 thirdly, in addition to those two, what other actions  
17 would be appropriate to bolster or facilitate  
18 coexistence among different agricultural production  
19 systems in the U.S.?

20           So the committee itself can address this.  
21 The chair of the committee is Russell Redding. He's  
22 Dean of the College of Agriculture and Environmental

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1 Sciences at Delmar Valley College in Pennsylvania; also  
2 former Pennsylvania Secretary of Agriculture and a  
3 great chair. The committee has been very, very  
4 diverse. Industry folks, organic folks, farmers of  
5 various types, some NGOs. We have one committee member  
6 who was impacted in the room today. There are also  
7 four ex officio members from other federal agencies who  
8 don't get to vote on things.

9           The committee was put to work quite hard.  
10 Since the first meeting in August of 2011, the end of  
11 August, there were five meetings, two-day plenary  
12 sessions, plus work of working groups, which -- some of  
13 which had some non-AC21 members on the working group  
14 for some balance. And I know we have at least one  
15 person in the room who's a member of a working group.  
16 And many conference calls among working groups to sort  
17 of set the stage, gather information for the full  
18 committee to consider.

19           In addition to work process, there were  
20 presentations from outside experts on things like farm  
21 practices that are used by different types of farmers  
22 to manage independent GE presence, past history of

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1 other groups that have worked on addressing coexistence  
2 concerns, information on what experts gathered on --  
3 data on economic losses, for example.

4           In addition, the Secretary, very involved in  
5 this process. Both the Secretary and the Deputy  
6 Secretary followed this work very closely. They showed  
7 up at three meetings of the committee, which is not the  
8 usual state of affairs. The Secretary repeatedly  
9 stressed the need for these folks to find middle ground  
10 so that these discussions would not be issues that are  
11 decided by the courts, but, in fact, could be decided  
12 by the people who are involved in agriculture.

13           The Secretary has stressed the need for  
14 having a very broad view of agriculture, and his sense  
15 of the importance of promoting the health of rural  
16 communities, providing different types of options for  
17 young farmers to want to stay on the land, different  
18 kinds of production opportunities, keeping people in  
19 rural communities and keeping up the health of those  
20 communities. And that meant promoting all different  
21 forms of agriculture.

22           And also he indicated his perspective that

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1 though people may differ on how serious a problem  
2 coexistence is from their perspective, from his  
3 perspective hearing all of the folks come into his  
4 office, he perceived it as a problem.

5           So addressing the charge. Before I talk  
6 about what's in the report -- and there are pages and  
7 pages of recommendations that I'm just going to go  
8 through very quickly, and there's lots of notes on  
9 them, but I'm just going to paraphrase. Let me just  
10 mention to you very briefly what some of the big points  
11 of contention were in the discussions.

12           First off, on the existence of data of actual  
13 economic losses, what exists is data that demonstrates  
14 that shipments of identity-preserved material that was  
15 supposed to meet a certain requirement for presence or  
16 absence of GE material, shipments that were out of  
17 specification and were rejected, but it's much more  
18 difficult to get the data that converts that into the  
19 existence of an actual loss, and this was a continual  
20 point of contention, and that data is, of course, very  
21 sensitive on the part of farmers. They don't  
22 necessarily want to reveal that they have a problem, et

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1 cetera, though they want to tell other folks that they  
2 have a problem, but they don't want to reveal that  
3 data.

4           Question -- a second point that comes up is  
5 the issue of contracts. If someone signs a contract,  
6 does that mean that they should therefore assume that  
7 they are assuming all of the risk for producing that to  
8 the particular specifications of the contract? Are you  
9 agreeing to do whatever is necessary to meet that  
10 contractual requirement, or do your neighbors have any  
11 responsibility to help you out in that process?

12           Should the AC21 report specify what might be  
13 a reasonable contract that you might sign and what  
14 could be an unreasonable contract so that if there was  
15 some sort of coverage for a loss, there might be some  
16 contracts that you would say, "Well, the government or  
17 whatever mechanism it is, we can't possibly cover that  
18 kind of loss because you signed a ridiculous contract."  
19 For example, saying that my material will have zero  
20 percent Biotech, and you discover one kernel in there  
21 or whatever it is that were out of spec, and you should  
22 cover that loss.

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1           Who should bear the costs for addressing any  
2 losses? The discussions around all these topics with  
3 folks ranging from organic farmers and producers and  
4 seed merchants to farmers of all sorts and biotech  
5 industry folks, the discussions were obviously  
6 difficult, but they were -- they were simple, and our  
7 Chair took a -- had a major role in keeping the  
8 discussions going in a productive way.

9           So a little bit about how the report came  
10 out, was produced. When the committee was reactivated,  
11 the charter and bylaws of the committee were changed  
12 slightly to encourage the production of reports with  
13 recommendations that -- in which we would strive to get  
14 consensus, but they wouldn't require absolute  
15 consensus.

16           Previous iterations of the committee, the  
17 committee wrote -- themselves wrote the report, and  
18 there needed to be perfect consensus before a report  
19 could be issued. That meant that there was a long time  
20 to write -- lightly skim over every word, and their  
21 reports had no recommendations in it, essentially.  
22 Procedures were changed so that reports could be

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1 finished at a particular time -- by a time certain, and  
2 we would try to get perfect consensus, but even if we  
3 didn't, we would go forward with recommendations.

4           That meant that the Chair and I wrote the  
5 reports, brought them to the group, got input. We  
6 attempted to capture the range of views that existed  
7 among committee members on the issues and then tried to  
8 find the recommendations that would gather the most  
9 support. So the process did allow for careful  
10 negotiations around recommendations, but did not dwell  
11 on fussing over every word in the rest of the report,  
12 but just not the recommendations.

13           So because this was a little bit more of an  
14 abbreviated process, what happened was at the end of  
15 the report, when the report -- a final draft was done,  
16 members were given the option to decide whether or not  
17 they would sign on to consensus on the report, and  
18 regardless of whether or not they would join consensus,  
19 if they wanted to, they were allowed to provide  
20 comments that would be appended to the report.

21           So that meant that their decisions on what to  
22 do on the report required consideration of the whole

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1 package of what was in the report and the willingness  
2 to compromise. So what the final result was -- what I  
3 think was a carefully crafted package of  
4 recommendations that ultimately 22 of the 23 members  
5 were able to sign on to. For most of the members, it  
6 was a complicated decision to decide whether to sign  
7 on, as, as we said to the committee, there's something  
8 in the report for everyone to dislike. But  
9 (indiscernible) 22 of 23 members signed on.

10 So a little bit -- now let me just quickly  
11 run through the contents of the report. I have fairly  
12 lengthy descriptions. Even though they are themselves  
13 paraphrases of the recommendations that are in there,  
14 I'm just going to sort of highlight some words about  
15 them. I wanted them to be in front of you.

16 First off, the working definition for  
17 coexistence for the report, the concurrent cultivation  
18 of conventional, organic, identity-preserved, and  
19 genetically engineered crops consistent with underlying  
20 consumer preferences and choices. So coexistence in  
21 the context of this report is a discussion about  
22 unintended presence -- the issues around unintended

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1 presence of GE material which is legal to be there.  
2 It's not a discussion about unintended presence of  
3 unapproved material. That's a regulatory issue, not  
4 this economic issue which is being discussed here.

5           The report itself is organized around four  
6 themes. In the report, for each of the themes, there's  
7 a discussion of the background and the nature of the  
8 committee's discussion, followed by one or two  
9 recommendations on each, and areas of agreement and  
10 disagreement are discussed in the text of the report.

11           So the four themes are compensation  
12 mechanisms, stewardship and outreach, research, and  
13 seed quality. I'll talk a little bit about highlights  
14 of what is in the recommendations for the committee.  
15 I'm going to present them in a different order from the  
16 order in which they're in the report, because it's a  
17 little easier to follow the logic. But because of the  
18 way the -- it's different from it -- from the order  
19 that's in the report. The report tried to more  
20 specifically focus based on how the charges of the  
21 committee  
22 Okay. So there are a series of research

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1 recommendations. First important one is USDA should  
2 research to quantify those actual economic losses by  
3 farmers and how those losses occur, where they are, how  
4 they occur over time, et cetera. Research on the  
5 efficacy of on-farm mitigation techniques for gene flow  
6 on a crop-by-crop basis and develop improved techniques  
7 as needed to help address the issue.

8           Same thing for seed production. Develop  
9 additional research on techniques, genetic techniques  
10 to help control gene flow and gathering data on an  
11 ongoing basis from seed companies about unintended  
12 presence of GE material in seed intended for IP and  
13 organic uses. And this is sort of one theme that came  
14 out in the committee that there are a lot of folks who  
15 have concern about the availability of seed for  
16 producing for markets that seek to avoid the presence  
17 of GE materials, and so this is part of a monitoring  
18 the availability -- consistent availability of seed  
19 that these folks needs, sort of part of that process.

20           Next item, compensation mechanisms,  
21 evaluating the data that came in on what actual losses  
22 are. If the Secretary determines that, based on that

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1 loss data, a compensation mechanism is warranted, it  
2 should be -- a mechanism should be established based on  
3 the model of crop insurance. For those of you who are  
4 not focused on the insurance world, which I certainly  
5 was not, you have to think of crop insurance as  
6 something that has a contribution by the purchaser of  
7 the insurance as well as a government contribution as  
8 well to help subsidize the cost of the insurance.

9           To implement that, research would need to be  
10 done to figure out the actuarial parameters.  
11 Eligibility and verification requirements would need to  
12 be set up. It could be tested via a pilot program.  
13 Additionally, importantly, the -- there should be set  
14 up incentives for creation of joint coexistence plans  
15 between neighbors, neighboring farmers, so some farmer  
16 producing some sort of identity-preserved crop and  
17 their neighbor that want to work together to eliminate  
18 -- to lessen the potential for problems because of  
19 unintended gene flow.

20           If they do something, that could be  
21 incentivized, perhaps by giving folks a break on their  
22 crop insurance premiums or some other method, and that

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1 could be for conventional crop insurance or for this  
2 new kind of crop insurance that would be for these  
3 particular kinds of economic losses. In addition, go  
4 back and look at the existing crop insurance system  
5 that exists for farmers that aren't producing for  
6 commodity markets. It's very hard for those farmers to  
7 have the same kind of access and benefits from crop  
8 insurance programs as the large commodity products.

9           Additionally, recommendation on stewardship  
10 and outreach, a broad campaign to educate farmers on  
11 the importance of coexistence, on how to do it, the  
12 value of neighbor-to-neighbor cooperation, the  
13 implications of the contracts they sign, risks and  
14 responsibilities of meeting those contracts, and  
15 accompanying that as well, working with stakeholders to  
16 develop sort of toolkit, package of mechanisms that  
17 would be available to farmers that foster coexistence,  
18 working with their neighbors, mitigate gene flow, and  
19 then incentivize farmers to adopt better stewardship  
20 practices.

21           So this will include, on the Department's  
22 side, development of toolkits. We will encourage the

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1 involvement of seed providers to help provide some of  
2 this information at the time of seed purchase so that  
3 farmers will get this information in a very easy way,  
4 and we'll -- and USDA will also support efforts to  
5 develop planting zones for groups of farmers that want  
6 to produce in a specific tax specification. Now, I  
7 should add that this outreach campaign and education is  
8 going to involve a broad range of stakeholders, so that  
9 means -- it definitely includes many folks that are in  
10 this room (indiscernible).

11           Final class of recommendations around seed  
12 quality. USDA should work with the National Genetic  
13 Resources Advisory Council -- or should task the  
14 council, rather, to develop a plan in conjunction with  
15 seed industry for ongoing evaluation of the pool of  
16 commercially available seeds that meet the needs of  
17 producers who are producing for various non-GE markets  
18 and work with seed suppliers to assure that a diverse  
19 and high-quality commercial seed supply for these folks  
20 exists.

21           Admittedly, that's a -- that's a  
22 collaborative effort that has to happen. We recognize

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1 the seed companies obviously have to produce for  
2 markets, and there have to be markets there that are  
3 willing to purchase the seeds, but the committee was  
4 clear about wanting there to be some additional USDA  
5 input in watching that process.

6           The NGRAC is a committee that is also being  
7 revived -- I should add that it's not quite up and  
8 running again. It was quiescent for a number of years.  
9 Additionally, USDA should recommit to maintaining the  
10 genetic identity of material, whether it's germplasm  
11 banks, have plans in place to address any unintended  
12 presence of material that is shown in those and work on  
13 helping farmers access seeds if they are organic or  
14 non-GE producers that meet their needs.

15           So, finally, let me just give you the wrap-up  
16 on where we are with this right now. The Secretary was  
17 very anxious to receive this report. He got the report  
18 on November 19th, presented to him by the Chair of the  
19 committee, with a few other members in attendance, and  
20 he thanked the committee for having accomplished a very  
21 difficult task, indicated the report was important and  
22 that USDA has a lot of work to do. And in going back

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1 over the report, there are lots of parts of the USDA  
2 that are involved in the response.

3 He said that the committee members could be  
4 sure that there would be a response, that certainly, in  
5 2013, there would be evidence of actual actions that  
6 USDA is taking in response, and he appointed a senior  
7 member of his inner staff to lead an effort to craft a  
8 response plan and figure out how to move forward.

9 So with that, I'll stop, and I'm happy to  
10 answer any questions that you have.

11 MALE SPEAKER: Well, first of all,  
12 congratulations on herding all those cats, considering  
13 that a year ago, that committee was evenly divided  
14 between those who wanted compensation mechanisms and  
15 those who thought it was unnecessary. If you read the  
16 comments that follow the actual report, there's a lot  
17 of heartburn in the organic community about the report.  
18 Can you give us any more detail as to how the Secretary  
19 is likely to proceed in this? I know it's still very  
20 early.

21 MR. SCHECHTMAN: The short answer is no, but  
22 I can expand on that just a little bit, and that is to

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1 say there are recommendations in the report that are  
2 not likely to require new legislative authority or new  
3 regulations. There are recommendations in the report  
4 that will be much more complicated to implement.

5           So I think the first step of the process is  
6 essentially sorting out the recommendations and  
7 figuring out what thing -- you know, what's the order  
8 in which things can be attacked and what's the game  
9 plan for going through the process? The one thing that  
10 I can say for sure is that the Secretary was very clear  
11 that this was not going to be a report that gathered  
12 dust on shelves.

13           MS. HOOD: Aimee Hood, Monsanto. Again,  
14 Michael, congratulations. I know that this required a  
15 lot of work getting -- there were a lot of different  
16 opinions throughout the deliberations. My question is  
17 as I read through the comments, there were several  
18 people who made comments about the safety of  
19 biotechnology, and I'm wondering if the Secretary or  
20 anyone from USDA has commented on those comments that  
21 were made.

22           MR. SCHECHTMAN: The Secretary, when he

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1 received the report, specifically emphasized that the  
2 Department's policy on biotech products is unchanged  
3 and that we have -- we still have entire confidence in  
4 the integrity of our regulatory processes. The issue  
5 is an economic issue (indiscernible).

6 MR. GEORGE: Other questions? Okay. Thank  
7 you very much, Michael. I would have to say that  
8 Michael and Russ Redding are really the consensus  
9 master builders, so hats off to them on getting this  
10 important report completed and also to all the members  
11 of AC21.

12 We've heard the APHIS perspective from Kevin  
13 Shea, a broad agricultural industry perspective from  
14 Michael Schechtman, and now it's time to go to our own  
15 program, BRS. Here again to fill us in on where we've  
16 been over the past year and where we're going, among  
17 other subjects, is Deputy Administrator Mike Gregoire.

18 MR. GREGOIRE: Thank you again, Dick. What  
19 I'd like to do today is two things. One is to reflect  
20 on the year past, 2012, and highlight what I think were  
21 important accomplishments and areas of focus. Then I'd  
22 like to turn to the year ahead, 2013, and talk about

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1 what some of our top priorities are for the year  
2 upcoming. I'll touch just very briefly on budget  
3 issues, but Kevin covered those very well, so I won't  
4 spend a lot of time on those issues.

5           In terms of looking back at the year 2012, I  
6 thought I would start with some of our core functions  
7 and activities; that is, the permitting work that we  
8 do, the inspection activity that we carry out, the  
9 compliance program that we carry out, and these are  
10 activities that maybe don't get as much notoriety as  
11 some of the other things that we're involved in with  
12 deregulation process and so on. And like a lot of  
13 APHIS programs that are prevention-type programs, you  
14 don't hear much about them. Maybe they're taken for  
15 granted a little bit, unless something goes wrong.

16           But I feel really good about the work that's  
17 going on in our permitting, inspection, and compliance  
18 activity, so I want to begin by talking about that.  
19 Kevin talked about the mission of APHIS being animal  
20 and plant health, and our mission in BRS is to ensure  
21 that the introduction of GE crops is safe for plant  
22 health, and one of the ways we do that is to assist in

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1 the permitting, inspection, and compliance to ensure  
2 that regulated material, when it's in the research and  
3 development phase, remains confined and remains  
4 accounted for, because we know from past incidents if  
5 regulated material gets into commerce, gets into trade,  
6 it can have significant economic impacts and  
7 disruptions and market and environmental impacts.

8           So I feel really good about the fact that we  
9 haven't had that kind of situation now in a number of  
10 years, knock on wood. I think that is not an accident.  
11 We have kind of quietly done a lot of work to enhance  
12 these activities over the last few years. Michael just  
13 made a presentation about coexistence, and one of the  
14 ways that the regulatory program contributes to  
15 coexistence is to ensure that, well, biotech crops are  
16 in the regulated phase, research and development, that  
17 they are confined and are causing disruptions in trade  
18 and commerce or causing environmental impacts.

19           So those are very important activities to us.  
20 In fact, most of the resources in BRS are devoted to  
21 these kinds of activities. In 2012, BRS processed more  
22 than 2,100 permits and notifications. There were

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1 11,602 authorized field release sites that were  
2 authorized through the permitting and notification  
3 process. Not all of those were actually planted. I  
4 think about 22 percent of the authorized notifications  
5 were planted, and 42 percent of the permits, and Doug  
6 Grant is going to be going over some of those details  
7 with you this afternoon.

8           We conducted almost 700 inspections last  
9 year, so this is an area that we've increased over the  
10 last couple of years. For years and years and years,  
11 we were doing about 500 a year. Now we're doing closer  
12 to 700 inspections per year. We're seeing a very high  
13 rate of compliance with those inspections. The  
14 Biotechnology Quality Management System, which we began  
15 to implement in 2010, has grown over the years. We're  
16 very happy with how that's going. It includes big  
17 companies and smaller companies and academic  
18 institutions that are now part of the program.

19           Last year in 2012, we recruited two  
20 participants to the -- into the BQMS program and one  
21 additional one in 2013, so we have 22 entities that are  
22 enrolled in the BQMS program now. Nineteen of those

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1 entities have gone through the whole program and have  
2 been recognized as having a full BQMS program in place  
3 and operating. They've had a thirty-party audit in our  
4 meeting ISO 9001 standards.

5           Importantly, 85 percent of the release sites  
6 and 90 percent of the acre -- 92 percent of the acreage  
7 of these field trials that we authorized through the  
8 permitting and notification process are being carried  
9 out now by regulated entities that have gone through  
10 the whole BQMS program. So the vast majority now of  
11 the field trials that are out there in place are  
12 operating under a recognized BQMS program. So that's  
13 really significant and something that we're delighted  
14 with.

15           Because we want to walk the talk, we  
16 subjected our own BQMS program administration to a  
17 quality management process, and so our administration  
18 of the BQMS program has recently passed an ISO audit,  
19 and I think we'll soon have the certificate that says  
20 we're officially ISO 9001 certified in terms of how we  
21 administer the BQMS program.

22           We have also made a concerted effort in this

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1 last year to reach out to small developers and  
2 university researchers to help them better understand  
3 the regulatory system that we have, what the  
4 requirements are, what kind of things they need to stay  
5 in compliance with the regulations.

6           The two things that we did in the past year,  
7 last December, we had a specialty cross-regulatory  
8 assistance workshop, along with the Environmental  
9 Protection Agency and the Food and Drug Administration  
10 here in Riverdale. We had 50 or so participants, and  
11 we worked with small developers to help them understand  
12 the process for navigating a petition for non-regulated  
13 status, and there were case studies from small  
14 developers that had gone -- that had gone through that  
15 process.

16           Additionally, we had five workshops across  
17 the country over the last year, different universities  
18 around the country. You'll hear more about that later  
19 today. And those workshops were targeted to university  
20 researchers and small developers. We had a good  
21 turnout at all of those and so folks could learn about  
22 the notification and permitting process and inspection

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1 and compliance activities. And we're continuing to see  
2 interest in having more of those this year.

3           So while the best majority of field trials  
4 are in BQMS programs, we're also trying to reach out to  
5 those that maybe don't have the wherewithal or the  
6 resources to go through that whole program to provide  
7 assistance in other kinds of ways.

8           Kevin talked at some length in his remarks  
9 about the petition process improvements. That, of  
10 course, was a significant activity for us in the past  
11 year. It was last November when USDA announced a  
12 number of different process improvements, one of those  
13 being ours in March of last year, and we published a  
14 Federal Register Notice that let the public know how  
15 the -- how the process was changing and how the public  
16 could interact with the agency in that new process.

17           The new process is designed to make the  
18 process a lot more timely, more predictable, without  
19 sacrificing any quality in the analytical work that the  
20 agency does to inform these regulatory decisions. In  
21 fact, the new process does have a second opportunity  
22 for the public to have input in the process, and that

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1 was all laid out in the March Federal Register Notice.

2 I look back on the remarks that I made last  
3 year about the petition process, and I was a little  
4 disappointed to see that I reported to you last year  
5 that we had 23 petitions before us right now, and we  
6 have 23 petitions before us right now still. That's  
7 not to say there wasn't significant movement. We did  
8 make determinations on six during the last year, but we  
9 got six more during that same period of time.

10 We do have a large number of these things, a  
11 bubble-up of these things, if you will, that are going  
12 through the process at the same time. In July of this  
13 year, we published 12 dockets for public comment. Nine  
14 were new process petitions where the complete petition  
15 was published for public input, and then there were  
16 three old process petitions where the agency also  
17 published for public comment, the draft risk assessment  
18 and the environment assessment, for public comment.

19 So the comment period on those 12 closed on  
20 September 11th, and we're dealing with the next steps  
21 on all of those right now. So we're still in a  
22 transition period. We are going to continue to be

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1 focused on those now. There are some internal  
2 procedures that we need to do. We're building a better  
3 tracking system for these. We have put significantly  
4 more resources into this kind of work in terms of  
5 additional staff and contract support, so that's going  
6 to be a continued area of focus. I'll also mention of  
7 the six approvals that we did over the last year, one  
8 of those was the one regarding sugar beets, and that  
9 culminated a two-year process of preparing an  
10 environment impact statement, so that was one of the  
11 six that was done.

12           Let me now turn to the international work  
13 that we do. We work very closely with the USTR and  
14 USDA's Foreign Agricultural Service to advance  
15 interests of American agriculture, and Ed Porter is on  
16 the agenda this morning to tell you a little more about  
17 USDA's trade promotion efforts.

18           In 2012, BRS continued to work with  
19 international partners to enhance coordination of  
20 regulatory approaches and to provide capacity-building  
21 assistance to developing countries for regulation of GE  
22 crops. We work closely with Mexico and Canada towards

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1 regional harmonization of biotechnology regulatory  
2 policies in North America through a trilateral  
3 technical working group and held individual bilateral  
4 sessions with China, Japan, and Korea in the last year.  
5 Our staff provided training and information about  
6 USDA's policies and regulations to officials from 13  
7 countries through a variety of venues last year.

8           Another specific interest in our work with  
9 China, during the past year, BRS has continued to work  
10 closely with the EPA, FDA, and Foreign Ag Service on  
11 technical and policy outreach activities with Chinese  
12 biotech regulators as well as Chinese biotech  
13 developers. This work is built upon the government-to-  
14 government discussions of past years and the September  
15 of 2011 workshop that we held along with FDA and EPA  
16 that we gave for Chinese researchers and developers of  
17 biotech crops, and the purpose of that workshop was to  
18 help them understand the requirements of the U.S.

19           regulatory system.

20           BRS also continues to provide leadership  
21 within the Organization for Economic Cooperation and  
22 Development to advance understanding of U.S. science-

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1 based approach to environmental review of biotech  
2 crops. BRS participates in, and Dr. Sally McCammon  
3 chairs, OECD's Working Group for the Harmonization of  
4 Regulatory Oversight in Biotechnology.

5           Approximately 40 countries participate in  
6 that working group, which prepares technical documents  
7 used by regulators around the world for their  
8 assessment of GE products and emerging issues, such as  
9 low-level presence of unauthorized transgenic plants  
10 and seed. And that's a focus of that working group  
11 right now.

12           Let me turn now to the year ahead, 2013.  
13 There are six areas that we are focused on in the  
14 upcoming year. One of those is, of course, to continue  
15 to work and get the new petition process fully  
16 implemented and in place and operating. As I  
17 mentioned, we have work to do to fully integrate it  
18 into our internal processes.

19           We're working with a company to help us build  
20 a tracking system, and one particular area we're going  
21 to take a real close at and evaluate this year is the  
22 NEPA pilot project that we announced and undertook a

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1 couple of -- well, about a year and a half ago, we  
2 announced this, in the April 2011 two-year NEPA pilot  
3 project, to try some different approaches for the  
4 preparation of NEPA documents to examine, the extent to  
5 which these alternative approaches would improve the  
6 timeliness, the quality, and the cost of preparing NEPA  
7 documents. And one of our agenda topics this morning  
8 is the report on the NEPA pilot project and some early  
9 observations from that work.

10           We're already getting a lot of feedback about  
11 this. I will just say it's one of our top priorities  
12 to evaluate this year. We're going to do that. The  
13 folks that have been participants in the pilot will be  
14 asked for their input in evaluating that, and I would  
15 just remind people that we went into the pilot project  
16 with the spirit of trying some different things out  
17 with the understanding that some things would work,  
18 some things might not work, and that's still how I'd  
19 look at it.

20           And our intent is to really examine what has  
21 worked and what has not worked, and what's worked,  
22 we'll keep and implement, and what's not working, we'll

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1 figure out a better way to do it. So we're very  
2 committed to that. It's a very important aspect of the  
3 work that we do. And so I just wanted to highlight  
4 that in particular.

5           A secondary area we're continuing to do work  
6 within BRS at this point is to examine our regulations,  
7 identify areas that we think could be improved or  
8 strengthened. As you all know, we published proposed  
9 regulations in 2008, and we got 66,000 comments on  
10 those regulations.

11           Typically, when the administration is  
12 changing or when the administration is entering a  
13 second term, there's a reexamination of what the  
14 regulatory priorities will be, so I don't know where  
15 our thoughts on this are going to fit into the larger  
16 scheme of things at this point, but I did want to let  
17 you know that at this point, anyway, BRS has not lost  
18 sight of these issues and examining the regulations to  
19 identify ways that they could be improved and  
20 strengthened.

21           Thirdly, we're going to continue to carry out  
22 increasingly effective and efficient permitting and

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1 inspection and compliance programs. I talked about how  
2 well I think those things are working. Nevertheless,  
3 we always want to look for ways to make them work even  
4 better. So we're going to continue to expand our  
5 compliance assistance activities this year through more  
6 outreach and more workshops. We'll be updating our  
7 internal guides for inspections and want to start  
8 looking at a BQMS program in terms of what impacts that  
9 is having, now that we've been into it a few years.

10           A couple of other areas that are important  
11 that we're focused on is working with other government  
12 agencies, low-level presence, policies, and issues and  
13 how those affect trade. That's a very important issue.  
14 We're not in a leadership role on that, but we have a  
15 very important contribution to make to those efforts,  
16 and we're committed to helping to move those areas  
17 along.

18           And we'll also be focused on comprehensive  
19 import policies for GE, animals, and plants. As a  
20 subject that was actually examined by the USDA Office  
21 of Inspector General a number of years ago -- well,  
22 actually, I don't remember the year of that audit, but

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1 there's some unfinished business there that we're going  
2 to try to advance in this upcoming year.

3           And then, lastly, we want to continue to  
4 focus on things that we can do to make our organization  
5 as efficient and effective as it can be. This is more  
6 of our administrative activities, but looking to ways  
7 to cut costs and ensure that we're putting all the  
8 resources that we can into the delivery of program and  
9 keeping our overhead costs low and things of that  
10 nature.

11           Kevin talked about the budget, so I'll say a  
12 little bit about that, as he mentioned, how the APHIS  
13 budget has been affected over the last couple of years  
14 and what may lie ahead. We've been really fortunate in  
15 BRS, actually, to be in a growth mode the last couple  
16 of years. Congress provided us with a significant  
17 budget increase last year, which has carried into this  
18 year, so unlike the rest of the agency, we've been in  
19 more of a growth mode than the rest of the agency has.  
20 We added 11 new employees last year. We were able to  
21 get some additional contract assistance to help us  
22 evaluate public comments and prepare environmental

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1 analyses and things of that nature.

2 I think that even if the worst were to  
3 transpire and there were across-the-board budget cuts  
4 that affected all of our programs, I feel like we would  
5 still be in a good position to do the work that we need  
6 to do and address the priorities that I've outlined  
7 here today and have the resources to continue to move  
8 forward on all of these areas.

9 We're following the Farm Bill and  
10 appropriations process closely. In the House Ag  
11 Committee version of the Farm Bill, there's a number of  
12 provisions related to biotechnology. I really have no  
13 idea what's going to happen with the farm bill or when  
14 that might happen, but just suffice it to say that's  
15 something we're keeping our eye on. In addition to the  
16 money part of the appropriations process, which, of  
17 course, we're following, there's also a biotech  
18 provision in the House version of the 2013  
19 appropriations that deals with biotech. That's one of  
20 the general provisions in their version of the bill,  
21 which we're watching as well.

22 So that's a quick summary of the past year

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1 and our focus areas for the year ahead. And at this  
2 point, I'd be very happy to take questions that you may  
3 have.

4 MALE SPEAKER: Mike, I have two questions to  
5 ask you. One is on the inspections, you said that you  
6 did about 700 inspections this year, and you said there  
7 was a high level of compliance. Can you give a little  
8 more analysis of how many of those inspections were in  
9 compliance and how many of those 700 were not in  
10 compliance and then if you've done any analysis of the  
11 types of noncompliance you've seen of those inspections  
12 that were not in compliance?

13 So that was my first question. The second  
14 one, you mentioned the -- both the House Farm Bill and  
15 the Appropriations Bill language, which would  
16 definitely impact the regulatory system that you have  
17 in place here at BRS, and I'm wondering if the  
18 administration or USDA or BRS has been asked its  
19 opinion or any analysis by any members of that -- of  
20 Congress about that, and if so, what was -- what was --  
21 what was provided to that -- to Congress about the  
22 administration or USDA or BRS' position or analysis on

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1 that.

2 MR. GREGOIRE: Okay. Thank you, Greg. Good  
3 questions. I thought you would ask me about the  
4 inspections because you asked me last year too when I  
5 reread. So, actually, we did 679 inspections last  
6 year. When we get the inspection reports -- are -- the  
7 inspections are done by Plant Protection and Quarantine  
8 field officers who we train and dispatch to do the  
9 inspections. They complete the inspection reports.  
10 They turn those back to BRS, and our folks evaluate  
11 those to make a determination of whether or not there  
12 was a compliance issue.

13 So we did 679 inspections. At this point in  
14 time, we've finished evaluating 500 of the inspection  
15 reports, and of those 500, four, there were  
16 noncompliance. One rose to the level of getting a  
17 letter of warning, and the others got letters of  
18 noncompliance. When we find noncompliance, the first  
19 thing we do is work with the developer to get the  
20 situation back into compliance. That's the first  
21 priority.

22 So, you know, violations range in their level

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1 of seriousness, so our response really depends on how  
2 serious the situation is. So sometimes it's just a  
3 matter of maybe some paperwork's not in order, it will  
4 work if you get it in order, fine. But something a  
5 little more egregious, maybe a letter of warning is in  
6 order, and for really serious violations, we do have  
7 authority under the Plant Protection Act to issue fines  
8 and civil penalties.

9           So that is an extremely high rate of  
10 compliance. As I said, we've only found four out of  
11 those 500 inspection reports. Now, the other thing I  
12 will say is the regulations require that developers  
13 self-report violations to us within 24 hours if they  
14 discover they've done something that is not consistent  
15 with the acknowledged notification or permit that they  
16 had, and I think we had 114 self-reports last year, and  
17 I don't -- I'm sorry, I don't have a -- kind of a  
18 breakout of those. I'll check out -- maybe that's  
19 something we can get a little bit more information on -  
20 - in the break.

21           The number of self-reports has gone up  
22 somewhat. I remember just a year or two ago -- this

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1 may be in the 80 to 85 range. And one of the things  
2 that we anticipated when we implemented the BQMS,  
3 because that involves the entity having better  
4 management and practices and monitoring in place, that  
5 they would be better discovering where things go awry.

6           So we thought we might see some additional  
7 self-reporting as BQMS was implemented, and it looks  
8 like we have. So that's what I'll say about the  
9 inspection activity. And we do have a more detailed  
10 presentation on the inspection compliance activities  
11 this afternoon.

12           With respect to the provisions in the Farm  
13 Bill, which I'll describe in just a minute, and in the  
14 Appropriations Bill, USDA has officially taken no  
15 position on those provisions. USDA, with respect to  
16 the House Bill, was asked and provided some technical  
17 assistance to committees, staff, which is just normal  
18 for that to happen.

19           But the Department has not taken any position  
20 on those provisions, and I think that's true of  
21 multiple Farm Bill provisions generally, that the  
22 Secretary has left that to the Congress to write the

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1 Farm Bill. The language in the Appropriations Bill or  
2 the House, it's a general provision, essentially says  
3 that if a court vacates an APHIS determination of non-  
4 regulated status, the Secretary shall, notwithstanding  
5 any other provisions of law, immediately issue permits  
6 or a partial deregulation to allow the continued  
7 cultivation of the crop in question under regulatory  
8 oversight.

9 In the House version, the Farm Bill has  
10 provisions that really deal with the petition process  
11 and sets a one-year statutory timeframe for decisions  
12 to be made on petitions for non-regulated status. That  
13 is one year from the time they're being complete. The  
14 provision would allow the Secretary to extend that by  
15 up to six months, provided the petitioner is notified,  
16 and at the end of that six-month period, the proposed  
17 language says that if USDA has not acted, then the  
18 product is automatically deemed not regulated.

19 The provisions also put some sideboards on  
20 the environmental -- it defines what the environmental  
21 analysis would look like and limits the environmental  
22 analysis to an examination of the plant's impact on

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1 air, water, soil, and non-target organisms, and then  
2 there's some other provisions, some reports, that would  
3 be due to Congress. And so that's kind of a snapshot  
4 of what those provisions are.

5 Other questions?

6 MALE SPEAKER: (Indiscernible), Monsanto.  
7 You briefly mentioned interagency coordination with the  
8 likes of FDA and EPA. My question is around those  
9 continued efforts, particularly around things like  
10 protecting endangered species analysis and the fact  
11 that we understand that particularly the EPA would not  
12 stamp a label for, for example, (indiscernible) USDA is  
13 deregulated. So can you describe a little bit some of  
14 the interagency coordination efforts that are ongoing  
15 specifically with EPA?

16 MR. GREGOIRE: Yes. Yes, thank you.

17 MALE SPEAKER: Yeah.

18 MR. GREGOIRE: It's been EPA's longstanding  
19 practice to not finish their process until USDA has  
20 made a regulatory determination on the petition for  
21 non-regulated status. And this would basically be for  
22 herbicide-tolerant crops, where there is a new

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1 herbicide registration that is required or a new use  
2 registration that is required.

3           The challenge that that presents is making  
4 sure that the analysis in our EAs is using the best and  
5 most current available scientific analysis. So we've  
6 been working really closely with the EPA this year and  
7 had discussions on the staff scientist to scientist  
8 level so that we're working with the same kind of basic  
9 assumptions in the analysis that we do. When we're  
10 looking at the GE plant and they're looking at a  
11 companion herbicide there that's going to be applied to  
12 that plant.

13           We want to be able to make reference to the  
14 most recent risk assessments that EPA has done for  
15 human health and environmental impacts and be able to  
16 incorporate those in our Environmental Assessments. We  
17 don't want to find ourselves in a position where we've  
18 made a final determination and final EA, only to have  
19 some new analysis come up just months later. So we're  
20 working closely with them to kind of map the two  
21 processes that the agencies have and make sure that  
22 we're coordinated, like a coordinated framework, as we

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1 should be.

2           In fact, in this last year, Secretary Vilsack  
3 and Administrator Lisa Jackson of EPA issued a joint  
4 statement about making this a priority for the two  
5 agencies to work together. The endangered species  
6 analysis specifically, it has been our contention, and  
7 it has been our practice, and we did argue successfully  
8 in one of the legal cases this year that APHIS'  
9 responsibility in terms of assessing the impact on  
10 engendered species goes to the impacts of the plant  
11 when threatening an endangered species. The herbicides  
12 or the pesticides that may be applied to these plants  
13 are under the jurisdiction of the Environmental  
14 Protection Agency. And that was really a major issue,  
15 and it was really kind of the main issue in moral  
16 arguments in the Alfalfa II litigations that challenged  
17 the agency's determination of non-regulated status that  
18 followed the publication of the final Environmental  
19 Impact Statement and the record of decision.

20           The Court found with respect to the  
21 endangered species, question in that case, the court  
22 said that APHIS is not the legally approximate cause of

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1 the herbicide use, that that is EPA's jurisdiction in  
2 the way APHIS examined those issues in the EIS were  
3 okay, and that was upheld. Now, that case was  
4 appealed. That is still one of the central questions in  
5 the appeal. There were oral arguments heard October  
6 24th, and a decision could come out of the Appeals  
7 Court at any time now, so that's one we're watching  
8 very closely, as is EPA.

9 MR. THIES: Greg Thies. I'm with Syngenta.  
10 To what extent do you take into consideration the so-  
11 called Biotech Blueprint -- Economy (ph) Blueprint in  
12 developing operational plans or policies?

13 MR. GREGOIRE: Well, the Bioeconomy  
14 Blueprint, I think we're actually a little ahead of the  
15 game on that. I mean, there's -- I think Page 32 of  
16 the Bioeconomy Blueprint, as a matter of fact, because  
17 I was looking at it yesterday for some -- for some  
18 other reason, talks about the importance of -- what  
19 role federal agencies should play in regulating  
20 emerging and new technologies and talked about things  
21 like having an efficient process, a predictable  
22 process, a transparent process, and so on.

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1           So I think the work we have put into the  
2 petition process improvements is entirely consistent  
3 with the Bioeconomy Blueprint. It's just that we  
4 started doing that before the blueprint was published,  
5 so that's how I see the two kind of fitting together.  
6 All right. Thank you.

7           MR. GEORGE: Thank you, Mike. In advance of  
8 this meeting, we invited our stakeholders to submit  
9 ideas for subjects to cover and questions to answer.  
10 Among the questions that came in were a couple of  
11 fairly specific ones dealing with agricultural trade  
12 barriers in general, and with China in particular, and  
13 another dealing with corn (indiscernible) in Mexico.  
14 This got us thinking it would be helpful to have  
15 someone here from the USDA's Foreign Agricultural  
16 Service, FAS, to talk about what they do with regard to  
17 biotech internationally while using the two questions  
18 as reference points. So here to fill us in is Ed  
19 Porter, Director of New Technologies and Production  
20 Methods Division in the Foreign Agricultural Service,  
21 FAS. Ed?

22           MR. PORTER: Thank you. And I see time's

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1 almost up, so I will start --

2 MALE SPEAKER: Sorry about that. Take your  
3 time.

4 MR. PORTER: No, no worries. Let's see if I  
5 can work this. I'll cut right to the chase. I'll  
6 start here, but I really want to get -- I'll go right  
7 to China. Yes, one of the questions that was posed was  
8 what is USDA doing to advance American agricultural  
9 interests and remove trade barriers, particularly with  
10 China? And what we're doing with China today I think  
11 offers a good example of how in general we work to  
12 remove trade barriers and advance U.S. agricultural  
13 interests.

14 Some of our top concerns are -- our top  
15 concern right now with China is asynchronous approvals;  
16 that is, that the gap in time between approvals of GE  
17 product in the U.S. for commercialization and approval  
18 in China. Another issue -- a current issue is, right  
19 now, the lack of approval of GE events that have been  
20 in the approval process or submitted to China for  
21 approval a while ago, and including reauthorization  
22 (indiscernible).

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1           What we -- what we do to address these issues  
2 is -- is, first, we try to maintain -- or we do  
3 maintain consistent communication at various levels and  
4 across Chinese ministries. We do this, for example,  
5 with our biotech working group and technical working  
6 group meetings. These are meetings that we try to hold  
7 annually. We've been successful in doing that until  
8 recently, when this past September, the Chinese  
9 declined to meet with us, we believe, because of the  
10 ongoing transition of government in China, but we're  
11 pushing to hold that meeting.

12           We believe that these meetings are very  
13 important to ensuring that Chinese officials are very  
14 aware of our concerns, that they're very aware of the  
15 possible impact on trade if we can't make progress on  
16 these concerns, and that they're very aware of our  
17 willingness to work with them to address their  
18 concerns. Some of the issues that they've brought to  
19 our attention include assistance with risk  
20 communication and risk management as they go forward to  
21 commercialize GE crops in their country.

22           So it's a balancing act, but the bottom line

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1 is we don't want them in any way surprised if, for  
2 example, there isn't progress on current approvals. And  
3 then decisions are made by trade that impacts trade.  
4 We don't want Chinese officials to be surprised that  
5 this may happen and what the impact might be. We want  
6 them fully informed, and we want to ensure that  
7 officials -- Chinese officials across ministries and at  
8 various levels, are informed.

9           We've also -- there's also regular -- I would  
10 say regular meetings at very high levels with Chinese  
11 officials. The Minister of Agriculture, for example,  
12 visits the U.S. and vice-versa. In fact, there's an  
13 upcoming meeting of high-level officials for JCCT this  
14 month, next week.

15           We also are working with -- well, it's back  
16 on the other slide. I apologize. But we also work  
17 with like-minded countries. We recognize that there  
18 are other countries -- Brazil, Argentina, Canada come  
19 to mind -- that have similar interests as we do and  
20 have similar concerns and problems with China and other  
21 important countries, and that it makes sense to work  
22 together when we can to advance our mutual interests.

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1           And so how we go about that, one recent  
2 example is -- it's not with China, but in Europe, we  
3 together drafted a letter that was signed by five or  
4 six countries, and it was delivered by ambassadors from  
5 those countries to European officials. We're working  
6 right now to get Canada and Argentina and Brazil to  
7 register their concerns with Chinese officials about  
8 the lack of approvals of biotech products in the  
9 pipeline right now. So in addition to reaching out  
10 ourselves, we work with other like-minded countries on  
11 area -- on issues of mutual concern.

12           The second question had to do with Mexico,  
13 what can USDA do to influence Mexican regulators to  
14 move faster on corn cultivation approvals? A short  
15 answer is not much. I say that because it seems -- I  
16 believe the question's referring, in part, to the corn  
17 map that was recently announced by Mexican officials.  
18 This is a -- this is a map that has identified centers  
19 of origin and centers of genetic diversity for corn in  
20 Mexico, particularly in the northern Mexican states,  
21 and under current law, no cultivation of biotech corn  
22 can take place in these areas. The map was recently

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1 revised and these areas expanded, and there's been  
2 concern about that.

3           According to Mexican officials, there are  
4 about 2.1 million hectares of land open for biotech  
5 corn cultivation in northern Mexico, but really only  
6 about one-fourth of this is suitable to corn  
7 production. There's been other events that have slow  
8 progress on the commercialization -- of the  
9 commercialization of corn cultivation in Mexico. I say  
10 there's not a lot we can do because, in my opinion,  
11 it's a political decision, and these decisions don't  
12 often lend themselves to rational response.

13           What we are doing, though, is, again, working  
14 closely to ensure that Mexican officials understand our  
15 concerns. We're also working with Mexican officials to  
16 educate Mexican farmers about the benefits of GE corn  
17 production. And, in fact, this is a top priority for  
18 some -- well, for our Mexican colleagues in the  
19 Ministry of Agriculture, and with the -- with the idea  
20 being that Mexican farmers, if they fully understand  
21 the benefits to them of cultivating GE corn in their  
22 country, they will bring pressure on their officials to

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1 make changes that would be necessary to permit  
2 effective commercialization of GE corn in Mexico.

3           We also meet with Mexico annually, and Canada  
4 under the North American Biotechnology Initiative.  
5 Again, this is an effort to work with a like-minded  
6 country, Canada, to address issues within our three  
7 countries. And we're also working with Mexico and  
8 Canada on other issues of mutual concern. In fact,  
9 other than this corn cultivation situation in Mexico,  
10 we have very good relations, and we've had some very  
11 good progress with Mexican officials as regards to the  
12 trade of GE products worldwide.

13           For example, Mexico is participating in a  
14 global LLP initiative that was started a few years ago  
15 in Vancouver, Canada. The second meeting took place in  
16 Rosario, Argentina. Mexico, in fact, just signed the  
17 statement that that group just recently publicized.

18           Mexico was very supportive and helpful during  
19 the last (indiscernible) protocol meeting and the COP-  
20 MOP/6 meeting that took place in October in Hyderabad,  
21 India. I attended that meeting. As you probably know,  
22 the United States is not a party to the protocol.

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1 Mexico is. And so they were very open to suggestions  
2 that we had, concerns that we raised, and they were  
3 willing to bring these concerns to the floor for  
4 discussion. And we were very -- I had a very good  
5 dynamic working relationship there.

6           And then, finally, we're working with Mexico  
7 to create -- what we call a CAS-NABI group. CAS is the  
8 Southern Cone of South American countries. It's  
9 comprised of six countries, including Brazil and  
10 Argentina, and Paraguay, Uruguay, Bolivia, and Chile --  
11 those are the six -- with the idea of possibly  
12 expanding on the discussions that now take place within  
13 NABI to include other countries in the Americas. It's  
14 a process in its infancy, if you will, but we feel that  
15 there could be some significant advantage to broadening  
16 a discussion of issues of -- related to the trade of GE  
17 products to include other countries in the Americas.

18           So in summary, in answer to the second  
19 question, I don't think there's much that we can do  
20 directly to sway decisions, political decisions made in  
21 Mexico with regard to GE corn production, but we are  
22 working to address the issue in part through further

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1 educating Mexican farmers to bring the issue to the  
2 attention of their officials and working with Mexico  
3 and other arenas where we have mutual interests.

4 That's it for me. Are there any questions?

5 MR. CLAPP: Steve Clapp with Food and  
6 Chemical News again. I want to ask about the 800-pound  
7 rat in the room. I'm referring to the French study  
8 that gained a lot of attention. It appears to be  
9 resonating worldwide, even though (indiscernible) has  
10 shot it down, and then a lot of other scientists as  
11 well. Apparently Kenya has just decided to outlaw all  
12 biotech commodities and remove them from the shelves  
13 and all of this kind of thing on health grounds. They  
14 don't cite that study specifically. And in Brazil,  
15 there's a movement in the Congress to create a  
16 subcommittee that would have health oversight of  
17 (indiscernible). So can you give us some indication on  
18 how this study is resonating in other countries?

19 MR. PORTER: Well, you're right. It's  
20 resonating, unfortunately, in Kenya, for example.  
21 That's an ongoing issue that just came up, I think it  
22 was last week, and you're referring to the Seralini

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1 report. Yes, we were rather surprised by Kenya's  
2 decision to basically ban the cultivation and import of  
3 biotech products. We understand the decision was taken  
4 without full consultation of the ministries involved  
5 with the regulation of biotech products in Kenya, but  
6 I'll use this an example of how we approach these  
7 issues.

8           As I mentioned earlier, we're working with  
9 other like-minded countries, including Argentina,  
10 Brazil, and Canada, to approach Kenyan officials, to  
11 get them to reverse the decision, is the bottom line.  
12 Yes, the report was not cited specifically, but we  
13 understand it's been mentioned as a reason. Frankly, I  
14 think that the report is an excuse that officials can  
15 use to make decisions that they may have been  
16 contemplating anyway. We -- as you may know, there is  
17 an upcoming election in Kenya, and this could be  
18 associated -- this decision could be associated with  
19 that. Would this decision have been made without the  
20 study? It could -- it may have, but it helps those  
21 decision-makers, if you will, and it's unfortunate.

22           We've worked with other countries, the ones

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1 I've just mentioned, in a strong effort to counter the  
2 impact of this study, but, again, we have to be careful  
3 in that the U.S. Government obviously has a reputation  
4 worldwide for supporting the safe trade of products  
5 derived from biotechnology. And we should have that  
6 position, but we will not -- we're not going to be  
7 perceived as a neutral party.

8           And so we need to work with others, and in  
9 this case, encountering the Seralini report, working  
10 with scientific organizations and other organizations,  
11 nongovernment organizations worldwide, to ensure that  
12 they're finding that the study, in a nutshell, really  
13 has no merit, but that that information gets out to  
14 decision-makers.

15           I think we've been successful in doing that,  
16 but nevertheless, we do have the situation in Kenya.  
17 I'll also note that the French are running with this  
18 study as well, and we may see further complications in  
19 France, although I can't imagine what they're -- what  
20 they could be. The French have already banned  
21 cultivation with GE products. And I hope that answered  
22 your question. Thank you very much.

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1 MR. GEORGE: Thank you, Ed. We're running  
2 just a few minutes behind, so what we'll do is we'll  
3 take a break now and come back around, I'm going to say  
4 ten after, ten after eleven. Thank you.

5 (Off the record.)

6 (Back on record.)

7 MR. GEORGE: Take your seats, please. Thank  
8 you very much. If you could take your seats, please,  
9 we'll get started then. Hello? Folks, if you could  
10 please take your seats, we'll get started then. I want  
11 to make sure we get to lunch on time. Thank you. Thank  
12 you. Last year in this meeting, we were talking about  
13 a revamped (indiscernible) determination process. Here  
14 now to provide an update on the implementation of that  
15 process is Director of BRS Environmental Risk  
16 Assessment program, John Turner.

17 MR. TURNER: Okay. Thank you very much,  
18 Dick. Good morning, everyone. As Dick just said, we  
19 talked extensively about this last year, which most of  
20 you have heard about it, so this is an update. We've  
21 started to implement the process, and so this is an  
22 update of where we are and some of the data we've

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1 received to date.

2           So in terms of background, you all know about  
3 our petition process. It's defined in 7 CFR 340.6,  
4 which says developers of a GE organism may petition  
5 APHIS for a determination of non-regulated status. So  
6 developers typically do field testing for one, two, or  
7 multiple years, and at some point after they believe  
8 their product is safe, they will petition us for  
9 deregulation. And we don't actually have any authority  
10 over commercialization, but a practical step, this is  
11 usually necessary to commercialize.

12           So in terms of defining our problem, early  
13 on, from 1992 to 1999, it took an average of 178 days  
14 for us to review and approve a petition. So this is  
15 about a half-year. More recently, however, we've seen  
16 this because much longer. It's been two to five years  
17 for most and even longer for a few. And as Mike  
18 Gregoire said this morning, you have 23 pending  
19 petitions.

20           So here's another way to look at the problem.  
21 You see this scattered diagram of how long it took us  
22 to reach a final decision, a graph from, you know, the

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1 early '90s up until now. So there are a couple of  
2 important things you can see in this graph. The first  
3 is if you did a regression line down through there, you  
4 certainly have an upward trend, and the other thing,  
5 just as problem -- what did I do? Sorry. Third slide.

6 I'll not attempt to use the pointer, but to  
7 show you that further out, more recently, there's also  
8 a lot of variability. So these two things, a long time  
9 period plus a lot of variability are both high,  
10 undesirable, if not unacceptable to us and many of our  
11 stakeholders.

12 So we used the Lean Six Sigma process  
13 improvement techniques to try to devise some solutions.  
14 Lean Six Sigma, as you may know, is a business process  
15 improvement toolset. It's been used by Secretary  
16 Vilsack in Iowa, and he's been a champion of these  
17 techniques. And this very project, to include  
18 petitions, was a high-priority goal of the Secretary.

19 In terms of our outputs and findings, using  
20 Lean Six Sigma, we came up with a new process which is  
21 streamlined and standardized with defined deadlines.  
22 This is very important. When we mapped out our entire

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1 process, we saw hundreds of steps, actually, each one  
2 which could be variable on how long it took. So there  
3 can be a cumulative effect of a few days too long here,  
4 a week too long there, and we found that all of those  
5 had the potential to throw the system off and  
6 cumulatively result in a very long review time. So now  
7 we've defined all those individual steps, but put  
8 deadlines on them.

9           We're developing resource management and  
10 tracking tools. You have the deadlines so management  
11 needs to know when they're coming up so that we can  
12 keep these things moving. We have clearer separation  
13 of the Plant Pest Risk Assessment, and NEPA functions,  
14 and we have an opportunity with the new public comment  
15 period for earlier public involvement.

16           So using our new process, all of these  
17 things, we have a new process which should take 13 to  
18 16 months, and, again, as Mike said earlier, we did  
19 this all while maintaining the quality of our analysis.  
20 So the intent is to maintain the very high quality that  
21 we've strived for in recent years.

22           So these maps show the old process compared

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1 to the new, and they're juxtapositioned in this way so  
2 that you can see the -- sort of compare the features of  
3 the two. If they were both, of course, graphed on a  
4 timeline, you could see the old process takes 31 months  
5 total, whereas the new, either 13 to 6 six months. So  
6 it's basically cut the time in half. And I'll go  
7 through the old process first, starting on the top, and  
8 the left box.

9 Under that process, the review for  
10 completeness averaged eight and a half months. Once we  
11 have complete petition, we prepared a draft Plant Pest  
12 Risk Assessment and an Environmental Assessment. This  
13 took 15 and a half months, on average. After that was  
14 a 60-day comment period on the petition and on the  
15 draft Plant Pest Risk Assessment and draft EA. That  
16 went out for 60 days.

17 Sixty days is actually required in our  
18 regulation for comment on the petition itself. There's  
19 more flexibility under NEPA. That can be as short as  
20 30 days, but because we were taking comments on all of  
21 these documents together, including the petition, was  
22 60 days. So that's obviously two months.

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1           The next step was to revise these documents  
2 and respond to comments. That took, on average, five  
3 months. And then publish your final decisions with  
4 these final decision documents, for a grand total of 31  
5 months. Now, below it, the improved process. The  
6 first step is really essentially the same, review for  
7 completeness, but we've broken down the individual  
8 steps and put tight timelines on that such that we're  
9 now aiming to do that in three months.

10           Once we have a complete petition under the --  
11 under the new process, it goes out for public comment,  
12 the petition itself. We don't have our own decision  
13 documents to go with it. So this accomplishes a couple  
14 of things. It gets the clock running on that mandatory  
15 60-day time period and provides earlier public input to  
16 us that we can use in preparation of our Environmental  
17 Assessment and finalizing our Plant Pest Risk  
18 Assessment. We go ahead and start drafting a Plant  
19 Pest Risk Assessment while the 60-day time period is in  
20 place.

21           So this process, 60 days, again is two  
22 months. After that, we prepare our Environmental

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1 Assessment. This takes -- this will take seven months  
2 under the new process, and then there are two paths  
3 that things can go on. On the top path, for things  
4 which are less familiar and may raise new issues, it  
5 will go up for a 30-day comment period on the Plant  
6 Pest Risk Assessment and the draft Environmental  
7 Assessment. This is very similar to what we're doing  
8 now -- to what we were doing previously, except for  
9 that it was 60 days.

10           So there's a comment period of one month. We  
11 would get it back, and over the next two months, we  
12 would revise our documents and prepare a response to  
13 comments. That would take about two months, and then  
14 in the end, we would publish our final decision  
15 documents for a grand total of 15 months.

16           The other path, on the bottom right-hand side  
17 of the slide, for things that do not raise new issues,  
18 is that we would reach a preliminary decision and  
19 publish that with our Environmental Assessment and our  
20 Plant Pest Risk Assessment, saying, "We believe we're  
21 going to choose this alternative," and we would put it  
22 out for a 30-day review period, in which time, again,

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1 the public could respond. If we saw no new information  
2 that would change our analysis over that time period,  
3 then the decision could become final in 30 days, and we  
4 would announce that on our website.

5           So one of the questions we've had is, so what  
6 are the criteria for determining whether something is  
7 new and novel or just more familiar? And it really --  
8 the key is whether it raises new issues. There's not a  
9 certain number of positions we would have had to have  
10 seen somewhere. It's not three or six. We could have  
11 seen the trait maybe as few as one time before, the  
12 crop as few as one time before. As long as the new  
13 crop trait combination, those new issues, then we think  
14 we could go the more familiar path.

15           But this would be informed -- this is also  
16 very important -- by the 60-day comment period. So we  
17 would be looking to the public to see if this crop  
18 trait combination that we were reviewing raised any new  
19 issues that we had not addressed before.

20           So our process improvements are now  
21 implemented. We first announced these in November of  
22 2011, and then, of course, Clint gave you a very

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1 thorough overview a year ago at our stakeholders'  
2 meeting. And then because there were important changes  
3 to the public comment period, we published that in the  
4 Federal Register so people would understand when and  
5 how they should comment under the new system. That was  
6 in March of 2012.

7           And then the first nine petitions to come in  
8 and go out for comment under the new system were  
9 published in July of 2012. At the same time, we drew a  
10 line through the list of petitions. There were six  
11 other older ones that, because they were so far through  
12 the process, it appeared that it would be much more  
13 expeditious to keep them going through the old system  
14 rather than backing them up and going through the new  
15 system, so there are some that are proceeding under the  
16 old process. And, finally, all new petitions that come  
17 in, of course, will come in under the new process.

18           As part of the new process, we created a new  
19 table on our website. Some of you have noticed it and  
20 had some questions, and one question is when do things  
21 get first posted -- when do they get announced and  
22 posted on this new petition table? And that is when it

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1 goes to the Federal Register to commence the comment  
2 period, that is when they will first appear on this  
3 table.

4           The table also has a section for petitions  
5 that are continuing through the old process, so it's a  
6 little bit -- I don't want to say confusing-looking,  
7 strange-looking, because you have two types of petition  
8 in here. The old ones eventually will move through,  
9 and everything will be under the new process, and I  
10 think at that point, the table will have at least a  
11 cleaner look.

12           Also, at one point, there were two tables up.  
13 It was the new table and the old table, and people had  
14 some questions about that. The old table is gone, so  
15 there's just the new table showing old petitions and  
16 petitions which have been -- and petitions under the  
17 new process, which have been announced in the Federal  
18 Register.

19           And, finally, here are some of the results to  
20 date in terms of what we're seeing. In terms of our  
21 initial review period, that's the time from the time we  
22 receive the petition until we send what's called a

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1 deficiency letter back to the petitioner. Based on  
2 five petitions, it's taken an average of 28 days,  
3 whereas previously, it took 205 days. So this is a  
4 sizable savings of 177 days.

5           In terms of the petitioner response, after  
6 they get the letter from us saying, "We need this data  
7 or this information," it's taken 23 days to receive  
8 that reply back based on five petitions, whereas  
9 previously, it was 107 days. Here, the savings is 84  
10 days. In terms of the final petition review, that's  
11 when we get the new information that we've requested  
12 back from the petitioner in response to our letter.

13           Based on seven, it's taken 41 days for us to  
14 complete the final review as opposed to 39 previously,  
15 so there's actually a slippage in the wrong direction  
16 of two days. I meant to go also to that very quickly  
17 and get to the next line. If you look at all the  
18 review steps together, there's 64 average now versus  
19 324 previously for a savings of 260 days, and Kevin  
20 Shea mentioned that number (indiscernible). That's how  
21 that was calculated.

22           In terms of preparing a draft PPRA, we've

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1 done six of these since we implemented the new process.  
2 It's taken an average of 73 days compared to 143  
3 previous, so this is another 70-day savings that's not  
4 reflected in the 260 above it. Then in terms of draft  
5 NEPA documents, we know that's taken 213 days  
6 previously. We don't have a data point, but it is  
7 certainly our goal to do it in a more expeditious  
8 fashion under the new system.

9           And with that, I'm done, and I think we'll  
10 have time for a few questions today.

11           MS. HOOD: Hi, John. Aimee Hood, Monsanto.  
12 So just curious, it's since July since the last public  
13 comment period started, and it would seem from the  
14 timelines that some additional petitions either should  
15 -- could be coming up for additional public comment or  
16 should be coming out on the other end for either final  
17 public comment or deregulation announcements. Is there  
18 -- you know, can you just comment on the lack that  
19 additional public comments since that bolus of public  
20 comment periods in July?

21           MR. TURNER: Well, the process that I've  
22 described today, you know, we've focused on those parts

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1 of the process which are internal to BRS and we  
2 control. There are some other parts, administrative  
3 steps, and review steps (indiscernible) our control, so  
4 I really can't answer to those, but we think we've made  
5 significant steps using the new system in terms of our  
6 working steps here in BRS.

7 MS. DANIEL: Renee Daniel, Perspective  
8 Consulting. Another question about your review for  
9 completeness process, because you've cut out like five  
10 and a half months out of that, and you mentioned adding  
11 some deadlines and things, so it's one thing to put a  
12 date on something, another thing to meet the date. So  
13 have you actually added people resources or tools such  
14 as checklists, or maybe people just get better about  
15 sending them in complete to meet the deadlines?

16 MR. TURNER: There are several factors. We  
17 have, over the past couple of years, increased the size  
18 of our staff. That's been very important. We've  
19 developed and continue to develop work inspections and  
20 templates such that they know exactly what data is  
21 required. One of the big keys to this was when we  
22 looked at a biotechnologist and how they spent their

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1 time, they work on a lot of other things, so they would  
2 work on a petition for a few days, they would work on  
3 something else, they would work on something else.

4           So we found that if you could consolidate  
5 their time such that they were dedicated to doing only  
6 one job, then we could really drastically reduce the  
7 timeline. So it's a management challenge for us to  
8 look at who's available and to defend them from other  
9 work such that they can dedicate their time purely to  
10 this.

11           But that's a very interesting question, and  
12 Clint Nesbitt, who's in the back, did a great job of  
13 leading us through this, and it was very enlightening,  
14 but one of -- one of the important steps was to find  
15 out if you did only this job and only this job, how  
16 long would it take if you didn't do anything else? So  
17 that sort of became the basis for some of these  
18 timelines. And typically, when you do the initial  
19 analysis, you have these diagrams that show it takes  
20 only this long to do the actual job, but the entire  
21 process takes way longer. So for us in terms of  
22 initial review, it was mostly dedicating staff to doing

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1 that and only that, and then tracking the deadlines.

2           The other thing, under the old system, there  
3 were so many steps involved that it was difficult for  
4 management to always know when something was lagging  
5 behind, so defining the steps, having tracking systems,  
6 and dedicating the staff, I think together, is what  
7 makes most of the difference.

8           MS. WISEMAN: Hello, this is (indiscernible)  
9 Wiseman (ph), Monsanto. I have a question. Are there  
10 -- are there parts of the timeline, let's say, that are  
11 outside the control of BRS? For example, if OTT (ph)  
12 wants to review an EA, is that accounted for in the  
13 current timeline, or is that additional time?

14           MR. TURNER: A review process is --

15           MALE SPEAKER: Repeat the question.

16           MR. TURNER: So I'm going to repeat the  
17 question, because some of you may not have heard, those  
18 in the room. It's for -- are there parts of the  
19 process, the total process, which are outside of BRS'  
20 control, and are those accounted for in the timelines  
21 or not accounted for in the timelines? Excuse me. We  
22 did account for those times in the timeline. It's

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1 built in. There's a step after we complete our  
2 document called agency review. At one point, it's  
3 three weeks, and we know that it can be done in that  
4 time period.

5 Obviously, there are a lot of things that can  
6 happen unforeseen both internal to us and external that  
7 can change that, but we did -- we did build all of  
8 those things into this timeline, and we think it's  
9 possible for something to go through from start to  
10 finish and make these timelines, although, to be  
11 upfront, we haven't had anything go all the way through  
12 under the new system yet, so we don't have data to  
13 verify that.

14 MALE SPEAKER: Hi, John. (Indiscernible) at  
15 Monsanto. Sorry all the questions are coming from  
16 Monsanto these days. Question for you regarding -- you  
17 know, many petitioners provide, you know, what we  
18 believe are very thorough and comprehensive  
19 environmental reports that the agency then can use when  
20 evaluating a petition and drafting the draft EA. So my  
21 question is, you know, how are those being used, and if  
22 they are very thorough, is there any way that the

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1 amount of time that it takes -- I think currently it is  
2 seven months -- the draft EA could be reduced?

3 MR. TURNER: That would be really a great  
4 question for Rebecca Stankiewicz Gabel this afternoon,  
5 because she's the NEPA specialist who's been working  
6 with that process. I will say that in terms of those  
7 documents and how we use them, we're looking at that  
8 right now as we evaluate -- well, we will be looking at  
9 that as we evaluate the NEPA pilot during the -- during  
10 the coming year.

11 We think they are very valuable, and we think  
12 high-quality documents are very useful, and exactly  
13 what that means and how it will fit into our review  
14 process in terms of possibly changing things or  
15 expediting them, we don't have an answer for that, but  
16 it's one of the things we'll be evaluating under the  
17 pilot process.

18 MR. GEORGE: I'm just trying to get us to  
19 lunch on time, and we have one more presentation, and  
20 the segue is perfect. Last year, BRS launched a pilot  
21 project to explore new processes for complying with  
22 NEPA, and here with an update is Senior Environmental

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1 Protection Specialist Rebecca Stankiewicz Gabel.

2 MS. STANKIEWICZ GABEL: Oh, this thing. I  
3 always end up going in the wrong direction. Okay. So  
4 can everyone hear me? Okay. So I have -- this is the  
5 third year that I've had the opportunity to stand up  
6 and talk about the NEPA pilot project. The first year,  
7 we announced that we were going to do it. Last year,  
8 we gave a little bit of an update, and, again, this  
9 year I'm going to update you all where we are.

10 I also have the (indiscernible) position to  
11 be the speaker before lunch for the third year in a  
12 row, so I always seem to stand between you and your  
13 lunch, so I'll try to keep us on track and make sure  
14 that we're done by lunchtime. So let me see if I can  
15 actually do this. Can you do this for me? Thank you.  
16 I always end up pushing the button in the wrong  
17 direction when I use that thing.

18 So NEPA pilot project, as I mentioned, the  
19 NEPA pilot project, we began just about -- it's a two-  
20 year voluntary project, and we started this project in  
21 April of 2011. So this particular NEPA pilot project  
22 addresses -- the goal of this, really, is to improve

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1 how we're using -- I want to say the goal of this  
2 project really is to analyze the methods that we're  
3 using to do effective NEPA analysis, to evaluate the  
4 quality of time -- evaluate quality, time, and cost of  
5 doing our NEPA analysis.

6           And in this particular pilot project, what  
7 we're doing is looking at the analysis -- NEPA analysis  
8 related to petitions for non-regulated status. So it  
9 doesn't involve NEPA analysis for other agency  
10 activities.

11           Okay. During this pilot project, we've  
12 actually held two workshops for participants.  
13 Participation in the pilot project is voluntary, and  
14 people that are submitting petitions to us can become  
15 involved in the pilot project. So we have hosted two  
16 workshops. One of them was in person in July of 2011,  
17 where we introduced guidance for environmental reports  
18 and also for cooperative agreements.

19           Environmental reports are petitioner-prepared  
20 documents that look at various environmental qualities  
21 that might be impacted by our decision related to the  
22 petition. Am I not being clear? And then cooperative

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1 agreements are a agreement between the agency and the  
2 petitioner that allows the petitioner to pay for the  
3 preparation of an environmental analysis by a third-  
4 party contractor.

5           In September of this year, we held an update  
6 to our -- update workshop, and at that workshop, which  
7 was a webinar, we talked about NEPA and the new  
8 petition process. We also introduced some  
9 environmental report evaluation tools that we're  
10 working on, and we looked at some early trends from the  
11 pilot project.

12           So I wanted to take a moment and just mention  
13 a few things about environmental reports. Environmental  
14 reports, as I mentioned, outline information that we  
15 use in our environmental analysis, and they can be  
16 submitted at any time from the time that the petition  
17 process is initiated up until the time that the team  
18 begins NEPA analysis. And we saw a little bit in the  
19 timeline previously where that falls within the  
20 timeline. We -- this should be a separate document  
21 from a petition, and we actually encourage people to  
22 submit them with their completed petition.

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1           These environmental reports are not published  
2 during the 60-day comment period for the petition. That  
3 first comment period is just for the petition. But they  
4 are published, if we are -- if one is submitted with  
5 the EA or the NEPA document, during the comment period  
6 associated with that.

7           So one of the reasons that we encourage you  
8 to submit environmental reports early -- and I know  
9 this is a question that people have been asking -- if  
10 we're making a decision to contract the work, having  
11 the environmental report can help us when we're forming  
12 the Statement of Work. It can also help contractors  
13 that are bidding on the project to know what types of  
14 resources they have available to them to help them  
15 prepare and bid for the project.

16           We've prepared environmental report guidance,  
17 and that's published on our website, and we're  
18 constantly looking for feedback on that guidance, and  
19 we're working on updating certain sections of that now.  
20 So look in the coming few months for some updates to  
21 that guidance. But along the way, if you're using our  
22 guidance and you have any questions or you have any

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1 comments -- I know some of the developers have given us  
2 comments, and we're using those to improve our  
3 guidance. If you could communicate that to us, we can  
4 use that to incorporate into our guidance.

5           For us, this is always -- is a constantly  
6 improving process. We want to keep evaluating and  
7 improving what we're doing, so we value your feedback,  
8 and we're using your feedback to try to give you the  
9 best guidance that we possibly can.

10           And the other thing that we've done recently  
11 is we've developed some tools that we're using to  
12 evaluate ERs, so looking at them as -- using those  
13 tools to help gauge the information that we're getting  
14 and the usefulness of that information, and we will be  
15 communicating that back to the developers as we begin  
16 to evaluate incoming environmental reports.

17           Next slide, please. So one of the tools that  
18 we've used that we're developing to evaluate  
19 environmental reports is a rubric, and for those of you  
20 who come from the academic world, you know what a  
21 rubric is. A rubric really is a tool that you use in  
22 order to evaluate whether or not all of the information

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1 is included within the document and the quality of the  
2 information in the document.

3           This slide is an example of a couple lines  
4 from the rubric, but it's not the complete rubric. The  
5 rubric goes on for many pages and covers in detail  
6 various pieces of information that we're asking for.  
7 But as you can see from the rubric, what we're doing is  
8 we have a particular section; in this case, the first  
9 section, the purpose and need. We have a set of  
10 criteria. Two is that it fully meets the criteria, one  
11 is that there's information that may be missing, and  
12 then zero would be that that information wasn't  
13 included at all.

14           And then the person who's using the rubric  
15 would give a mark of two if it was complete, and if  
16 there was information missing, they would note a one,  
17 and then they could list their detailed description of  
18 what was missing in the document. And the idea is for  
19 us to use this to help improve our guidance, because if  
20 we're seeing reoccurring information gaps in the  
21 information provided by petitioners in the  
22 environmental reports, we can reach out and include

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1 that in our guidance.

2           Okay. So in addition to introducing our  
3 rubric during our last workshop, we also used the  
4 rubric to look at some of the early environmental  
5 reports that we received during the pilot project. Now,  
6 I have to give this caveat. The reports that we looked  
7 at, because they were some of the earlier ones that we  
8 received, didn't necessarily have the full benefit of  
9 having the guidance that we prepared during the pilot  
10 project, and so some of the information that we were  
11 looking at that was missing in those documents have --  
12 we've been seeing in documents that are coming in more  
13 recently.

14           So at the workshop in September, we used that  
15 information, and we communicated that to the workshop  
16 participants, the types of information gaps that we  
17 were seeing and places where we were looking for  
18 additional information or where there could be an  
19 improvement in the ERs. And our hope is that with very  
20 high-quality ERs that have complete information, that  
21 that will improve the efficiency of our process.

22           Okay. So the other thing that we reported on

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1 during our workshop in September were preliminary  
2 measures. Now, the pilot project at this point has  
3 been running for just about a year and a half. It will  
4 be concluding in April of 2013. So what we looked at  
5 were some of the initial information that we could get  
6 from information that we've been collecting on  
7 petitions going through the process.

8           What we did was we -- so what we did was we  
9 looked at four petitions that are going through the  
10 process that were contractor prepared and four that  
11 were prepared in-house. We also looked at four that  
12 had ERs and four that did not. Okay? And so we're  
13 comparing those for the first stage of our NEPA review.

14           In the pilot project, in collecting the  
15 information, we've actually broken the process up into  
16 three stages. The first stage is the preparation of  
17 the draft EA. So the data that I am talking about  
18 really only focuses on that timeframe in the process.

19           Next slide, please. So based on our  
20 preliminary data -- and, again, I want to emphasize  
21 this is early-stage preliminary data -- what we have  
22 found is that petitions that have an ER are completed

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1 in fewer staff hours than those without an ER. In this  
2 pilot project, what we're measuring when we're  
3 measuring time is actual APHIS staff hours. So it's  
4 not time from start to finish, it's time that APHIS  
5 staff works on the project. Okay? And so in cases  
6 where there is an ER, we have seen that there are fewer  
7 staff hours.

8           As ERs improve, and they have been, and as  
9 our guidance gets better, we're hoping that we can all  
10 work together to improve those, we would expect that  
11 the time -- the staff hours that we take, those trends  
12 would continue. So we would continue to see a decrease  
13 in staff hours associated with those petitions that  
14 have ERs.

15           However, when we were looking at contractor-  
16 prepared EAs, we did not find that there was an overall  
17 reduction in APHIS resources associated with  
18 contractor-prepared EAs. And so -- and, again, these  
19 are preliminary studies, and this is just based on the  
20 four first kind of EAs going through the process that  
21 are contractor prepared.

22           Okay. Next slide, please. So through the

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1 completion of the pilot project, we're going to  
2 continue to evaluate ERs that are submitted to the  
3 agency. We're going to use our rubric, and along the  
4 way, we'll be improving our rubric, and we'll be  
5 communicating information back to developers on the ERs  
6 that they're submitting to us now.

7           We're going to continue to provide feedback  
8 to our pilot project participants and seek feedback  
9 from our pilot project participants, because, again,  
10 what we really want to do is be able to improve our  
11 overall process. And we're going to continue to  
12 evaluate the cost and efficiency of using different  
13 methods of -- to prepare a NEPA analysis, and as we do  
14 our analysis, we're going to consider all of the  
15 potential variables that are affecting staff hours and  
16 time and cost on our projects.

17           Our intention at this point is that petitions  
18 that are still in the NEPA pilot project, that we're  
19 going to continue to collect data on those throughout  
20 the end of the project and until it completes the  
21 petition process. Some of them may extend slightly  
22 beyond the official end of the pilot project, but we

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1 want to have a robust dataset in order to do our  
2 analysis and make decisions on the outcomes of the  
3 pilot project.

4           Next slide, please. So our ultimate goal in  
5 taking on a pilot project really is to look at our NEPA  
6 analysis and how we're doing them and build them into a  
7 robust and efficient petition process. And, again,  
8 along the way, we're looking to you for feedback, so  
9 please keep giving us feedback and asking us questions,  
10 and we will continue to update our guidance and  
11 hopefully communicate with you along the way.

12           Thank you. Anyone have any questions? I  
13 feel like I...

14           MS. COLLINS: This is Susan Collins with J.R.  
15 Simplot Company. I think it's interesting that ERs  
16 save time, but contractor EAs did not. Could you share  
17 with us a little more on that?

18           MS. STANKIEWICZ GABEL: Well, what we're  
19 looking at is we're looking at total staff time that is  
20 -- that people in APHIS are working on a particular  
21 project. So when we're looking at contracting out EAs,  
22 there are additional steps that staff must take in

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1 order to do a federal contract. That's one of the  
2 things, like writing a statement of work, evaluating  
3 proposals, reviewing contract, or meetings with -- and  
4 feedback.

5           So when we're looking at it holistically,  
6 right now, we're not seeing (indiscernible) associated  
7 with that process. I do want to emphasize, though,  
8 that these are really preliminary data as we work  
9 through the -- you know, the remainder of the petitions  
10 in the pilot project, and that information, you know,  
11 may change with more data.

12           MS. COLLINS: Okay.

13           MS. HOOD: Hi, Rebecca. Aimee Hood,  
14 Monsanto. Just a comment, it would be great if the  
15 latest version of the guidance document was published  
16 as soon as possible in case the petitioner was planning  
17 to submit the ER sometime in the near future so they  
18 can reflect those changes in that ER.

19           And then we understand as well APHIS has a  
20 template that they use to populate their EAs as they're  
21 going forward. Is there -- has there been any  
22 consideration given to sharing that as well with

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1 petitioners, or can we assume that the guidance  
2 document reflects that's in that template? Just a  
3 question about, you know, the more information the  
4 petitioners have, the easier it will be for us to write  
5 an ER that will be as useful as possible.

6 MS. STANKIEWICZ GABEL: Uh-huh. And you're  
7 correct. We do have templates that we use to write our  
8 EAs, make sure that we have consistent information in  
9 our EAs and everything's organized in the same fashion  
10 from EA to EA. And the guidance document is actually  
11 based on that template outline, so we try to make sure  
12 that we're paralleling that. And as we update our  
13 template, we also need to update our guidance.

14 And your point is well-taken that the sooner  
15 we get the guidance out, the better it would be for  
16 those of you that are currently writing the ERs. In  
17 the absence of that, I can offer please call if you  
18 have any questions, and we can talk about any changes  
19 or information that we're looking for in those  
20 documents.

21 MS. ROOD: Hi, Rebecca. Tracy Rood for  
22 Pioneer DuPont. Two questions from me quick. One is

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1 do you envision the need and the desire for petitioners  
2 to submit an ER after the close of the two-year NEPA  
3 pilot project in April of 2013?

4 MS. STANKIEWICZ GABEL: Well, what we're  
5 doing in the pilot project, as both Mike and John  
6 mentioned earlier, is we're evaluating tools, and what  
7 we would like to do at the end of the pilot project is  
8 look at the various things that we've tried and things  
9 that seem to actually work, to keep them and improve  
10 upon them, and things that maybe aren't working as  
11 well, not to pursue them.

12 So based on our preliminary data, it does  
13 appear that ERs are decreasing the amount of staff time  
14 it takes to prepare an EA. And so I don't see us  
15 discouraging you from submitting them in the future.

16 MS. ROOD: And then I also wondered if you  
17 could just clarify whether the ER does or does not go  
18 out with other documents for public comment, either in  
19 the first 60-day scoping comment period or the second  
20 30-day comment period.

21 MS. STANKIEWICZ GABEL: It would go out  
22 during the second period. It is a document to support

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1 a document that we relied on to write an Environmental  
2 Assessment or other NEPA document, and so any  
3 supporting documents that are not readily available to  
4 the public, we do publish at regulations.gov. So  
5 anything that you submit to us, whether it be an ER or  
6 a report, we would put that up if it's not something  
7 you can pull right off the Web or get at your library.

8           Okay. Well, thank you. And it looks like  
9 lunch -- is lunch here? I'm sorry. I'm looking back  
10 there.

11           MR. GEORGE: Oh, well, we're right on time,  
12 and the food is here, and it's just about as beautiful  
13 as it can be. I will mention, for those of you who  
14 maybe -- if you're going to scoot, we do have some  
15 survey forms, and if you would please take a minute or  
16 two to fill one out so it may be better in the future.  
17 Also, a reminder, Steve Bennett is here, alongside the  
18 wall over there. If you need help with  
19 eAuthentication, either getting eAuthenticated or  
20 updating your eAuthentication, Steve's here to help.  
21 And we'll reconvene at one o'clock. Thanks so much.

22           (Off the record.)

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1 (Back on record.)

2 MR. GEORGE: Thank you. Thank you. One  
3 subject that we always receive questions about is  
4 ePermits. Here to answer some of those common  
5 questions and also to talk about whether and when and  
6 how ePermits will be updated are three of our staffers.  
7 They'll be coming up one at a time, starting with our  
8 Permits Branch Chief Steve Bennett, followed by Senior  
9 Biotechnologist Lee Handley, and then BRS Associate  
10 Deputy Administrator Mike Firko. Steve?

11 MR. BENNETT: Good afternoon. I hope  
12 everybody enjoyed their lunch. It's always a good  
13 opportunity for us to talk and see people that we talk  
14 to so often on the phones, but never really had a  
15 chance to meet in person. And it's good to see that  
16 some of you are real, and we're real too.

17 So what I wanted to talk about was about four  
18 or five topics that kind of generated the most calls  
19 and questions and concerns as of this past year, and  
20 I'm going to kind of group up the browser compatibility  
21 and eAuthentication kind of together, because they kind  
22 of go hand in hand. And this is in the context within

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1 ePermits, and ePermits is our electronic permitting  
2 platform that's used for submitting the BRS  
3 notifications and permits.

4           But we've had some inconsistencies with  
5 browsers. Originally, ePermits was written to operate  
6 off of Firefox and Internet Explorer, and what we've  
7 seen as recent is with Internet Explorer 9, I guess  
8 there's even different versions of ePermits that could  
9 have problems. And for users that are doing their  
10 submissions with Internet Explorer 9, if you don't have  
11 your compatibility view setting on, it's not going to  
12 allow you to submit your applications.

13           Some of the things you may see within that  
14 environment, both in ePermits and eAuthentication, is  
15 when you're signed in to eAuthentication and you're  
16 putting in your credentials, your user ID and your  
17 password, it might keep putting you through a loop  
18 process where it's not giving you access into the  
19 actual system. And what we found is it could be an  
20 incompatible browser, or it could be Internet Explorer,  
21 but version 9, which we're seeing more of now, and they  
22 don't have the appropriate settings. They don't have

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1 the compatibility view setting on.

2           But some of the, you know, off-browsers, like  
3 -- there are so many out there. It's amazing how many  
4 different browsers I've learned since I've been in this  
5 role, but, you know, things like Opera, Cyberdog,  
6 SeaMonkey, Google Chrome. You know, a lot of these  
7 browsers are just not compatible, so if you are having  
8 problems when you are trying to do things within the  
9 ePermit environment, it could be a browser issue. So,  
10 you know, I'm always available as well as the other  
11 folks here at BRS to help, you know, try to identify  
12 those problems and work through those issues.

13           Another big problem we had -- and this is  
14 probably more so for the folks that do multiyear  
15 applications -- is there was a big challenge with the  
16 eAuthentication, where they purged out all inactive  
17 accounts, so anybody that had an account that had sat  
18 for more than 400 days, their information was purged.

19           And even though they were able to go in and  
20 create new accounts, one of the problems that presented  
21 was that they no longer had access to that data of  
22 their prior submissions, which was, you know,

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1 problematic because there was a lot of data entry that  
2 went into those applications that they could now no  
3 longer support or get that information.

4           Most of that has been corrected. Folks can  
5 go into those older accounts now and access that data.  
6 But what we would strongly encourage is that if you are  
7 one of these types of users who have got these three-  
8 year permits, is that at least once a year, just log  
9 into ePermits and log out, and that will remove a lot  
10 of these challenges in trying to recreate it and get  
11 that data back to you.

12           So I do appreciate people's patience that  
13 were involved with that, and my understanding is that  
14 that has been corrected, and so if you did create an  
15 additional account, but most of your data was in an  
16 older account, you should be able to go back into that  
17 other account and get access to that information.

18           Another thing I wanted to bring up, and this  
19 really applies to the folks that are doing the XML  
20 uploads. In the event you may be doing some data  
21 management to where you may be migrating databases or  
22 you may be getting rid of one set of data -- a database

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1 and migrating some legacy data or something into a new  
2 database system. When you're doing any upcoming  
3 submissions, I really encourage that you go through and  
4 review those applications for accuracy and  
5 completeness, because what we're seeing on the backend  
6 is that when these scenarios take place, you may have  
7 data elements that are missing that you think should be  
8 on that application. There could be parsed data.

9           So we really encourage that before you go  
10 ahead and hit that certify and submit button on those  
11 XML uploads and you've had a scenario like that, that  
12 you go in and do that, because if you don't, what ends  
13 up happening is, you know, we could get hundreds of  
14 applications at a time that we go in and we do the  
15 reviews on, only to find out that we have to end up  
16 withdrawing them all and getting them resubmitted  
17 because at a later date, somebody might have found out  
18 that a lot of information was missing as a result of,  
19 you know, data migration between old and new databases.  
20 So, you know, I would pay attention, you know, work  
21 with your IT departments if that is a scenario that  
22 you're going to be challenged with or you're currently

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1 dealing with.

2           On a good note, you know, one of the things  
3 I'm doing here is doing the validation for Level II,  
4 because currently you have to be -- see somebody in  
5 person to do that, but good news is that, you know, in  
6 the near future -- I wish I had a date for you all for  
7 the meeting today, but I don't, but in the near future,  
8 there is going to be an enhancement to eAuthentication  
9 that will allow for a Level II credentialing to be done  
10 over the Internet.

11           So I don't know exactly what that looks like  
12 and feels like, but it is something that's up and  
13 coming, and that will really make it a lot easier for  
14 folks to get that Level II validation to where you  
15 don't have to go to a service center or when you're  
16 here at a stakeholder meeting or, you know, seeing  
17 somebody from USDA in person. So we're real  
18 optimistic, and we think that's going to be a big help  
19 to people, especially out in rural areas that it's more  
20 challenging to try to get assistance for that.

21           The last thing I just wanted to bring up was  
22 on import labels. We did a lot of inquiries on these,

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1 and one of the things that, you know, I want to make  
2 sure we go over is that when you're doing an  
3 application and you know you're going to need more than  
4 the traditional eight labels that we send you, on your  
5 initial input, under the "Additional Comments" field,  
6 you can request additional labels right at that time.  
7 It's not something you have to do on a backend  
8 communication, but, you know, simply request them  
9 upfront, and then when we send out that initial package  
10 of labels, you know, if you want 50, we can send you  
11 50. So that makes it a lot easier.

12           And also, we seem to get a lot of calls and  
13 emails about "How do I get additional labels?" It's  
14 real simple. Within your ePermits environment, there's  
15 a "My Shipments and Labels" field on the left-hand side  
16 at your Home box. All's you need is simply click on  
17 that link, and you can go in and request labels right  
18 through within the ePermits system. It comes directly  
19 to us. The appropriate program specialist can process  
20 that and get those labels sent out to you right away,  
21 but there's no need to call or email. It's best if you  
22 do it right within that environment within the ePermits

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1 system.

2           And one last thing about labels. For those  
3 of you who are doing applications or activities that  
4 may have other regulatory requirements, like through  
5 PPQ, if you know that you're going to be doing  
6 something that requires both our labels and theirs, if  
7 you could also communicate that to us on the front end,  
8 we could make that process for that import.

9           And this is only on imports. We could make  
10 that process a lot more streamlined if we know ahead of  
11 time, because we could match our labels up with PPQ's  
12 labels so that there's no conflicts in port of entry  
13 and issues that CBP (ph) or anybody else might be  
14 concerned with.

15           So at this time, I'm actually going to bring  
16 Lee Handley up, and he's going to talk more about some  
17 ePermits activities. And then we're going to be up  
18 here to answer questions afterwards. Lee is one of our  
19 Senior Biotechnologists.

20           MR. HANDLEY: Okay. I'm going to talk a  
21 little bit about the reporting module that I think in  
22 the last year, we've talked about. We had just

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1 launched it a little bit over a year and a half ago,  
2 and now it's fully functional. And we are getting  
3 planting reports coming in through ePermits on a  
4 regular basis now.

5 I had Linda Bardo, one of our IT specialists,  
6 run a query last week, and we're up to about 28 percent  
7 of all of our planting reports coming in through  
8 ePermits. And that's very encouraging. Of course, we  
9 would like that to be 100 percent in the future, but I  
10 know a number of the companies are currently retooling  
11 their databases to talk to ePermits so you could XML  
12 upload the planting reports.

13 One of the things that people are doing,  
14 after you submit your planting report, then you could  
15 submit your final field test report through ePermits,  
16 and there have been a couple of questions or issues  
17 that have come up. One of the things with the  
18 reporting module -- it is quite complicated, as people  
19 who've tried to submit reports have commented to us --  
20 but once you get into it and kind of get a feel for how  
21 it works, I think it's pretty straightforward, but some  
22 of the error messages can be a little bit confusing,

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1 and one of the things is that people are trying to  
2 submit their final field test reports, and they haven't  
3 accounted for every location in the permit and the  
4 notification.

5           So the way the system works is it won't let  
6 you submit your final field test report unless you've  
7 accounted for each location you've planted or not. So  
8 there's an option in ePermits to say -- if you didn't  
9 plant at a particular location, you just say "no  
10 planting." And so the system looks to see if I've got,  
11 you know, 25 locations in a notification, has that been  
12 accounted for? Then it'll let you move forward.

13           There's another issue that people are seeing  
14 on planting reports is the planting report is the  
15 planting report module lets you submit a planting -- an  
16 initial planting, and you don't have to list the  
17 constructs that you planted in that initial planting,  
18 but before the very -- before you roll everything up,  
19 you have to -- you have to submit all your constructs.

20           So, again, the final field test report,  
21 before you submit it, it will look to make sure that  
22 you have entered at least one construct per location.

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1 We're working on trying to get the error messages a  
2 little bit more clear, but those are the main issues  
3 that have come up.

4           One thing that also last year came up was  
5 what if I don't plant under a notification or a permit,  
6 and how do I close it out? And so the system now lets  
7 you submit no plantings for every location so that you  
8 could say, you know, basically, I didn't plant under  
9 this, but I need to close it out. So you say, "I  
10 didn't plant anywhere," and then the final field test  
11 report is real simple. You just submit the final field  
12 test report and put a comment, "We didn't plant under  
13 this notification permit."

14           So that lets you -- lets the system basically  
15 -- we know that you're done with it; otherwise it just  
16 sort of hangs there, and we say, "Well, did they plant?  
17 Did they not?" So we had to basically tweak the system  
18 tool down to plantings.

19           The other thing is that the XML upload test  
20 site is still available. We have a test site that's  
21 set up for you to XML -- to do test XML uploads for  
22 applications, planting reports, field test reports. We

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1 -- the contractor recently changed that so that it  
2 requires eAuthentication to do the uploads. This is a  
3 different eAuthentication account. It's not the same  
4 account that you have on the production side.

5           So I know most people already have their test  
6 site, eAuthentication IDs, but if you need one, contact  
7 us. Don't contact the ATAC or the 800 help line.  
8 They'll just get confused, and they won't know what to  
9 do. Call me, or call Steve, or call anyone on the  
10 staff. We could get the contractor to set you up with  
11 your separate eAuth account just for XML upload  
12 testing.

13           The other thing to remember is don't -- do  
14 not put CBI data on the test site. We had an incident  
15 this past year where someone accidentally uploaded a  
16 real application onto the test site, and we had to  
17 purge the data. So most everybody realizes that, you  
18 know, it is a test site.

19           And, again, we would like to encourage people  
20 to continue to use the reporting module, as I think  
21 it's been fairly successful. I think once people start  
22 using it, they discover how much they really like it. I

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1 know a couple of folks who were very trepedatious (ph)  
2 about trying to use it, and then once they did, they  
3 said, "Oh, this goes so much faster than submitting my  
4 paper." So we would encourage anyone to use it.

5 So with that, questions? No questions.  
6 Cool.

7 MR. BENNETT: All right. Since there's no  
8 questions at this time, we're going to -- I'd like to  
9 introduce Mike Firko, who's the BRS Associate Deputy  
10 Administrator, and he's going to talk about beyond  
11 ePermits.

12 DR. FIRKO: There will be life beyond  
13 ePermits. So let me start by saying that I am now, and  
14 I always have been, a very strong advocate for  
15 ePermits. It was an enormous step forward for APHIS  
16 when this was implemented in 2005, 2006. But it's  
17 2012, almost 2013 now.

18 APHIS is going to be building new electronic  
19 systems. The primary reasons are there's a new  
20 emphasis in APHIS to have APHIS-wide platforms to  
21 server our information technology needs. And we need  
22 to upgrade the technology, not only within ePermits,

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1 but in other regulatory information technology  
2 solutions that we've been using. So in terms of the  
3 system integration part, APHIS conducts a variety of  
4 different regulatory functions. We have nine systems  
5 to perform these various regulatory functions.

6           Now, within Biotechnology Regulatory  
7 Services, we only have the permitting function. We  
8 don't do certifications, accreditations, registrations,  
9 or licenses, but other parts of APHIS do those  
10 functions, and we currently have nine separate systems  
11 for those, because we have multiple systems for some of  
12 these functions. These systems don't really talk to  
13 each other, and that's a pretty costly way to do  
14 business, because in each of these nine systems, we had  
15 to write code that said, "What's your name?" In each  
16 of these nine systems, we had to write code that said,  
17 "What's your address?"

18           Now, when we first implemented these systems  
19 last decade, you know, they were steps forward. For  
20 those of you who have been in the biotechnology  
21 regulatory business for ten years or so, you remember  
22 submitting almost everything by paper or on disc or by

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1 fax. ePermits was an enormous step forward. Well,  
2 information technology is changing very quickly, and  
3 we're trying our best to keep up with changes in  
4 information technology.

5 In terms of current activity towards the goal  
6 of building new information platforms within APHIS,  
7 we're currently engaged in a business process review.  
8 It's a bit of jargon. I might fall into the BPR jargon  
9 here in a minute. I'm talking about business process  
10 review. We're examining what our needs are across  
11 APHIS for the various systems that we have. And we're  
12 examining how different do our different regulatory  
13 systems need to be?

14 As you might imagine, some of the answers  
15 we're coming up with is they don't need to be as  
16 different as they are, so this is part of the continual  
17 improvement process, the overall business process  
18 review and business process improvement that Kevin and  
19 Mike have both talked about today. We're constantly  
20 trying to improve our efficiency.

21 In terms of the technology and the fact that  
22 ePermits is old technology, we started building

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1 ePermits ten years ago, in about 2002. And the IT  
2 platform that we used was not new in 2002, so it's  
3 getting pretty long in the tooth at this point. Because  
4 the platform is old, it's difficult and expensive to  
5 maintain. Various contractors that we've worked with  
6 to help maintain our system have had trouble hiring  
7 people who are willing to work on such old systems.

8           When you hire new people in the information  
9 technology field, they want to work with the new  
10 technologies, the cool new stuff. ePermits isn't quite  
11 so cool and new anymore. And because our systems have  
12 a limited ability to share information across  
13 resources, we need to get -- need to take advantage of  
14 modern technologies where information exchange is much  
15 more of a standard operating procedure in these IT  
16 systems. We want to do less stove-piping and more  
17 intercommunication among our systems.

18           So our new permitting system will be called  
19 eFile. So in terms of next steps, we need to complete  
20 the business process review. We're pretty deeply into  
21 that process, but we have a ways to go, and we're  
22 looking at things like what are our basic processes in

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1 the various permitting programs? There are currently  
2 three different permitting programs in APHIS, and a  
3 fourth one will be coming on board pretty soon in Plant  
4 Protection and Quarantine and Veterinary Services and  
5 Biotechnology Regulatory Services, and our Animal Care  
6 program will be starting a permitting program pretty  
7 soon.

8           And we're asking questions like what are our  
9 current practices, and when they're different, which  
10 they often are, we have to ask ourselves do they need  
11 to be different? Because if you're going to build a  
12 common platform to serve the different permitting  
13 functions, you want to minimize redundancy within the  
14 system. There's a lot of redundancy within ePermits,  
15 and we want to reduce that or eliminate it.

16           So I've lost my ability to advance the slide.  
17 There we go. So when we complete the business process  
18 review of APHIS permitting, we're going to publish a  
19 statement of objectives and a request for proposal.  
20 This is -- the statement of objectives is a little bit  
21 of new jargon for us. Many of you may be familiar with  
22 the term "statement of work," where an agency goes out

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1 with a very specific set of things that they want done.  
2 With a statement of objectives, we're going to go out  
3 and say, "Here's what we're trying to accomplish. Why  
4 don't you various vendors out there give us proposals  
5 about how we can accomplish that?"

6           So after we publish the statement of  
7 objectives and we get proposals, we will award a  
8 contract to build eFile. So we've got a ways to go.  
9 I'm here talking to you about eFile today, but it's to  
10 give you plenty of advance warning that there is a new  
11 system coming.

12           So in eFile, what are our goals? As I  
13 mentioned, we certainly want to reduce existing  
14 redundancies within ePermits. Actually, since  
15 Veterinary Services has multiple different types of  
16 permits, since Plant Protection and Quarantine has  
17 multiple different types of permits, since BRS has both  
18 permits and notifications, I'm not sure I can count on  
19 both hands how many times we have lines of code that  
20 say, "What is your name?" and "What is your address?"  
21 We want to do that once, not only within our permitting  
22 system, but across the various permitting

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1 certification, accreditation, and licensing  
2 applications.

3           So we're definitely moving towards a more  
4 efficient system. This will increase APHIS efficiency.  
5 Part of the BRS -- part of the business process review  
6 that I mentioned has to do with looking at our own  
7 internal processes, and just like we did with the  
8 business process improvement for petitions, we're doing  
9 some of that for permitting. We're asking ourselves  
10 for every step that we do in our permitting process,  
11 why are we doing that, and do we need to continue doing  
12 it, with the intent of being much more efficient in our  
13 permitting and notification process.

14           It's really expensive to maintain ePermits.  
15 Because the technology is old, it's based on an old  
16 platform, and it's difficult to find people who  
17 understand it and can work on it, it's expensive. Many  
18 of you have heard that we are not investing in  
19 development, modernization, and enhancements, DME, for  
20 ePermits, and that's because we've made a commitment to  
21 build a new system. So when you've made a system --  
22 when you've made a commitment to build a new system, it

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1 doesn't make a lot of sense to spend a lot of your  
2 money on enhancing the system that's on the way out.

3           We had a very active operations and  
4 maintenance budget for ePermits, so we're constantly  
5 working on keeping ePermits going, but it's expensive.  
6 We need to move to a new platform that is more cost-  
7 efficient. And I want to assure you that, just as we  
8 did about eight years ago, at some point during the  
9 build of eFile, we will invite all of you to come here  
10 to Riverdale, look at the work that we've done so far  
11 on eFile. We want to do that after we've done enough  
12 work so that we have something to show you, but before  
13 we're done with the thing, because what we've found --  
14 and, Adrienne, I think you were at this meeting eight  
15 years ago, weren't you, when we were doing ePermits?

16           MS. MASSEY: No.

17           DR. FIRKO: No? What we found when we had  
18 stakeholders come in to look at the development system  
19 is we got a lot of really good input from folks, folks  
20 who raised their hand and said, "You know, if I could  
21 do A, B, and C, you know, that would be good for me,  
22 and it would be good for you," so we will definitely be

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1 inviting folks to come in partway through the build  
2 process of eFile to show them what we've got and ask  
3 them for input about how we could improve. Thank you.  
4 Questions? Oh, did I miss -- yeah.

5 I should add that last little note down  
6 there. When -- we've already done some market research,  
7 if you can characterize the phase that we're in now as  
8 market research. We're looking at what's out there,  
9 and when we did our initial market research on this and  
10 we asked companies to come in and give us input, one of  
11 the things we asked anybody who was interested is  
12 "Could you do some build around XML downloads?" And  
13 virtually every single one of them said, "Yeah, no  
14 problem. We can do that."

15 So I know that's something that's very  
16 important to most of the folks out there who deal with  
17 ePermits. We will continue to have it be part of our  
18 requirements for eFile. Any questions?

19 MR. GEORGE: Thank you, Mike. Okay. Here to  
20 talk about successes in our compliance program as a  
21 result of stakeholder teamwork are Western Compliance  
22 Assurance Branch Chief Doug Grant, and he'll be

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1 followed by Compliance Assistance (sic) Branch Chief  
2 Samantha Simon. Doug, you're on.

3 MR. GRANT: All right. Thank you. Okay.  
4 Thanks, Dick. Well, thanks, everyone, for showing up  
5 today. I'm from Fort Collins, Colorado, so for any of  
6 you that traveled in from places west of the East Coast  
7 time zone, I'm with you on feeling the after-lunch  
8 effects of the jet lag.

9 So I'm with the Compliance Assurance Branch  
10 in the Western Region, and my counterpart, Wendy Jin,  
11 is not able to be with us today, but she did help put  
12 together this slideshow presentation, and she is  
13 located out of the office in Raleigh, North Carolina.  
14 So the Compliance Assurance branches are essentially  
15 those branches that deal with verifying adherence to  
16 regulatory requirements, including standard and  
17 supplemental permit conditions, design protocols, and  
18 then with notifications, of course, that would be  
19 performance standards.

20 So we take the information that is submitted  
21 in planting reports, and then we use that information  
22 to figure out what needs to be inspected. So your

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1 planting reports are critical to us. We don't work on  
2 trying to inspect anything that we haven't received a  
3 planting report for, because, as Mike indicated  
4 earlier, we authorized a lot more sites than end up  
5 actually being planted.

6           So one of the things that we've done to sort  
7 of improve our efficiency is to make sure that we don't  
8 have a lot of cancellations. And cancellations can  
9 occur for various reasons. Most of the time, when they  
10 occur, it's because we receive the planting report, and  
11 then in the process of getting that information  
12 compiled into our database, selecting a site for an  
13 inspection, sending that request out to the State Plant  
14 Health Director who works for Plant Protection and  
15 Quarantine, then that gets assigned to an inspecting  
16 officer, and that officer contacts the operator, the  
17 trial has been terminated or harvested already.

18           So there ends up being a whole lot of work  
19 that goes into that process, and we don't end up with  
20 an inspection to verify those regulatory requirements  
21 have been met, so we want to try to minimize those, and  
22 we've been doing a much better job of that over the

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1 last few years by taking that information that comes in  
2 those planting reports and trying to deal with it in  
3 realtime so we're not delayed by weeks or months from  
4 the time we get the planting report until we request  
5 that inspection.

6           Now, there are other times when a  
7 deregulation occurs, and, you know, sometimes those hit  
8 in the middle of the growing season or after some  
9 things have been planted, so there are some times when  
10 things get cancelled because we got planting reports,  
11 and those planting reports were correctly submitted.  
12 The material was regulated at that time, and then  
13 through the petition process, something has achieved  
14 non- regulated status, and, therefore, there's no  
15 longer any APHIS oversight, so we don't -- we don't  
16 want to complete those inspections, so we cancel them.

17           We can get those planting reports, as has  
18 been mentioned, in a number of formats. They could be  
19 submitted by email to the compliance inbox. They can  
20 be submitted directly into ePermits through XML  
21 uploads. And that's our preferred method of receiving  
22 them. And then some folks were still submitting them

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1 via hard copy. And we understand that that is  
2 necessary for -- some organizations don't have the  
3 infrastructure to allow them to put it into an XML  
4 format, but we really would like to encourage folks to  
5 try to move in that direction.

6           So this slide just shows the number of  
7 planting reports that we received in FY12. There are  
8 about 400 total planting reports received, and the  
9 industry reports are represented in the blue on this  
10 graph, and then the academics are represented in the  
11 green. And what we can see is, you know, the majority  
12 are coming in in electronic format. There aren't that  
13 many coming in in hard copy. And we have, you know, a  
14 number coming in through ePermits, and we're just  
15 trying to encourage people to -- let's keep this trend  
16 moving in this direction from right to left across this  
17 screen.

18           This slide looks at the number of different  
19 organizations submitting planting reports, and,  
20 actually, the colors have been reversed. So looking at  
21 industry, we're receiving, you know -- over 20  
22 companies are submitting planting reports through

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1 ePermits, and over 15 academic institutions, and about  
2 34 in total through the ePermits -- I'm sorry, through  
3 the compliance inbox.

4           So these are just to illustrate that we do  
5 get a variety of planting reports from different  
6 organizations, and most of those planting reports are  
7 going to contain a lot of information. They may  
8 contain information on a dozen or more different  
9 notifications or permits. So it depends on the  
10 organization, though. It might be a university, and  
11 they only have one permit, and so we would get a  
12 planting report for that.

13           I'm going to try to move through these slides  
14 pretty quick to save time for questions, but I just  
15 wanted to give people some idea of what we're getting  
16 in terms of planting reports. So then looking at  
17 notifications, we can see that we had a similar number  
18 of authorized sites in FY12, as we did in FY11, and  
19 kind of a similar number planted. So we went down a  
20 little bit. It's about 25 percent of the notification  
21 sites that we've authorized have actually -- end up  
22 getting planted, and of those, we don't inspect every

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1 notification (indiscernible) that's planted out there,  
2 not by a long shot, because we don't have the resources  
3 to inspect every location that's planted out there, and  
4 our notifications are our lower-risk category of field  
5 trials.

6           So what we can see is that we have maintained  
7 sort of a consistency in terms of the percentage of  
8 sites that actually end up getting inspected, and at  
9 some of these sites, there may be multiple plantings  
10 that have occurred during a growing season. So that's  
11 going to be, you know, a similar number that we're  
12 going to see, again, in FY13. It's not going to change  
13 drastically, but we will be continuing to have a higher  
14 number of inspections than we did five or six years  
15 ago, so we'll probably be looking at, you know, close  
16 to 700 inspections, again, in FY13.

17           Now, looking at permits, we have a higher  
18 number of sites planted in terms of percentage of those  
19 authorized. So we actually have a pretty good uptick  
20 in the number of sites authorized in FY12 versus FY11,  
21 from 1,600 up to 2,700, an increase in the number of  
22 actual sites planted, from 864 to 1,160, and then,

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1 looking at that on a percentage basis, we can see that,  
2 you know, it's roughly half, a little bit less than  
3 half of the sites that are authorized end up being  
4 planted.

5           Now, there may be various reasons for us  
6 seeing a higher percentage of those authorized sites  
7 planted under permit than notification in that this is,  
8 you know, a little bit more work to get that  
9 authorization under a permit than it is for a  
10 notification, and oftentimes permits include a number  
11 of constructs, a great number of different sites, and  
12 so companies generally know that this is going to get  
13 planted, whereas under a notification, you know, a lot  
14 of times there's -- as Lee had indicated, there ends up  
15 being no plantings under a given notification, but  
16 under permit, people know this is what we're going to  
17 do, so it gets put in the ground.

18           So then in terms of the percent inspected,  
19 about a third of the permit sites were inspected in  
20 FY12, and that reflects not only things that were new  
21 authorizations in terms of annual plants that would  
22 have been planted, you know, corn and soybeans and

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1 cotton, but also we have multiyear trials. Okay. So  
2 these may have been things that had been authorized in  
3 2010 or 2011, and those multiyear permits are  
4 authorized for three years, and then they can be  
5 renewed, in a sense, by getting a new permit that will  
6 continue to cover that authorization.

7           So for perennials like trees or alfalfa or  
8 switchgrass or things like that, they get put in the  
9 ground, they stay in the ground for multiple years, but  
10 we still are going to go out there and inspect them on  
11 a fairly regular basis, and I'll get to a little bit  
12 more about how we do that.

13           So in terms of your planting reports, you  
14 know, you all are pretty aware of this, but we do need  
15 to make sure to get all the notifications and permit  
16 numbers on there of what has been planted. We want to  
17 know what species, the planting date, the planting  
18 location, unique location IDs, and then we need to get  
19 that acreage. And those are things that help us make  
20 sure that things are being done in compliance with  
21 regulatory requirements, because obviously if you have  
22 an authorization period, you have an allowable acreage.

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1           And then we're going to go out and do some  
2 inspections based on that planting report information.  
3 So we did complete 679 inspections in FY12. That's out  
4 of 731 inspections that we requested, so about 50  
5 cancellations, and, as I mentioned, those can be for  
6 various reasons. We had 327 in the Eastern U.S. and  
7 then 352 in the Western U.S., so for all of us  
8 Westerners, we won. But it's generally a fairly even  
9 number. We actually do make efforts to try to make  
10 sure that those numbers are fairly even between Eastern  
11 and the Western across the course of the fiscal year.

12           So just a little bit about how do we select  
13 inspections. It's interesting in that we had developed  
14 a system that's moved away from an algorithm that had a  
15 whole bunch of variables in it that were sometimes hard  
16 to populate, because we didn't always have that data  
17 available, to a randomly selected system for  
18 notifications.

19           So when we get your planning report, your  
20 notification has an equal chance of being selected for  
21 inspection as the same notification from any other  
22 regulated entity, whether it's a small college that has

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1 one notification, or whether it's a big company that  
2 has many.

3           And then once we select that notification for  
4 inspection, then we try to determine which site or  
5 sites should be inspected that have been planted under  
6 that notification. The majority of the inspections  
7 occur during the growing season, so we are really busy,  
8 you know, from April through September in terms of the  
9 inspection side. We have increased the number of --  
10 the frequency of inspections in the winter nursery  
11 location.

12           So in Hawaii and Puerto Rico, we have higher  
13 frequency of inspection than we do in the continental  
14 U.S., and with permits, our policy -- I don't have that  
15 slide up yet -- the bullet is to do at least one  
16 inspection per state of release per year. So if a  
17 permit is planted in five different states, if there's  
18 ten sites in one state and one site in another, that  
19 one site for sure is going to get inspected in  
20 Nebraska, where it's the only site. Out of those ten  
21 sites planted in Missouri, we will maybe only inspect  
22 one, we may inspect more, but at least five inspections

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1 are going to come from that permit, because it's been  
2 planted in five states. So hopefully that makes sense.

3           Then with the formal industrial permits, we  
4 consider those to be our highest-risk type of  
5 authorization, and therefore those are inspected with a  
6 much higher frequency, where we actually inspect every  
7 trial site that's out there, and they're inspected  
8 multiple times, so they're inspected five times during  
9 the growing season for an annual plant, followed by two  
10 times the next year, which are considered post-harvest  
11 inspections, and then for perennials, we will inspect  
12 each location at least once per year.

13           So moving forward in FY13, we want to just  
14 encourage people to submit those planting reports via  
15 ePermits as much as possible until we move to eFile, as  
16 Dr. Firko just mentioned, and then when that happens,  
17 please continue to submit them electronically, right?  
18 And even if you don't submit them with an XML upload,  
19 if you can submit them in an Excel spreadsheet format,  
20 we can create macros that'll then take the data that  
21 you've submitted and put it into our system so that we  
22 have consistency that way. And there is guidance -- if

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1 you're submitting them to the compliance inbox in an  
2 Excel format, there is guidance in the BRS Notification  
3 User's Guide on Page 43.

4           And if you're amending a planting report,  
5 you've added a new site, you've changed acreage at a  
6 different site, and then you're submitting that  
7 planting report based on an amended permit, or you're  
8 adding more plantings that have occurred under a given  
9 notification or permit, please be specific when you  
10 submit that updated or amended planting report to let  
11 us know what's changed. That's very helpful for us.

12           So one of the things that we're looking at  
13 doing for FY13 that's a little bit of a change is  
14 increasing the number of post-harvest inspections, and  
15 this is basically to hopefully make sure that we're  
16 checking on people even if we did call to schedule that  
17 inspection and it turned out that it had already been  
18 harvested or terminated. So we do want to still check  
19 to make sure the reporting requirements are being met  
20 in terms of looking at those post-harvest field  
21 operations, storage, shipping, handling,  
22 devitalization, and disposal of regulated material

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1 that's been harvested, and then also making sure that  
2 people are all set up to do the volunteer monitoring  
3 that they have specified in their design protocols, and  
4 some of these may even occur in the following growing  
5 season, and they should have conducted that volunteer  
6 monitoring, or started it, and checking to see how  
7 that's going.

8           Most of the inspections, as has been  
9 mentioned, are conducted by PPQ, and they are going  
10 through a reorganization right now, but that's really  
11 not going to impact anything in terms of the  
12 relationship between BRS and PPQ or anything with  
13 biotech inspections. We in BRS are the ones who train  
14 the PPQ officers that do those biotech inspections, so  
15 if you have questions about something that you got  
16 asked by an inspector or issues related to a compliance  
17 inspection that's for biotech, feel free to call us in  
18 BRS, and we'll do our best to bridge that gap between  
19 you and the inspecting officer.

20           As has been mentioned, the total number of  
21 inspections will be similar to what we have in FY12,  
22 and we're actually working to improve our inspection

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1 worksheets, and this is sort of a continual process,  
2 but we do have specific guidance for all the questions  
3 on the worksheets for the officers, and something we're  
4 really looking forward to in calendar year 2013 is  
5 actually making these worksheets, the questions on  
6 those worksheets, available to the public via the BRS  
7 website.

8           This has been something that we've been  
9 talking about some time -- for some time, but it's been  
10 kind of difficult to get traction, but we're going to  
11 push really hard to make sure that this gets done in  
12 2013. And then that's going to really help us as part  
13 of our transparency to make sure that the regulated  
14 community knows what we're looking for, that the people  
15 who are doing the inspections know what they're looking  
16 for and that everybody's on the same page.

17           So with that, I will hand it off to Sam Simon  
18 and answer any questions in the interim. And here's  
19 the contact information for myself and Wendy Jin, as I  
20 mentioned, my counterpart (indiscernible). So please  
21 feel free to call us or email us at any time if you  
22 have any questions. So any questions for me before I

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1 hand it over to Sam? Okay. Thank you very much.

2 MS. SIMON: Good afternoon. So I'd like to  
3 start by telling you about a achievement that BRS had  
4 on November 7th. The Office of Compliance Assistance  
5 was recognized for operating a quality management  
6 system that complies with the requirements of ISO 9001  
7 2008. And the scope of OCA's recognition is limited to  
8 the Biotechnology Quality Management System program and  
9 the compliance assistance services that are provided  
10 through it.

11 This was a long-term goal for BRS and a  
12 accomplishment -- a big accomplishment for OCA. We  
13 spent a year getting our quality management system in  
14 place, and our audit actually occurred on Wednesday  
15 while Hurricane Sandy was visiting the East Coast. The  
16 BQMS program, we continued that to provide compliance  
17 assistance services to the program during 2012. As was  
18 mentioned earlier, we now have 22 participants in the  
19 program. Nineteen of those participants have achieved  
20 a recognized BQMS, and two of the remaining three are  
21 working to implement their BQMS and achieve the  
22 recognition, while one has placed their process on

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1 hold. A list of all participants -- the recognized  
2 participants is available on the BRS website.

3           During 2012, the third-party audits  
4 identified very few non-compliances, and overall, the  
5 audits confirmed that the participants are maintaining  
6 and continually improving their individual BQMS. It's  
7 important to note that approximately 85 percent of all  
8 release sites and 92 percent of all release acreages  
9 authorized by BRS during fiscal year 2012 via issued  
10 permits or acknowledged notifications were within the  
11 scope of a BQMS managed by the 19 recognized  
12 organizations. And that's a significant  
13 accomplishment, but there's still an opportunity to  
14 increase those percentages, one that we're looking  
15 forward to.

16           Also during 2012, BRS continued its  
17 partnership with the Excellence Stewardship. Under the  
18 ETS BQMS Memorandum of Understanding, five third-party  
19 audits were conducted for the BQMS at no expense to the  
20 agency. And with the current budget climate, that was  
21 very helpful, because it helped us focus our resources  
22 on other compliance assistance opportunities.

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1           The partnership has also resulted in a  
2 combined BQMS ETS auditor training class that we're  
3 going to be holding next week in Kansas City. We've  
4 received a significant amount of interest in the class  
5 from both internal auditors from participating  
6 organizations and from third-party auditors. So once  
7 third-party auditors are trained and have successfully  
8 completed the training, they'll be able to be selected  
9 for future third-party audits, so that gives our BQMS  
10 participants greater variety.

11           Over the past year, BRS released two new  
12 compliance assistance tools. They are the templates  
13 for the permit and notification design protocols. These  
14 templates are available on the BRS website as well.  
15 You'll see them on the Environmental Risk Assessment  
16 program website for permits and notifications. These  
17 templates can be used for the development of standard  
18 operating procedures for the induction of regulated  
19 articles.

20           They address the operational controls for the  
21 movement and environmental release processes, and while  
22 they do address BQMS program standard Clause 7 for the

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1 planning and process realization, an organization  
2 doesn't have to have a BQMS to use the templates. In  
3 fact, we're encouraging all organizations to use them.

4           Once completed, the resulting SOP can be  
5 submitted with the -- with the applicable information  
6 within ePermits' fields to address containment,  
7 confinement, and safeguarding protocols. In addition,  
8 they can be submitted to the Environmental Risk  
9 Assessment program for review prior to submitting an  
10 application.

11           So the templates are really intended to  
12 facilitate the notification of permitting process in  
13 compliance with regulations, and they also further  
14 explain the link between the BQMS program standard and  
15 the regulations.

16           New in fiscal year 2012, BRS worked to  
17 develop an educational workshop, which was focused  
18 towards (indiscernible) and public researchers. We  
19 worked diligently to find five universities that were  
20 willing to host the workshops, and the five  
21 universities were Arizona State University, the  
22 Universities of Missouri and Florida, North Carolina

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1 A&T State University, and SUNY (ph) .

2 Overall, there were approximately 132  
3 participants at the five workshops. The primary  
4 objectives of the workshop were to increase the  
5 participant's knowledge about the risk assessment  
6 application process and the compliance inspections and  
7 enforcement processes to understand the regulatory  
8 differences between permits and notifications and  
9 introduce them to the available compliance assistance  
10 opportunities.

11 Based on the positive feedback from  
12 participants, we believe that we achieved the goals and  
13 that the workshops were beneficial. We had numerous  
14 questions during the workshops, and we worked over the  
15 past few months to try to see if there were any trends  
16 in those questions. And what we found were that the  
17 most frequently asked questions were about the  
18 application process and ePermits and the compliance,  
19 how to maintain compliance with the regulations; also  
20 the compliance inspection process and then compliance  
21 and enforcement actions.

22 So for fiscal year 2012, in terms of

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1 compliance assistance activities, it looks like we're  
2 going to be just as busy, and BRS will continue to  
3 focus on compliance assistance services through the  
4 BQMS and additional workshops. We're already accepted  
5 a new participant into the BQMS program and hope to  
6 accept more by the end of the fiscal year, and we'd  
7 like to see an increase in the percentages of release  
8 sites and acreages managed (indiscernible) BQMS.

9           We're currently at the beginning stages of  
10 improving the educational workshop based on the  
11 questions that were asked and feedback from  
12 participants and the presenters, and we're also in the  
13 process of determining who will host the workshops this  
14 year. So if you know anybody, please give us names.

15           And, finally, we're going to be assembling  
16 and analyzing data to determine the success of the BQMS  
17 program. The original intended outcome of the BQMS  
18 program was to improve the management of the  
19 organization's domestic research and development of  
20 regulated genetically engineered organisms. And we're  
21 now three full years into the program. That should  
22 give us enough data to determine if we're meeting this

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1 outcome.

2           We also want to determine if there are trends  
3 in the data that will help provide us with some  
4 direction. Where can we better assist the regulated  
5 community? What methods work best to disseminate  
6 information? Are there other methods that we can use  
7 to disseminate the information? And what additional  
8 tools are needed? And, of course, your input to these  
9 questions is always helpful.

10           And with that, are there any questions? Yes?

11           MALE SPEAKER: A question concerning the  
12 people at your public institutions and educational  
13 workshops. Were they scientists, generally, or  
14 (indiscernible) people or administrative? What kinds  
15 of people were actually at these meetings?

16           MS. SIMON: Primarily, they were the  
17 principal investigators. We did have some of like the  
18 field -- the managers for the fields and also the IBC,  
19 the Institutional Biosafety Committees. Yes?

20           FEMALE SPEAKER: It's a similar question. Of  
21 the 132 attendees, were all of those from either  
22 academic institutions or government sector?

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1 MS. SIMON: The majority of them were. We  
2 did have a few of our recognized BQMS program  
3 participants that attended, but most of them were from  
4 an academic circle.

5 FEMALE SPEAKER: And even though I can look  
6 it up on the Web, I'm lazy. Of the 22 participants in  
7 BQMS, how many of those are active in the public  
8 sector?

9 MS. SIMON: That's the one number I didn't  
10 write down. Thanks for asking.

11 FEMALE SPEAKER: I'll look it up. I'll look  
12 it up.

13 MS. SIMON: That's okay. I believe that  
14 there are four. Anyone else? All right. Thank you.

15 MR. GEORGE: Thank you, Sam. Appreciate  
16 that. Okay. I'm going to ask you to indulge me just  
17 for a second. I'm looking around the room. I'm seeing  
18 something called the pasta effect. So I'm going to ask  
19 everybody to please stand up. Everybody just stand up.  
20 Just stand up. Okay. All right. Let's stretch a  
21 little bit. Stretch those arms, shake those legs out.  
22 A couple -- cleansing breath. In, out, yes, indeed.

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1 Stretch it out, very good. Okay. All righty. Well,  
2 let's get on with it.

3           So I told you this morning we'd be going from  
4 a very broad perspective and getting more and more  
5 detailed as the day went on, and here now to talk about  
6 some of the fine points of notifications and permits  
7 and design protocols, with an emphasis on the most  
8 common mistakes and the most commonly asked questions  
9 is Branch Chief Susan Koehler. Susan?

10           MS. KOEHLER: Well, I know you guys are all  
11 thirsty back there, and we wouldn't want to break that  
12 up. And I'm not sure how this happened, but how I got  
13 selected to be in the last slot before the break, but I  
14 guess the always save the best until last, and I'll try  
15 to do my best. Can everybody hear me okay in the back?  
16 Okay, good.

17           As Dick mentioned, I'm going to be covering  
18 pretty much the nuts and bolts of notifications and  
19 permits and design protocols emphasizing, you know, the  
20 differences and similarities between the requirements  
21 of those processes and also common mistakes or issues  
22 or questions that occur by applicants in that process.

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1 So -- is this working properly?

2 MR. GEORGE: Yeah, it is. Just keep talking.

3 It's

4 MS. KOEHLER: Okay. So as you know,  
5 notifications are a more streamlined and quicker  
6 process for introductions of genetically engineered  
7 plants (indiscernible) by the genetic constructs that  
8 (indiscernible) meet the eligibility criteria outlined  
9 in our notification regulations that are designed to  
10 reduce the risk potential.

11 These can be conducted according to  
12 performance standards or outlined in the regulations  
13 that are designed to achieve confinement and also the  
14 design protocols are then attached to the folder for  
15 notifications, compared to permits, where they're  
16 entered directly into the permit application itself.  
17 Permits are used only for plants that would otherwise  
18 not meet the eligibility criteria for multiyear  
19 permits; also for microorganisms and other regulated  
20 particles that are not plants.

21 The confinement details, again, are described  
22 directly in the permit application itself, and Doug

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1 already mentioned the differences in the inspections  
2 for notifications and the permits, so I won't go over  
3 that. And the types of reports that are submitted are  
4 pretty much the same, except for the release permits  
5 also include a volunteer monitoring report requirement,  
6 and also for multiyear reports, they would require an  
7 annual report be submitted.

8           Since a lot of the issues regarding  
9 notifications, why notifications might be denied, had  
10 to do with the notification criteria, I'd like to walk  
11 through those notification criteria. The first --  
12 there are six notification criteria, and the first has  
13 to do with the regulated plant itself. The regulated  
14 plant cannot be a noxious weed or considered a weed in  
15 the area of release. Obviously, the most common crops  
16 are not considered weeds, but if there's any question  
17 that the plant species that you're working with could  
18 be considered a weed in the area of release, you should  
19 contact (indiscernible) early in the application  
20 process.

21           The introduced genetic material has to be  
22 stably integrated. That means it could be integrated

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1 into the nuclear genome, chloroplast genome, or the  
2 mitochondrial genome. And the factors that can  
3 mobilize or replicate would not be considered to be  
4 staple transformation, and crosses that are designed to  
5 mobilize, alter, or replicate stably integrated cloned  
6 genetic material are also not eligible for notification  
7 unless those constructs are inserted in a very stable  
8 form.

9           The function in the plant has to be known,  
10 and that can be determined either by empirical  
11 observation or (indiscernible) sequence similarities to  
12 sequences whose function hasn't been demonstrated.  
13 This would exclude uncharacterized sequences that might  
14 just be, for example, isolated (indiscernible) some  
15 external stimulus, response to a chemical or some other  
16 environmental stimuli.

17           The genetic material cannot produce an  
18 infectious entity. It can't (indiscernible) likely to  
19 be toxic to non-target organisms (indiscernible) or  
20 encode products that are intended for pharmaceutical,  
21 industrial, or product remediation. So if the genetic  
22 sequence would encode a complete virus, then obviously

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1 it would be not eligible under notification.

2           Also, expressing products that require  
3 approvals by FDA or from APHIS as animal or human drugs  
4 or veterinary biologics would be excluded, as would  
5 products intended for non-food, non-feed industrial use  
6 that are new to the plant and not commonly found in  
7 food or feed.

8           The eligibility criteria also include  
9 restrictions on certain sequences from plant viruses.  
10 These restrictions were designed to prevent the  
11 creation of new plant viruses and minimize risk from  
12 certain virus sequences.

13           So plant virus-derived sequences have to be  
14 either non-coding regulatory sequences with known  
15 function, or they have to be from viruses that are  
16 prevalent and endemic where the introduction occurs and  
17 that normally infect the regulated plant species and  
18 don't encode a functional (indiscernible) movement  
19 protein. These proteins have been demonstrated to  
20 facilitate long-distance cell-to-cell movement in a  
21 plant and -- movement of viruses in the plant, and so  
22 we want to minimize the potential for that to occur.

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1 They can't include donor sequences from human or animal  
2 pathogens that are viruses or that are likely to cause  
3 disease in animal or humans.

4           The genetic information requirements are  
5 pretty much the same for both permits and  
6 notifications. The component, type, and name should be  
7 clearly given, and it's important to put -- like the  
8 genes of interest that you're introducing should be  
9 under gene of interests. Component type, if it's a --  
10 if it's a gene-silencing construct, it should be listed  
11 under gene silencer type of component. If it's a  
12 marker gene, put it under that. If -- don't mix them  
13 up.

14           If you need to include a short, descriptive  
15 name for each type of component you have, and you  
16 should only use common abbreviations, and if an  
17 abbreviation is used, there should be a brief  
18 description of what it stands for or encodes.

19           Remember, we review thousands of constructs  
20 every year, so (indiscernible) we have a certain number  
21 of turnover in biotechs, and not everybody is an expert  
22 in everything, so just -- don't assume just because

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1 it's your favorite gene, that everybody's going to know  
2 what it means. You need to include some information  
3 about that.

4           Also, with respect to the donor organism, the  
5 complete scientific name should be used. That includes  
6 (indiscernible) species, and if you have a bacterium,  
7 it should also typically include the strain. It's  
8 important to use the drop-down menu. This helps to  
9 avoid spelling errors. If you don't find it in the  
10 drop-down menu, of course, you can always enter it  
11 directly.

12           If the donor is strictly -- if the gene is  
13 strictly synthetic, if it was derived purely by  
14 synthetic means and it's not based on a donor sequence  
15 as described in the literature, then it's appropriate  
16 to use the term "synthetic" as a donor organism. If  
17 gene shuffling is used, then all the potential or known  
18 donors should be included on the application.

19           So some of the common mistakes that we see  
20 and that might require that your notification be  
21 rejected or denied or that different genetic components  
22 are used -- or there's the same name that's given for

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1 each of those, and so if you're using different -- if  
2 you have identical components, that's fine, but  
3 otherwise if there's a modification to the native gene  
4 sequence, if you've changed the amino acid sequence or  
5 there's deletions, you should describe those, but use a  
6 different name for that, to describe that.

7           Sometimes common names are used as donor  
8 organisms. Obviously, that's not allowed. If it's a  
9 virus, the full virus name should be given, not just  
10 the abbreviation. And sometimes not all the genetic  
11 components have their donors listed. This is often a  
12 problem when people are not really very familiar with  
13 the factor that -- the sequences and the base factor  
14 that we're using. Selectable markers are often  
15 amended. Now, sometimes silencing constructs include  
16 both the sense and the anti-sense component, and then  
17 donors for those (indiscernible) donor for that, so  
18 make sure that all of those are included in those  
19 silencing constructs.

20           Also, some virus sequences don't meet the  
21 criteria included in notifications. A common mistake  
22 is that plant virus sequences are from viruses that

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1 either are not prevalent or endemic in the area of  
2 release or they are from viruses that just don't infect  
3 the regulated plant species. And a quick way you can  
4 check that is you can go to plant viruses online, and  
5 it gives you information on the typical host for a  
6 given plant virus. It's a very nice resource of  
7 information.

8           Another common mistake is that small  
9 sequences that are used for tandem affinity  
10 purification tags, these so-called TAP tags, often have  
11 sequences that are derived from animal or human  
12 viruses, including some insect viruses, and so those  
13 would need to come under permits, unfortunately.

14           Some other common questions we get have to do  
15 with perennial plants, can a genetically engineered  
16 perennial come under notification, and the answer to  
17 that would be yes, if, in fact, it meets the other  
18 eligibility criteria, it's not a weed in the area of  
19 release, and the release is terminated in one year or  
20 less.

21           There are other instances where a particular  
22 release that might otherwise qualify for notification

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1 may be required to come under permit. I've given some  
2 examples here. One of those is sorghum. We've been  
3 asking that those releases come under permit because  
4 sorghum can hybridize, really, Johnson grass, which is  
5 a noxious weed, and also can hybridize with  
6 Shattercane, and these species can be pollinated by  
7 wind, and the weeds are quite prevalent in some areas,  
8 so we want to make sure that we have appropriate  
9 isolation instances and monitoring post-season to make  
10 sure that gene flow doesn't occur, especially when we  
11 have herbicide tolerance transgenes you could use as  
12 selectable markers and genes of interest in those  
13 plants. We don't want to be transferring those to  
14 really bad weed populations and then having those  
15 relatives serve as a reservoir for future gene flow.

16 Camelina is another situation where the plant  
17 itself is considered weedy in some places and can also  
18 hybridize with weedy relatives. In some areas, there's  
19 at least three different species or subspecies that it  
20 can hybridize with, so we've asked those to come in  
21 under permit as well.

22 If you have any questions about where some of

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1 these wild relatives or sexually compatible species  
2 exist, you can always contact our staff, and we can try  
3 to help you out with that. The other situation is for  
4 large acreage releases for a given construct, that this  
5 typically occurs when scaling up in anticipation of  
6 deregulation. And these can involve oftentimes many  
7 sites and many cooperators, so there's a need for more  
8 regulatory oversight and management plans in place that  
9 ensure that there's appropriate communication between  
10 the applicant and the cooperators. And these often  
11 also involve a lot of amendments, because you have a  
12 lot of sites and not a lot of cooperators, and so this  
13 is much more readily done under permit.

14           Yeah. Did I do something wrong there? Okay.  
15 Next I'm going to focus on the performance standards.  
16 As I mentioned, notifications have to be conducted in  
17 such a way as to meet the performance standards and the  
18 regulations to maintain confinement or containment and  
19 identity of the regulated material, and design  
20 protocols can be attached directly any permits and  
21 should address each one of six performance standards  
22 that are required with the notification.

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1           The first of those has to do with maintaining  
2 appropriate shipment protocols so that the material is  
3 not disseminated during transit. So there should be an  
4 adequate description of how that material is packaged  
5 and labeled and stored during the transit process.

6           The second performance standard has to do  
7 with preventing inadvertent mixing of regulated  
8 material and during environmental release so that it's  
9 completely been segregated from non-regulated material.  
10 This involves describing planting and harvesting  
11 protocols, including separation from non-regulated  
12 plants, protocols for planting equipment, which is  
13 really one of the most important things. All right.

14           Doug's shaking his head. Yes, definitely.  
15 Equipment cleaning is so important. I don't know how  
16 much more we can stress that. So if you're using  
17 research-type equipment, you know, the protocol should  
18 be appropriate to that, but if you're using more large-  
19 scale type equipment, you really need to go through and  
20 describe those protocols very carefully. Describe how  
21 any seed or fruit produced would be kept on the food  
22 and feed supply. That's also important.

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1           The next performance standard has to do with  
2 maintaining identity and devitalization. The identity  
3 of the regulated materials must be known while it's in  
4 use, and it must be devitalized when it's no longer in  
5 use. So you need to describe how the labels are going  
6 to be applied throughout the process of using that  
7 material and packaging methods to identify the release  
8 site. This could be through the use of flags or field  
9 markers, recording the GPS coordinates, or other  
10 barriers or buffers that could be used to distinguish  
11 the site, and methods to devitalize and regulate  
12 material after use, autoclaving, burning, burial,  
13 whatever.

14           The next one is making sure that any viable  
15 vector agent is eliminated, and this is really only an  
16 issue with -- mostly with clonally propagated crops  
17 when an agrobacterium is used as a transformation  
18 vector, and typically you just need to indicate how  
19 those materials are treated with antibiotics to make  
20 sure that those are no longer associated with  
21 transgenic plants.

22           Performance standard five refers to making

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1 sure that the transgenic crop itself does not persist  
2 in the environment or any progeny that are produced  
3 from that -- those plants don't persist in the  
4 environment. So you need to describe methods to make  
5 sure that the regulated material and progeny are  
6 confined to the field test site.

7           This has to do with describing how you're  
8 going to maintain reproductive confinement as well,  
9 describing isolation distances and the other methods  
10 used, such as border rows, fallow zones, temporal  
11 isolation from other sexually compatible plants, cages  
12 or tents or flower removal or bagging.

13           And then describing the proximity of sexually  
14 compatible crops and relatives, this includes  
15 describing what those sexually compatible relatives  
16 are. You really need to know what your crop is and  
17 what it can cross with. If you have any questions  
18 about the sexually compatible relatives and where  
19 they're located, then contact APHIS. We have a lot of  
20 information about the distribution of, for example,  
21 switchgrass on this campus and Camelina and some other  
22 plants that have sexual compatibility. So please just

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1 contact us early in the process.

2           The last performance standard has to do with  
3 making sure that the volunteer plants either don't  
4 occur or that they're managed in such a way that they  
5 don't persist in the environment, and this includes any  
6 that are derived from progeny of a transgenic plant.

7           So you need to describe how the field trial  
8 will be terminated and how those volunteers will be  
9 managed, and this includes the frequency and the  
10 duration of monitoring which would be adequate to  
11 detect and destroy all volunteers before they flower  
12 for as long as those volunteers could be emerging  
13 immediately after the field test and throughout the  
14 next growing season, as long as they could be coming up  
15 from seed in the seed bank. And that should take into  
16 consideration seed dormancy.

17           BRS doesn't have a requirement that fields  
18 remain fallow after the field test. I know there's  
19 been some concerns expressed about fallow fields  
20 contributing to erosion and particularly in situations  
21 where we have a lot of drought, that creates problems,  
22 because then you've got, you know, erosion and dust

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1 issues coming along.

2           So we don't have a strict fallow requirement,  
3 but whatever you are going to plant after the field  
4 test, if you plant anything, if you plant like a cover  
5 crop, needs to be a crop that will allow easy detection  
6 of the volunteers and in such a manner that they could  
7 be devitalized so that any cover crop or fallen crop  
8 needs to be easily distinguishable from the regulated  
9 crop and, again, allow for removal of that regulated  
10 crop.

11           And it should be -- if you are going to be  
12 planting a crop in a -- during a monitoring season, you  
13 need to make sure that there are no volunteers coming  
14 up in that before that regulated -- I mean, that non-  
15 regulated crop is harvested. In most cases, it's best  
16 not to be planting a harvestable or crop on that field  
17 after -- I mean, during a monitoring season.

18           Design protocols issues. Most of the issues  
19 that come up with respect to design protocols had to do  
20 with reproductive environment. The Association of  
21 Official Seed Certifying Agencies has certified seed  
22 production distances that are commonly used, and these

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1 should really be those that are the most restrictive  
2 ones listed there.

3 I mean, the idea is that you're trying to  
4 prevent gene flow and persistence of those genes, those  
5 transgenes, in seed or regulated commodities. So  
6 greater distances may be required, especially when seed  
7 production fields of the same or sexually compatible  
8 crop species are within pollination distance or they're  
9 sexually compatible relatives.

10 APHIS will consider applicant constraints and  
11 applicant data and published data to arrive at  
12 measures, which may include multiple approaches to  
13 achieve reproductive confinement, and, as I mentioned  
14 before, there are other ways, besides isolation  
15 distance, which can be used. And we need to make sure  
16 that those are adequately described in your design  
17 protocol.

18 So, for example, for bagging and tenting, it  
19 would be important to describe the time that those bags  
20 or tents are placed on the crop to make sure that it  
21 covers the full period when those crops will be  
22 pollinating and how those are going to be secured and

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1 monitored to make sure that they're secured.

2           For protocols involving temporal isolation,  
3 where you want to make sure that your flowering period  
4 for your genetically engineered crop is separated in  
5 time from any other sexually compatible crops that it  
6 could potentially cross with within a pollination  
7 distance, the methods need to be described in  
8 sufficient detail to indicate how you're going to  
9 document that you've actually achieved that.

10           So if an inspector comes out, you should be  
11 able to show him how you've documented that temporal  
12 isolation was achieved. If you're using buffer rows to  
13 attract pollinators -- sometimes these are called  
14 border rows -- those should be of sufficient size to  
15 efficiently reduce the outcrossing, and they have to be  
16 continuous with no gaps, and you need to describe how  
17 is it going to be managed after the pollination period?

18           Because obviously, those could be containing  
19 transgenes, since the whole purpose is to attract the  
20 pollinators. You want to make sure that those are  
21 adequately destroyed and monitoring includes monitoring  
22 for volunteers in the area where the border rows are.

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1           APHIS does have a process for design protocol  
2 approval, and this is -- we have a preapproval process.  
3 Applicants have been making use of that fact. We've  
4 been -- we're currently in the season where we are  
5 accepting those and reviewing those. We review these  
6 prior to receiving the notifications, and, of course,  
7 it's open to all applicants, and any changes that are  
8 made after the approval then should be reapproved, so  
9 if you decide after you've started your notification  
10 season, "Oh, I wanted to make a change in this  
11 protocol," make sure that we are aware of that and had  
12 a chance to review and approve that.

13           Ideally, the design protocols should be  
14 divided in separate sections for each crop or a  
15 separate design protocol document submitted for each  
16 crop. It just makes our review process go a lot  
17 smoother. It also -- really, it's -- I think it's  
18 better in terms of when the states review -- well, I  
19 guess the states don't see the design protocols, but  
20 for the biotechs, that makes it a whole lot easier for  
21 us if these are on separate documents or separate  
22 sections.

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1 Samantha mentioned that there's guidance  
2 documents available for BQMS and templates for making  
3 the design protocols, so I really won't go over that  
4 anymore, but I think they're a really nice tool. I've  
5 looked at them, and they're very, very thorough.

6 The release site information requirements are  
7 the same for both permits and notifications, and, you  
8 know, it requires that GPS coordinates be submitted,  
9 and the guidance in the permit says to provide the GPS  
10 coordinates for the proposed release site.

11 If one coordinate pair is entered, they  
12 should be located close to the northwest corner of the  
13 proposed release location. And if the exact location  
14 of the release site is yet to be determined, provide  
15 GPS coordinates for the boundaries that encompass the  
16 possible area that will contain the release and the  
17 area to be monitored. This includes the separation  
18 (indiscernible) monitored.

19 So ideally, GPS coordinates should be limited  
20 to the small (indiscernible) considered for the  
21 planting (indiscernible) to be monitored and must be  
22 large enough, though, to include the whole

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1 (indiscernible); otherwise, the description of the land  
2 use history is meaningless. So if two coordinates are,  
3 you know, three counties large, that doesn't really  
4 help us. If the GPS coordinates fall in a county  
5 different than the release location, this is going to  
6 raise questions, and we'll probably get a call from  
7 biotech to explain that.

8           So if your coordinates do fall in a different  
9 county, it helps if you could put a little explanation  
10 in there about why that's the case. BRS staff do check  
11 the GPS coordinates to see if they are a critical  
12 habitat for threatened endangered species or also for -  
13 - whether or not they're near tribal land.

14           If the release site and the action area for  
15 isolation or monitoring are in or very near the  
16 critical habitat, it's best to provide at least four  
17 GPS coordinates, although biotech may have to contact  
18 you to get the information, which then could slow down  
19 the process.

20           You're required to provide the land use  
21 history for the release location. If the release site  
22 and the area to be monitored have been under

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1 (indiscernible) specify the type of agricultural  
2 activity that's been going on so (indiscernible) land  
3 could be fallow. The land could be used for pasture  
4 for a long time. If it's in pasture or fallow for a  
5 long period of time, it raises the question about  
6 whether or not some threatened, endangered species may  
7 be in that land. So it's important to describe how  
8 much time that land has been in fallow or pasture.

9           Again, if we can't come to conclusion if  
10 there's no effect on a threatened, endangered species  
11 or critical habitat, we have to consult Fish and  
12 Wildlife, and that take some time. If the release site  
13 or area to be monitored is in the designated critical  
14 habitat, you need to indicate that, and if so, you need  
15 to provide the species whose habitat has been  
16 designated as critical in that area, and you need to  
17 analyze the effects of the proposed release on the  
18 critical habitat.

19           And this should be focused on the primary  
20 constituent comments that are listed for that critical  
21 habitat in the Federal Register Notice that announces  
22 that critical habitat designation. If there are

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1 measures that you have ongoing to minimize the service  
2 of critical habitat, that should be explained as well.

3           Some of the common mistakes or issues that  
4 come up, sometimes the GPS coordinates are not in the  
5 correct format. They have to be in decimal format, and  
6 the longitude is typically negative, unless you're  
7 planting someplace very strange.

8           Websites are available for converting these  
9 from different -- the different coordinate types into  
10 decimal format. And if you're not in agricultural  
11 land, it might raise a question. If your GPS  
12 coordinate lies in the ocean or it's somebody's  
13 swimming pool, you might get a call.

14           The -- sometimes people are indicating that  
15 the release site and action area is in the designated  
16 critical habitat when, in fact, it isn't. We would  
17 prefer that you not indicate it is in a critical  
18 habitat unless it is.

19           Okay. Now moving on to permits, four  
20 standard permits are used when the regulated organism  
21 is a plant and doesn't meet notification eligibility  
22 criteria or if it's not a plant. Obviously, it would

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1 have to be introduced on a permit. These are  
2 traditional permits, unless there is an industrial form  
3 (indiscernible) intent, and courtesy permits are  
4 generally only for genetically engineered  
5 (indiscernible) when they do not meet the definition of  
6 a regulated article.

7           If you have an application that's been  
8 previously submitted, the permit can be copied and  
9 resubmitted. From the home screen, you just go to "All  
10 Saved Applications" and select "Copy." Of course, one  
11 of the advantages of permits is that in addition to the  
12 standard permit conditions in the regulations  
13 themselves, APHIS can customize the specific  
14 (indiscernible) permit conditions to the type of permit  
15 and to the species being introduced and to consider  
16 specific environmental conditions related to that  
17 release site in the presence of sexually compatible  
18 species.

19           So the typical types of specific conditions  
20 relate to methods to control pollination, separation  
21 from wild relatives, and monitoring for that. Post-  
22 harvest volunteer monitoring is a component on all of

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1 the release permits, and for certain types of permits,  
2 like (indiscernible) or some of the large-scale  
3 permits, we may have a requirement for a management  
4 plan or SOP to training programs.

5           The applicant has to agree to each condition  
6 or indicate why they don't agree, and then there's some  
7 back and forth between Biotech. For conditions that  
8 are added by the states, those aren't forced by APHIS,  
9 but it's important to check, because some of those  
10 state conditions might ultimately mean that you can't  
11 do an introduction of a particular type in a particular  
12 state.

13           Recently, Oregon has, for example, been  
14 adding a condition related to an existing quarantine  
15 regulation for a Brassica species, so that's a new one  
16 that you might be seeing on some of your applications,  
17 if you're doing Brassica releases in Oregon.

18           If you have any questions about state  
19 conditions, of course, you should contact the state  
20 regarding those. I know Gwen Burnett has been also  
21 helping when there are issues that come up, and she's  
22 been in the back of the room shaking her head. When

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1 issues come up with state conditions that raise  
2 questions, we will try to help, you know, the  
3 applicants work as a state to resolve this. But  
4 ultimately, it's the state that enforces those  
5 conditions.

6           Pharmaceutical, industrial, and  
7 (indiscernible) permits have additional permit  
8 requirements in the form of supplemental permit  
9 conditions. These include dedicated storage  
10 facilities, a requirement for dedicating planting and  
11 harvesting equipment, and SOPs for cleaning field  
12 equipment, seed-cleaning, drying equipment, storage  
13 facilities, requirements for APHIS-approved training  
14 programs, and also increased separation distance from  
15 adjacent fields. We have a requirement for  
16 (indiscernible) fallow zone, and the fallow zones are  
17 typically used to provide (indiscernible) prevent  
18 mechanical mixing of the regulated particle with other  
19 plants used for food or feed.

20           Typically, the field site must be left  
21 fallow, or it could be planted to a cover crop, as long  
22 as it allows for the detection and destruction of the

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1 volunteers and is not harvested or used for food or  
2 feed. If you're going to plant a (indiscernible)  
3 species that's going to be harvested for food or feed  
4 (indiscernible) plot following -- you know, in the next  
5 season, then you need to request for variance  
6 (indiscernible). If mixing with food or feed crops is  
7 not really an issue; for example, if you had tomatoes  
8 following genetically engineered corn (indiscernible).

9           As was mentioned, one of the advantages for  
10 permits is that they can be amended quite easily. So  
11 after a permit is issued and before the expiration  
12 date, you can amend a permit. The administrative and  
13 review steps are similar as for an original permit  
14 submission, so you need to take that into  
15 consideration. Usually they're quicker, but  
16 administratively the timelines are the same. They can  
17 only be amended via the Web form (indiscernible), not  
18 via XML at all.

19           You should clearly describe the proposed  
20 changes. There's an area at the beginning of the  
21 application under, I think it's "Additional  
22 Information," where you can put that information, and

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1 that includes if you make changes to genetic  
2 constructs, release sites of facilities, let us know  
3 which constructs, which facilities, or release sites.

4           If there's changes in SOPs or design  
5 protocols or disposal methods, those are allowed. Size  
6 of shipments or acreages are allowed. You can change  
7 the planting date, but as long as it's after the  
8 effective date and before the expiration date.

9           Amendments cannot be used to change the  
10 effective or expiration date, add the recipient  
11 species, or add new plantings or releases that extend  
12 beyond the expiration date and cannot remove a release  
13 location or construct. If -- as Doug mentioned, if  
14 you're not going to mention a release location, just  
15 simply indicate that when you submit the planting  
16 report.

17           Permit renewals. Renewals are used to repeat  
18 a similar introduction to one that has been approved  
19 previously; for example if you have the same crop and  
20 trait and release location or you're going to continue  
21 a multiyear permit that's going to expire. Excuse me.

22           You need to provide the permit number that's

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1 being renewed, and all the information from your  
2 previous permit, then, is copied into the new e-permit  
3 application, and it can be modified as needed. You  
4 just have to describe in the information -- "Additional  
5 Information" section what the changes are.

6           One of the things you'd really need to pay  
7 attention to is updating the land use history to  
8 include any release activities. So if you're doing a  
9 multiyear trial, your plants have been in the ground  
10 for three years, land use history shouldn't say, "This  
11 plant -- this site was previously planted to some other  
12 crop. It was previously planted to your last  
13 transgenic plant." I mean, transgenic plants  
14 (indiscernible). Make sure you include that history.

15           Again, a reminder here that movement permits  
16 are only good for one year. If you have a multiyear  
17 permit that was a -- that also included a movement,  
18 then that movement part is only good for one year, not  
19 the full three years that the release would be good  
20 for. So you'll need to renew any -- your movement  
21 permit if you want to continue to do movement of  
22 material that's coming out of your multiyear permit.

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1           For the latter case, APHIS has been  
2 implementing a new process to remind applicants that  
3 their multiyear permit is about to expire and to renew  
4 it and to submit their required annual and final field  
5 test reports. So I hope that's been helpful.

6           Now, we have some common questions that are  
7 maybe questions that apply to both permits and  
8 notifications. These are generally addressed in the  
9 guidance document, which I failed to mention, I think,  
10 but we do have new guidance documents, fairly new. The  
11 one on notifications was introduced in 2011, and we  
12 have one on permits that was posted in 2012, and  
13 they're pretty comprehensive. They have examples of  
14 all different kinds of permits and notifications and  
15 questions related to how to submit your reports, and  
16 I'm going to be showing a slide at the end that's got a  
17 link to that, so if you want that, wait a few minutes.

18           So one of the common questions that we have  
19 relates to applicants and who's the responsible party  
20 and what are the qualifications for being a responsible  
21 party? A responsible party has to be a U.S. resident  
22 and not a -- it should ideally not be a temporary

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1 employee. So if you're a postdoc or other temporary  
2 employee, it's best that you could be the preparer, and  
3 then your -- the PI could be the submitter.

4           The length of the review by APHIS in the  
5 states, of course, can vary, depending on the type of  
6 introduction. Of course, that's covered in the regs  
7 also in the guidance documents, but -- and it's  
8 important to realize that those regulations were  
9 written at a time when applications were quite simple.  
10 Now we're getting extremely large applications with  
11 thousands of constructs or, you know, hundreds of  
12 release locations. Those take a lot of time to review.

13           So there can be problems if the applications  
14 get to be too large. If they're over 500 pages, it  
15 tends to gum up the system. The applications time out.  
16 The states have a hard time opening them. The biotechs  
17 have a hard time opening them. They can really bog  
18 things down, so we ask you to please keep them less  
19 than 500 pages. Really, I start to see problems a lot  
20 of times even around 450 or so. So please don't make  
21 them so large that people can't work with them.

22           Another issue that comes up is unique

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1 location ideas. I think Doug touched on that briefly,  
2 and there's a lot of description about that in the  
3 guidance documents, so I'm not going to go over that in  
4 any more detail. Shipping container requirements --  
5 oh, and one more thing I wanted to say.

6           With regard to these large applications, one  
7 of the things you can do, and some of the companies are  
8 doing this, is to -- if you have a really large  
9 application with a lot of constructs on it, you can  
10 attach supporting documents to the ePermits folder,  
11 like an Excel spreadsheet that lists all of the  
12 constructs in your application, whether or not they've  
13 been previously approved or a permanent notification.  
14 That really helps Biotech reviewing those to know which  
15 ones are new that might require, excuse me, a little  
16 bit more attention than some of the others.

17           Shipping containers. For permits, if you are  
18 going to be shipping in a way -- in a container type  
19 that doesn't meet the requirements under 340.8, you  
20 need to request a variance. I know this can be a bit  
21 of a pain, but we do have a process in place that's  
22 quite easy. Once you get your variance request

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1 approved, it can be applied to other permits with the  
2 same kind of material.

3           For notifications, you just have to meet the  
4 performance standard for shipping. Questions related  
5 to permits, being on the outer package, of course, all  
6 shipments require that the permit number be displayed  
7 on the outer shipping container.

8           Another common question we get is is my  
9 genetically engineered organism regulated? Does it  
10 meet the definition of a regulated article? So we have  
11 some guidance on our website. The link is provided  
12 here. It's on a page that includes information about  
13 our regulations, and you can request an opinion from  
14 APHIS. Ideally, that's -- you should do that before  
15 you submit your application.

16           We have issued responses to at least 15  
17 different requests for an opinion about whether or not  
18 genetically engineered organisms are, in fact,  
19 considered regulated articles. You can go to the  
20 website, and you can view some of those responses.

21           So courtesy permits, those can be requested,  
22 then, to facilitate movement. If, in fact, maybe you

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1 don't meet the definition of a regulated article, but  
2 you want to get some kind of permit anyway to  
3 facilitate movement through ports, you can request a  
4 courtesy permit.

5           Sometimes your movement of your regulated  
6 material requires permits from other parts of APHIS.  
7 Most typically, these involve a requirement for import  
8 permits for certain plants or permits for movement of  
9 soil that might be associated with plants that are  
10 moving in pots. BS (ph) might require a permit for  
11 import or movement of certain animal products or  
12 biologics. So if you have any questions about those,  
13 the best place to go for information are the specific  
14 PPQ or BS Web pages. And the biotech can usually help  
15 direct you to the appropriate page.

16           Another question that comes up, sometimes we  
17 have donor organisms that are on select agent lists.  
18 This might require us to do a consultation with the  
19 select agent program. And this past year, we've  
20 developed a streamlined process for that. We have  
21 developed a list of previously reviewed and approved  
22 sequences, from organisms that are either on the select

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1 agent list or that produce toxins that are on the  
2 select agent list. And this is -- really helps a lot.

3           So with that -- oh, wait, one more slide.  
4 CBI. CBI is frequently an issue that we have to deal  
5 with that causes a lot of heartache. Justification  
6 statements, any time you're going to claim information  
7 is confidential business information, you have to  
8 include a CBI justification statement. Justifications  
9 have to be related to competitive harm, and all the  
10 categories of information that you're claiming is CBI  
11 have to be included in that CBI justification  
12 statement.

13           So if you're going to claim the acreage or  
14 the gene of interest or the donor organisms, all of  
15 those have to be broken out, and a justification  
16 forgiven -- given for why revealing that information  
17 could cause competitive harm.

18           Information that could be claimed as CBI and  
19 definitions of commercial and financial harm are  
20 provided in my BRS document preparation guideline  
21 that's on our website, and the link is listed here.  
22 Included in that document prep guideline are examples

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1 of things that can typically be claimed as CVI and  
2 those that can't. And included in the ones that cannot  
3 are names and addresses of responsible parties and also  
4 phone and email addresses of responsible parties,  
5 because the states need to be able to contact these  
6 people.

7           Organizations, recipient organisms,  
8 (indiscernible) categories in the county and state. So  
9 if you have any questions on CBI, the best person to  
10 talk to is Cindy Eck, my Document Control Officer.  
11 There she is waving her hand at the back of the room.  
12 Thanks. So with that, I'll take any questions. And  
13 since I promised you I would have a link to the  
14 guidance documents, there it is. Thank you.

15           MR. GEORGE: Questions?

16           MS. KOEHLER: Any questions? No? I must  
17 have covered everything.

18           MR. GEORGE: Thank you. Well, this concludes  
19 the formal part of our presentations and the formal  
20 part of our day. The schedule shows a break, but  
21 basically what's going to happen now is that BRS staff  
22 is going to stick around, and so if you have individual

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1 questions that you want to talk to us about, we'll be  
2 happy to stick around and have those conversations.

3 I will ask you, please, to take a look at the  
4 survey forms that are being passed out at the moment at  
5 your tables. We would love to have your comments. It  
6 will help us make this a better meeting next time  
7 around. Also, I want to thank all of you for coming.  
8 That includes our online visitors as well, so I'm going  
9 to look into the little camera over there and say thank  
10 you for joining us as well.

11 And this has been a bit of an experiment, but  
12 it seems to have gone quite well. And we might be  
13 surveying you folks that are online as well here  
14 sometime in the next week or so, so if you get an email  
15 from us, please take a minute or two to answer a couple  
16 of questions. This seems like something that works,  
17 and we want to make it as good as we can next time  
18 around.

19 So having said that, I want to thank  
20 everybody for coming, and BRS staff will stick around  
21 for a while to answer any other questions that you  
22 might have. Thanks very much.

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1 (Whereupon, at 3:48. p.m.  
2 the meeting was adjourned.)

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1 CERTIFICATE OF COURT REPORTER

2 I, Erick McNair, the Court Reporter before whom  
3 the foregoing proceeding was taken, do hereby certify  
4 that the proceeding was recorded by me; that the  
5 proceeding was thereafter reduced to typewriting under  
6 my direction; that said transcript is a true and  
7 accurate record of the proceeding; that I am neither  
8 related to nor employed by any of the parties to this  
9 proceeding; and, further, that I have no financial  
10 interest in this proceeding.

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Erick McNair  
Digital Court Reporter

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1 CERTIFICATE OF TRANSCRIPTION

2

3 I, MARY YOUNG, hereby certify that I am  
4 not the Court Reporter who reported the proceeding  
5 and that I have typed the transcript of the  
6 proceeding using the Court Reporter's notes and  
7 recordings. The foregoing/attached transcript  
8 is a true, correct and complete transcription of the  
9 proceedings.

10

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12 \_\_\_\_\_  
Date

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Mary Young  
Transcriptionist

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