

Capital Reporting Company
Biotechnology Regulatory Services: Public Stakeholder Meeting 12-13-2011

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

Biotechnology Regulatory Services
Public Stakeholder Meeting
Tuesday, December 13, 2011

USDA Center at Riverside
4700 River Road
Riverdale, Maryland 20737

Reported by: Natasha Thomas
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1 P R O C E E D I N G S

2 MR. GEORGE: Good morning, and welcome to the
3 2011 BRS Stakeholders Meeting. It could be a little
4 too hot. Can everybody hear me? Hear me now? Still
5 (indiscernible). I'm Richard George, BRS
6 Communications Branch Chief. Thank you for joining us
7 today. I just want you to all see you'll see I am
8 flocked. We have a full schedule on the
9 (indiscernible).

10 A couple of housekeeping items. Please put
11 your cell phone on vibrate if you would please. If you
12 haven't already, please be sure to sign in at our sign-
13 in table. We do have coffee and water in the back of
14 the room. Down the hall is a cafeteria with Dunkin
15 Donuts' coffee if you want to take a minute go back
16 there during the breaks. Can you hear? No?

17 How is that? Is that better?

18 FEMALE SPEAKER: Yes.

19 MR. GEORGE: Very good. How's our corporate
20 board? Can you hear okay?

21 Great. Also during the break and at lunch,
22 our Permits Branch Chief, Steve Bennett, is here to

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1 help those who would like to get e-authenticated in
2 order to access our ePermits system. Steve is right
3 over there. Wave your head Steve. So please take
4 advantage of that during the break and at lunch if you
5 care to.

6 Today's presentations are also available as
7 printed handouts that are on the sign-in table, so if
8 you'd like to follow along, takes notes from the
9 handouts, be sure to pick them up if you haven't. If
10 you'd like one, just give us a wave, and we'll get a
11 set of them to you now. Anybody still looking for
12 handout? In the back?

13 Okay. Gail, I think somebody put their hand
14 up in the back there. Anybody?

15 These PowerPoint presentations will be
16 available on our Web site. We have a court reporter
17 here, Natalia Thomas, who's sitting up here in the
18 front. She will produce a transcription of the meeting
19 that will also be posted on our Web site in the next
20 few weeks.

21 I would ask that if you have a question
22 during the meeting that you wait until we get a

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1 handheld microphone to you before you ask your
2 question, and then please identify yourself and your
3 organization so we can keep track of it on the record.

4 Also, please hold your questions until the
5 end of each presentation as we've allowed time for
6 questions at the end of the presentations. If there
7 are questions we can't get to, we'll put them on the
8 parking lot and try to get to them later in the day.

9 Today's meeting we've designed in two parts.
10 The morning session will be devoted to more high-level
11 look at biotechnology BRS activities. Deputy
12 Administrator Michael Gregoire will give us a summary
13 of 2011 activities and a look ahead to 2012. Then
14 we'll have a report on AC21, the Advisory Committee on
15 Biotechnology and 21st Century Agriculture. They just
16 completed the second meeting last week. AC21 is
17 working on coexistence issues, and we'll hear from Mike
18 Schechtman, the Executive Secretary and Designated
19 Federal Official for AC21 about the latest meeting and
20 the work (indiscernible).

21 After a break, we'll dive into the petition
22 process improvements and recommendations with BRS Chief

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1 of Staff Clint Nesbitt. Then we'll finish the morning
2 with presentation about the status of the NEPA Pilot
3 Project with Rebecca Stankiewicz Gabel. At the end of
4 the morning, we will allow time for additional
5 questions.

6 The afternoon session focuses on more nuts-
7 and-bolts issues regarding permitting and
8 notifications, ePermits, confidential business
9 information, and compliance with training with the
10 staff from our Environment Risk Analysis and Regulatory
11 Operations Programs. Again, there will be time for
12 questions.

13 So at this time, we'd like to have everyone
14 introduce themselves, so we'll pass the microphone
15 around. Just give us your name and your organization.
16 Pass that microphone. Start in the back.

17 MR. WHALEN: Dave Whalen, Forage Genetics.

18 MS. FITZPATRICK: Sharie Fitzpatrick,
19 Metabolix.

20 MS. RUSZCZYK: Renata Ruszczyk, Metabolix.

21 MR. REDDY: Srinu Reddy, Forage Genetics.

22 MR. JOHNSON: Jim Johnson, Dorsey & Whitney.

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1 MR. WARD: Dennis Ward, Syngenta Seeds.

2 MS. WIETZKI: Christine Wietzki, Betaseed.

3 MS. HARTMAN: Christy Hartman, ICF

4 International.

5 MR. WERNER: Mike Werner, Avatar

6 Environmental.

7 MS. DESAGUN: Maria Desagun, Ceres.

8 MS. WEST: Carla West, AgBiotech Planning

9 Committee.

10 MR. MENCHEY: Keith Menchey, National Cotton

11 Council.

12 MR. WITUCKI: Greg Witucki, Syngenta.

13 MR. BOTTOMS: Jeff Bottoms, Syngenta.

14 MR. PEARSON: Les Pearson with ArborGen.

15 MS. MILLER: Samantha Miller, ArborGen.

16 MS. THOMAS: Anita Thomas, ArborGen.

17 MR. WEGENER: Randy Wegener with Bayer

18 CropScience.

19 MR. WEEKS: Michael Weeks, Bayer CropScience.

20 MS. COATS: Isabel Coats, Bayer CropScience.

21 MS. MCKEAN: Angela McKean, BASF Plant

22 Science.

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1 MR. HOWIE: William Howie, BASF Plant
2 Science.

3 MR. SHERROD: Josh Sherrod, Bayer
4 CropScience.

5 MS. SUTHERS: Alison Suthers, Holland & Hart.

6 MR. SHELTON: Mike Shelton, Scotts Miracle-
7 Gro.

8 MR. CLAPP: Steve Clapp, Food Chemical News.

9 MR. ORR: Greg Orr, Dow AgroSciences.

10 MS. SCOTT: Ali Scott with Bayer.

11 MS. WEBER: Natalie Weber, Pioneer/DuPont.

12 MR. OBRIEN: Dana O'Brien from BIO.

13 MS. HOOA: Amie Hooa, Monsanto.

14 MR. DOHRMANN: Todd Dohrmann, Monsanto.

15 MR. CAVATO: Tracy Cavato, Monsanto.

16 MR. JENKINS: Dan Jenkins, Monsanto.

17 MS. GRUSWITZ: Ariel Gruswitz,

18 Pioneer/DuPont.

19 MS. GUTSCHE: Annie Gutsche, DuPont.

20 MR. KING: Trip King, ArborGen.

21 MS. VANSAN: Juliana Vansan, ArborGen.

22 MS. QUINN: Cathy Quinn, ArborGen.

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1 MR. GILL: Mike Gill, Crowell & Moring.

2 MS. HOOD: Nancy Hood, ArborGen.

3 MR. JAFFE: Greg Jaffe, Center for Science in
4 the Public Interest.

5 MS. KOCH: Muffy Koch, Global Biosafety.

6 MS. COLLINGE: Susan Collinge, the J.R.
7 Simplot Company.

8 MR. GEORGE: Is that it? Did we miss anyone?
9 More in the back? We might as well capture the BRS
10 staff that sits here as well(indiscernible).

11 MS. KOEHLER: Susan Koehler, APHIS.

12 MR. NESBITT: I'm Clint Nesbitt with APHIS.

13 MS. IADICICCO: Rachel Iadicicco with APHIS.

14 MS. CARTER: Sarah Carter, J. Craig Venter
15 Institute.

16 MR. JHEE: Edward Jhee with APHIS.

17 MS. SNOW: Patricia Snow, APHIS.

18 MR. HANDLEY: Lee Handley, APHIS.

19 MS. JONES: Margaret Jones, APHIS.

20 MS. HOPP: Good morning. Chessa Hopp, APHIS.

21 MS. SPAINE: Pauline Spaine, APHIS.

22 MS. PARDOE: Linda Pardoe, APHIS.

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1 MR. BLANCO: Carlos Blanco, APHIS.
2 MS. VONGPASEUTH: Kham Vongpaseuth, APHIS.
3 MS. SIMON: Samantha Simon, APHIS.
4 MR. SETHURAMAN: Karthik Sethuraman, APHIS.
5 MS. LALLI: Donna Lalli, APHIS.
6 MS. BOWMAN: Tracey Bowman, APHIS.
7 MR. MINOR: Lincoln Minor, APHIS.
8 MR. TURNER: John Turner, APHIS.
9 MR. SOTTOSANTO: Jordan Sottosanto, APHIS.
10 MR. REINHOLD: David Reinhold, APHIS.
11 MS. GRAY: Shelley Gray, APHIS.
12 MS. STANKIEWICZ GABEL: Rebecca Stankiewicz
13 Gabel, APHIS.
14 MR. ABEL: Sid Abel, APHIS.
15 MS. REED: Genna Reed, Food & Water Watch.
16 MR. FEINSTEIN: Jon Feinstein, VHB
17 Environmental.
18 MR. CORDTS: John Cordts, APHIS.
19 MR. HERON: And Dave Heron, APHIS.
20 MR. GEORGE: Is that it? Well, good morning
21 to all, and thank again for being here. With that, I'm
22 going to turn the podium over Mike Gregoire.

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1 MR. GREGOIRE: Thank you, Dave. Good
2 morning, everybody. Sound okay in the back there?

3 Turn it up?

4 FEMALE SPEAKER: Yes, please.

5 MR. GREGOIRE: How is that? Is that better?

6 Okay. Good morning, everybody. I'm Mike
7 Gregoire, and I am also with APHIS.

8 MR. GREGOIRE: Want to welcome you to our
9 annual BRS Stakeholders Meeting. We're really pleased
10 with the turnout today. I think this is the biggest
11 gathering we've had at one of these meeting at least as
12 long as I've been a part of the program, and we really
13 look forward to interacting with you today. I see this
14 meeting as not just an opportunity for us to provide
15 you with information about what's going on in the
16 program, but as an opportunity for us in APHIS to
17 listen and learn and get ideas about how we can make
18 the program and our operations more effective.

19 I guess I'd like to just start by letting you
20 know about staff changes in BRS since our meeting last
21 year. We have a number of new employees in the
22 organization, and we have some folks in acting

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1 positions. Hopefully, you'll have the opportunity to
2 meet and talk with some of the BRS staff today, folks
3 that you would otherwise only get to interact with via
4 email or through the telephone. This meeting is always
5 a good opportunity, and we often get feedback from
6 folks who say that they enjoyed the opportunity to meet
7 and interact some of the staff face to face.

8 So with respect to new employees that we have
9 brought onboard over the last year. Those employees
10 are as follows and not in any particular order. Umesh
11 Kodira. I don't know if Umesh is here yet today, but
12 he's the new head of our Government Relations Branch,
13 and they coordinate our interactions with other
14 agencies and government be they international
15 governments or state governments or tribes. Dick
16 George, who has already introduced himself, is our
17 Communications Branch Chief. Jeff Beaman who is a
18 Senior Regional Biotechnologist with the staff; he is
19 stationed out on Fort Collins, Colorado.

20 Diane Sinkowski is a new member of our NEPA
21 team. She's an environmental protection specialist.
22 Karthik Sethuraman who is an IT specialist in our

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1 Resource Management Programs. Bill Hughes is the new
2 financial manager in our Resource Management Programs.
3 Lori Kerber who is a biological scientist in our
4 Regulatory Operations Programs. Samantha Simon, who I
5 saw come in, Samantha is our Compliance Assistance
6 Branch Chief. She will be running the BQMS Program.
7 She's stepping in behind Ed Jhee, who was promoted this
8 year to the Director of our Regulatory Operations
9 Programs after Tom Sim retired.

10 Sharon Talley who is a biotechnologist in
11 Fort Collins, Colorado. Lou Forgetz (ph) who is also
12 an environmental protection specialist in our NEPA
13 team. He come Plant Protection and Quarantine; and
14 Patricia Snow, who introduced herself already, a new
15 biotechnologists in our Environmental Risk Analysis
16 Programs. Patricia comes to us from Plant Protection
17 and Quarantine as well.

18 So we're very happy to have the new staff
19 onboard to help us with our heavy workload that we
20 have. A couple of other personnel changes that you may
21 or may not be aware of: Bev Simmons, who is the
22 Associate Deputy Administrator of Biotechnology and

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1 Regulatory Services has been on detail since this
2 summer as the Acting Deputy Administrator for APHIS
3 International Services. In her absence, Mike Firko has
4 been serving as the Acting Associate Deputy
5 Administrator of Biotechnology and Regulatory Services.
6 Mike is covering another meeting for me this morning,
7 but he will be here this afternoon, and we'll have the
8 opportunity to introduce Mike to you. He is in the
9 Plant Protection and Quarantine organization. He's
10 been with APHIS since 1992, and his regular job is EDQ
11 is to lead the permitting function in Plant Protection
12 and Quarantine and Select Agent Program. He's
13 currently serving as the Acting Associate Deputy
14 Administrator of BRS.

15 I'd like to turn now just to look back on
16 fiscal year 2011 and highlight some of what our
17 priorities were and what our goals were and how we did
18 vis-those priorities and goals last year. We had
19 several key priorities that were identified and tracked
20 as part of USDA's high priority performance goals, and
21 this was an initiative that was really a Government-
22 wide initiative across the executive branch where a

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1 limited number of operational priorities were
2 identified and tracked very closely by the
3 Administration. So one of those high-priority
4 performance goal -- and there are about seven in all in
5 USDA -- dealt with biotechnology.

6 Specifically, the biotechnology priorities
7 were centered around improving the timeliness and the
8 predictability of the petition process, increasing the
9 number of petition determinations that the agency
10 makes, increasing the enrollment in the Biotechnology
11 Quality Management System Program and increasing the
12 number of inspected of regulated field trials. So
13 those were the focus areas for the program last year.
14 Several of those were carried into this year's
15 priorities.

16 During fiscal year 2011, which ended on
17 September 30, we made six final petition determinations
18 that were published in the Federal Register. Those
19 included herbicide-tolerant alfalfa, partially
20 regulation of GE sugar beets, analyzed corn, seed
21 production technology corn, and insect-resistant cotton
22 and an altered-colored rose. In October, we made two

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1 more petitions determinations for an insect-resistant
2 cotton, and the other was for a glyphosate tolerant,
3 an insect-resistant soybean.

4 So far in this calendar year, we've made
5 eight petition determination, and I expect it will be 2
6 more announced before the end of the calendar years,
7 which would bring to 10 the total number of petition
8 determinations that will have been made in calendar
9 year 2011. And that's the most such determinations
10 that have been made in many years. I think the last
11 time there were that many made in year probably goes
12 back to the 1990s.

13 While that's good news for us and we're happy
14 to have made that progress, the challenge is that new
15 petitions are coming in almost as fast as the older
16 ones are moving out. In all, seven new petitions for
17 nonregulated status were submitted to us in fiscal year
18 2011, and another new one came in late last week. So,
19 today, we have 23 pending.

20 We're certainly aware that the petition
21 process has room for improvement, and to that end, we
22 applied the techniques of what are known as Lean Six

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1 Sigma to the petition determination process. And the
2 results of those efforts is that we've designed a
3 revised process that would take about half the time
4 that it's been taking in recent years and reduced the
5 amount of variability in the timing of the process.
6 You'll be getting a more detailed presentation on the
7 process changes from Clint Nesbitt later this morning.

8 We also launched a NEPA Pilot Project in
9 April 2011 to examine the extent to which two
10 alternative methods of preparing NEPA documents could
11 improve the timeliness, quality, and cost of preparing
12 most NEPA documents that inform our petition
13 determinations. And you'll also get a briefing on that
14 this morning. We have had a good response to that, a
15 lot of interest in that program, and a number of
16 projects are underway to test those two alternatives
17 approaches to preparing NEPA documentation. That will
18 be discussed in the presentation later today.

19 With respect to the Biotechnology Quality
20 Management System program, we continue to build this
21 program. In 2011, eight new participants enrolled in
22 the program, so we now have 18 entities participating.

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1 Our goal is to reach 20, so we didn't quite make that
2 number. Nonetheless, the 18 participants that are
3 enrolled in the program account for more than 90
4 percent of all the notifications and permits that we
5 process. In fact the vast majority of field trials
6 that we regulate are being carried out under the
7 auspices of the BMS program, which we're very pleased
8 with. I think that's the subject of one of our
9 presentation this afternoon as well.

10 With respect to inspections and compliance,
11 in fiscal 2010, APHIS/BRS along with Plant Protection
12 and Quarantine conducted a little over 500 inspections.
13 That was about the number we had been running at for a
14 number of years. Our goal is to get that number up
15 last year to a little over 600, the objective being to
16 increase the inspection program to keep pace with the
17 growing number of field trials that we have seen over
18 the last several years.

19 So in fiscal year 2011 as it turns out, we
20 completed more than 800 inspections, so we actually
21 overshot our target somewhat. That was a big increase
22 over 2010, so we met the target there, and we continue

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1 to find very high rate of compliance based on the
2 inspection activity.

3 In addition to the more than 800 inspections
4 of the regulated field trials that we conducted, we
5 also scheduled more than 2,000 inspections of the
6 (indiscernible) crop that was grown under compliance
7 agreements pursuant to the partial deregulation the
8 agency branded last February.

9 And finally with respect to permitting,
10 although we didn't have a numerical goal for the number
11 of permits that we would issue largely in response to
12 the applications we get, we issued more than 2,500 new
13 permits and notifications last year. And that was a
14 significant increase from the prior year. This
15 afternoon I think there's going to be some data
16 provided about some of the details of the numbers, and
17 you'll get a presentation and the discussion on
18 ePermits.

19 Turning to the year ahead, 2012, I'm going to
20 start by talking about the budget situation. We're
21 lucky in the sense that we have now an appropriation
22 that covers the whole fiscal year, so we know what we

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1 have to work with. Congress did pass an appropriation
2 bill for the whole year that covers several agencies,
3 Agriculture being one of those. I think it also covers
4 Transportation and Commerce and maybe some other
5 agencies. So that was good news.

6 The bad news for APHIS is that the APHIS
7 budget was cut by a little over \$46 million or 5.5
8 percent. The amount appropriated for the Biotechnology
9 Regulatory Services program, however, was increased by
10 \$5 billion, bringing the total appropriation for this
11 program to \$18.1 billion. Last year, it was a little
12 over \$13 billion; so percentage-wise, this is a big
13 increase. We're currently evaluating and updating our
14 plans for using the additional funding. Priority will
15 certainly be given to those functions related to
16 implementing process improvement in the petition
17 process dealing with petition backlogging and
18 maintaining the high rate of the compliance activity
19 that we have established last year.

20 So our top priorities for this year are to
21 implement the petition process improvements and make
22 progress toward eliminating the petition backlog. So

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1 while we spent last year analyzing the petition process
2 and designing a new one, the test before us now is to
3 actually implement that, and we're going to be talking
4 about that more today.

5 A second top priority for BRS this year is to
6 move forward on regulatory revisions to the agency's
7 biotechnology regulations. With respect to those
8 changes, we have had discussions with senior USDA
9 policy officials, and we have some direction and
10 decisions on a path forward. I'm not at liberty to
11 discuss today the details of that direction or provide
12 you with the specific timeframe. There is still a good
13 deal of work yet to be done on rule writing and
14 discussing the regulations with other USDA agencies and
15 other agencies in the Federal Government. I think
16 we'll have more information to share on this in the
17 coming months. So those are two top priorities.

18 There are several other areas where I think
19 we'll be expending considerable resources this year
20 that are also important. I talked about the higher
21 compliance activity that we have established, so
22 sustaining that and managing that effectively will be a

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1 focus area for us. We will have been in the BQMS
2 program a few years. We want to begin to evaluate the
3 result and impact of that program.

4 We'll be contributing to a U.S. Government-
5 wide efforts to find solutions to low-level presence
6 policy issues as they affect trade. We'll be helping
7 to advance the comprehensive USDA import policy for GE
8 products. There is an IG report that came out a few
9 years ago, and there's work to be done on that.

10 And 2012 is also a year when Congress will
11 working on a new farm bill, the 2012 farm bill, so I
12 expect we will be devoting time, energy, and resources
13 to helping the Congress by informing their decisions on
14 farm bill issues in 2012.

15 So that concludes my formal remarks this
16 morning. I'd be happy to take you questions at this
17 time before we move on to the next agenda item. And I
18 think we'll have a roving microphone going around, so
19 if you would just raise your hand, we'll bring a
20 microphone over so everyone can hear the question.

21 You can't let me off that easy.

22 MR. JAFFE: I had a couple of questions about

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1 inspections. You said that you did about 800
2 inspection and that you had a high rate of compliance.
3 I'm curious if you could tell us what your level of
4 compliance versus noncompliance was in those inspection
5 and then the types of noncompliance that you found and
6 what did the BRS do about that noncompliance?

7 And then also I'm curious also about the
8 2,000 beet inspections and what was the results of
9 those inspections.

10 MR. GREGOIRE: Okay. Thank you. Good
11 question. In the inspection that we do on regulated
12 field trials, which is sort of ongoing inspections that
13 we do each year, we find that the compliance rate based
14 on those inspections run to about 99 percent. Where
15 there is noncompliance, it can vary. Most are I would
16 say are minor infractions, and the follow-up actions
17 really depend upon what we find. The first priority is
18 to bring things into compliance, so we'll work with the
19 developers to bring things into compliance. Other
20 actions that might be taken might include a letter of
21 warning. The agency also have the authority to issue
22 civil penalties for more egregious violations of the

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1 regulations.

2 With respect to the inspections of the
3 sugarcane root crop compliance agreements, I don't have
4 the compliance rate figure for that right off the top
5 of my head. Maybe that's something we could check
6 during one of the breaks, but we are finding a high
7 rate of compliance there. There have been some reports
8 to us perhaps of seed that has been spilled and what
9 actions were taken to clean up seed spills, and
10 sometimes these happen with truck accidents or what
11 have you.

12 So in addition, the regulations require as
13 the compliance agreements for sugar beets that if there
14 is a violation that the regulated entity has to report
15 that within 24 hours to us as well. So in addition to
16 our inspection program, we have self-reporting as well.

17 MR. JENKINS: Hi, Mike, Dan Jenkins with
18 Monsanto. I'm just curious as to that's a pretty
19 massive budget increase particularly in these times.
20 What do you attribute that to, that requisition to give
21 an additional \$5 billion?

22 MR. GREGOIRE: Well, the Administration

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1 proposed in the President's budget that was sent to
2 Congress an increase in funding in that neighborhood of
3 increase, which was really designed and justified
4 because of the increased workload that we've
5 experienced both in the number of permits that we issue
6 and the petitions that we have to deal with and the
7 cost of preparing NEPA documents either in house or
8 through contract.

9 Congress is also aware of the fact that in a
10 couple of the lawsuit in the first lawsuits on alfalfa
11 and sugar beets the agency may be liable for kind of
12 attorneys' fees in those cases, which are both being
13 adjudicated still.

14 MR. JAFFE: I have one other question. You
15 mentioned BRS spending some time on the farm bill in
16 2012, and I'm curious. What issues do you anticipate
17 BRS being involved in? Or what are the issues, the
18 biotech issues, that you think will be in this farm
19 bill coming up?

20 MR. GREGOIRE: The Ag Committees are
21 interested in the petition process, the time it takes
22 to move things through that process. They are

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1 concerned with the litigation issues that the agency
2 has had to deal with and the cost of that litigation.
3 So we especially in this process are called on to
4 provide information to the committees, to provide them
5 with briefings, to perhaps respond to or provide them
6 with input on proposals that they may be considering.
7 I don't know what USDA plans or what process will
8 ensure within USDA to make farm bill proposals, but I
9 just know -- my experience has been in farm bill years
10 on programs that are of interest in the Ag Committees
11 staff time is devoted to providing them with
12 information and answering their questions and things of
13 that nature, and it can be rather considerable when
14 they get into the thick of things.

15 If there's no more questions at this time, I
16 think we'll move on to the next agenda item. If you
17 think of additional questions though during the day,
18 I'll be around, and we can talk during the break. I
19 think we'll have any opportunity at the end of the
20 meeting if there are additional questions that people
21 think about or have. We'll build time in to talk about
22 those too. Thank you.

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1 MR. GEORGE: Thank you, Mike. We will have
2 lots of time at the end of the morning. We've put some
3 time available for other questions and also at the end
4 of the day.

5 Many of you know that advisory committee
6 known as AC21 have just completed the second set of
7 two-day meetings. This group has been charged by
8 Secretary Vilsack with working on coexistence issues.
9 It's a very diverse group with wide and varying issues
10 and background. The job of keeping it a focused on the
11 task at hand belongs to our next speaker. Michael
12 Schechtman is the Executive Secretary and Designated
13 Federal Official for AC21 as well as being
14 Biotechnology Coordinator for the Office of the Deputy
15 Secretary of Agriculture. And we're very pleased that
16 you're joining us today to fill us in. Michael.

17 MR. SCHECHTMAN: Thank, Dick. It's a
18 pleasure to be here, to be back in APHIS. I will say
19 before I start that Dick is one of the people that
20 could be doing this briefing himself because he has
21 been in attendance particularly diligently at the
22 meetings and taking notes. And I would also mention

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1 that we have one member of the committee at least --
2 and there may be other if my vision isn't working well
3 enough -- who's on the committee who is here at the
4 meeting and has been asking questions already, Greg
5 Jaffe.

6 So it's a pleasure to be here to brief you on
7 the AC21, what it is, how it works, what it's charged
8 with, what it's doing, how it got started, and a little
9 bit of history.

10 The AC21, the Advisory Committee on
11 Biotechnology and 21st Century Agriculture, which is a
12 funny acronym, but the real acronym doesn't roll off
13 the tongue, has been around since the beginning of the
14 George W. Bush Administration with a predecessor
15 committee that existed under the Clinton
16 Administration. It's been around for a long time. It
17 was quiescent for a couple of years, but its revival in
18 the past year is an outgrowth of the regulatory
19 decision last January on GE Roundup Ready Alfalfa.

20 You'll remember that last fall of 2010 there
21 was final environmental impact statement published as a
22 result of some legal action and judges' decisions

1 around the NEPA requirements for evaluating potential
2 impacts of podetency (ph) regulation of GE alfalfa and
3 specifically in the ruling, the need to more thoroughly
4 document, consider potential impact on the deregulation
5 on non-GE farmers. And there wear alternatives that
6 were considered in that environmental impact statement
7 that could have resulted in restrictions on the
8 planting of GE alfalfa.

9 There was a process that was undertaken at
10 the end of last year by stakeholders during the holiday
11 period last year to try to come up with a solution that
12 would address coexistence and satisfy the concerns of
13 those who were worried about the potential impacts of
14 GE alfalfa on their seed forage crops. When the
15 Secretary in January of this year announced the
16 decision to fully deregulate GE alfalfa, he
17 concurrently announced a number of measures to bolster
18 coexistence in alfalfa and other crops, one of which
19 was the reestablishment of the AC21.

20 I'll just sort of mention a few of the others
21 as well. There was additional research that was to be
22 done on gene flow in alfalfa. There was the revival of

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1 the Genetic Resources Advisory Council to address the
2 issues around the initiative of adequate purity of our
3 germination to germ plasma resources in alfalfa and the
4 adequacy and of crops and the adequacy of seed supply
5 to address the needs of all producers. There were some
6 small business grant opportunities and some other
7 things.

8 So the announcement of the revival of the
9 AC21 was, again, directed toward the issue of
10 strengthening coexistence among different agricultural
11 production types. So a process was undertaken in the
12 past spring to solicit nominations from a very broad
13 spectrum of stakeholders and experts, and members were
14 announced in June of this year. There are 23 members
15 on the committee with a range of interest represented
16 by the biotechnology industry to the organic food
17 industry, various farming communities, the seed
18 industry, the food manufacturers, state government,
19 consumers and community development groups, farmer
20 groups including one person who is a medical doctor,
21 and academic researchers. The chair if the committee
22 is Russell Redding who is a dean at the Delaware Valley

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1 College in Pennsylvania, and he's also the former
2 Pennsylvania Secretary of Agriculture, and he's a very
3 good Chair.

4 There are also ex officio members on the
5 committee. Currently, there are four of them from EPA,
6 the Department of State, USDR, and NIST, National
7 Institute of Standards and Technology for the
8 Department of Commerce.

9 Before I say more about what the current
10 committee is doing, let me digress for a second and
11 mention that in the previous iteration of the AC21
12 there was work that was done on coexistence as well and
13 a report that was produced at that time. And it was a
14 report that was written by the committee members
15 operating under rule where the reports were to be
16 produced by consensus. And that report, which was a
17 consensus report, described factors promoting and
18 factor inhibiting coexistence, but it did not have much
19 in the way of serious recommendations for what the
20 Department should be doing. And again, I think that's
21 part a function of the fact that it was a report that
22 had to be agreed upon by the entire committee.

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1 And our current Secretary, Secretary Vilsack,
2 wants more; and consequently, in the charter of the
3 committee, the rules have been changed somewhat to
4 facilitate the development of recommendations emanating
5 from the committee, not necessarily making it definite
6 that there will be, but to make it easier to do. So
7 for the new committee, what is going to happens is that
8 the Chair and I will draft a report, which is going to
9 capture the states of agreements and disagreements
10 around the issue and around recommendations on
11 coexistence, the state of consensus around these; and
12 if we don't capture it correctly, members will have an
13 opportunity to write (indiscernible) report if they
14 wish; not that that wasn't always possible
15 (indiscernible).

16 So the first meeting of the committee
17 occurred on August 30 and 31 of this year. The
18 Secretary spoke, actually, both he and the Deputy
19 Secretary were in attendance for a part of each of the
20 meetings. The Secretary spoke at both. The Secretary
21 spoke of the criticality of the agriculture for the
22 U.S., something that is too often taken for granted,

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1 the importance of preserving the livelihoods of all
2 farmers.

3 And he noted that different kinds of
4 agriculture all serve important and perhaps different
5 roles for the vitality of the farming community in the
6 U.S. as a whole so that, for example, production
7 agriculture is really very critical for U.S.
8 productivity and for our trade surplus in agriculture,
9 one of the few areas where we have trades surpluses,
10 but smaller farmers who may be employing other
11 production methods not involving GE may be very
12 important for the strength and vitality of rural
13 communities, keeping people on the land. He stressed
14 the reliance on science and his support for all farmers
15 and farmers' choice.

16 So the charge to the committee that the
17 Secretary gave them at the first AC21 meeting was three
18 parts, and I'll read each of them, but you should note
19 that parts 1 and 2 according to the charge are to be
20 accomplished first followed by part 3. The first part
21 of the charge was to address the question what type of
22 compensation mechanisms if any would be appropriate to

1 address economic losses by farmers in which the value
2 of their crops is reduced by unintended presence of GE
3 materials; so compensation for farmers because of
4 unintended presence of GE materials.

5 Second part: What would be necessary to
6 implement such mechanisms; that is, what would be the
7 eligibility standard for a loss and what tools and
8 triggers such as tolerances and testing protocols would
9 be needed to verify and measure such losses and
10 determine if claims are compensable.

11 Then the third part to be completed after the
12 other two would be, in addition to the above, what
13 other actions would be appropriate to bolster or
14 facilitate coexistence among different agricultural
15 production systems in the United States.

16 Let me point out two things about this
17 charge. First, is that it says what types of
18 compensations mechanisms, if any. So the Secretary has
19 indicated that he is not presupposing or prejudging the
20 response to that question. And the second one is the
21 compensation for farmers, not necessarily for everyone
22 who might be in the entire food production chain.

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1 So this charge addresses unintended presence
2 of GE materials in nonorganic, organic, and conceivably
3 in other GE crops. The Secretary also told the
4 committee not to be limited to what can be done under
5 current law, but to consider what are the
6 possibilities, what might work best if a solution is
7 warranted and to leave any further work on the issue of
8 how to get there to (indiscernible).

9 And again, I'll put as to the matter, the
10 work of the committee is a matter of keen interest to
11 both the Secretary and the Deputy Secretary having them
12 both in attendance at both of the meetings so far as --
13 it's a pretty rare thing in my experience on advisory
14 committees.

15 I should point out just to clarify. This may
16 obvious to everyone, but when we're talking about
17 coexistence in this context, we're talking about
18 coexistence of materials that are legally present in
19 crops, so we're not talking about materials that are
20 still regulated. We're talking about things that have
21 been approved for commercial use, and coexistence in
22 the framework of what the committee is thinking about

1 is the concurrent use of bio-FGE and identity preserved
2 non-GE consistent with farmer preferences to consumer
3 choices.

4 So at the first meeting, there were a number
5 of background presentations to the committee. The
6 committee decided at that meeting to set up four
7 working groups to do some work in between meetings to
8 help address this.

9 The first of these was in part to help
10 address if any question is a group addressing what are
11 the size and scope of risks that are out there and
12 either to think about the topic really of what is a
13 risk. Is it a detection of GE materials where it's not
14 supposed to be? Is it an economic loss? And kind of
15 think about those questions. A second group to work on
16 what are potential compensations mechanisms? What's
17 the range of possibilities? Third, what are the tools
18 and standards that might be needed to verify
19 eligibility and determine losses. And four, who pays.
20 Simple question to answer.

21 The working groups themselves do not make
22 decisions. They gather and organize information for

1 the full committee. Consequently, working groups don't
2 need to meet in public sessions. They report all of
3 their stuff to the full committee in public sessions.
4 They typically meet via conference call. The working
5 groups are composed of both AC21 members as well as
6 some selected additional folks from outside as well.
7 This helps to broaden the representation and ensure
8 that we don't need to use individual members on more
9 than one working group.

10 So the agreement in the first meeting was
11 that the first two of those working groups on the size
12 and scope of risk and potential compensation mechanisms
13 will have met already in the time leading up to the
14 second plenary session of the committee, which was just
15 last week. And much of the discussions at the plenary
16 were, of course, about the working group what they
17 should be doing, what they're requiring at this point.
18 So let me talk just very briefly about that.

19 The first group on size and scope of risks.
20 I've been grappling for a start to put the issue of I'm
21 having to gather decent data about what losses there
22 have been, what there is about detections of GE

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1 materials where it's not supposed to be, to be able to
2 evaluate what's the current situation. Some of the
3 members of the working group who work in a non-GE or
4 organic world have some data. USDA has a little bit of
5 data that it's looking at analyzing, and the committee
6 also wants to reach out to other organizations such as
7 Astea (ph) and BIO and also to the state seed testing
8 organizations under AYASCO (ph) who's done a lot of
9 testing, where we will be in all these cases looking
10 for scrub-and-sanitize data so as not to reveal any
11 confidential information that companies may have.
12 Also, we'll be working with the Economic Research
13 Service to do some of the analysis of this.

14 The working group in the first meeting talked
15 in general about the magnitude of rejections. It seems
16 there's sort of a consensus that risks at some level
17 exists, but the task to the committee is going to be is
18 not to decide if there are any risks or if there are
19 any lawsuit but rather to decide if any questions,
20 which essentially in my mind at least means is the cure
21 going to be worse than the problem and what's equitable
22 for the situation and what would be the broader impact

1 to competition where there isn't.

2 The second working group on potential
3 compensation mechanisms basically talked about what
4 kinds of mechanisms one could conceivably envision, and
5 there were basically four kinds -- to be fair three and
6 a half kinds of mechanisms that were noted. One was
7 some sort of general insurance mechanism of a farm
8 insurance.

9 Another is a risk retention group in which a
10 group of affected folks, which could be entirely self-
11 insured, could be a somewhat broader group, would get
12 together in what's called risk retention groups which
13 are a somewhat easier mechanism than crop insurance.

14 A third would be an actually compensation
15 identification fund, and the half that I mentioned for
16 the 3.5 would not be a actual payment mechanism but
17 some kind of increased use of agricultural remediation
18 services such as exist in 34 of the 50 states. And
19 what the potential compensation mechanisms working
20 group is going to be doing is describing each of these
21 and evaluating each of the different kinds of
22 mechanisms in terms of pluses and minuses based on a

1 number of evaluation criteria that are listed in the
2 plan of work for that working group, and these things
3 include things like avoiding conflict, cost and
4 benefits to consumers, cost and benefits to farmers,
5 cost and benefits to technology developers, potential
6 impacts on litigation and litigants, incentives for
7 development of upstream technologies to prevent risk,
8 impact on trade relations, and greater technology
9 development and use. So a pretty broad range of factors
10 to look at each of these to see what are the pluses and
11 minuses.

12 At the meeting last week also, the other
13 working groups were discussed as well. Some ideas were
14 offered about kinds of tools that could be relative to
15 making compensations mechanism work and bolstering
16 coexistence in general. And with respect to who pays
17 working group, that group is going to start its efforts
18 by trying to come up with suggestions and principles
19 that could guide the decision it made by the Department
20 as to who pay. So some general principles that would
21 help you decide what make sense and what doesn't and
22 what's equitable. And those principles could also be

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1 rounded to talking about compensation mechanisms as
2 well.

3 The expectation is the committees got to meet
4 four times a year. The intent is that a set of
5 recommendations will emerge for the Secretary by the
6 meeting that will take place around September. Each of
7 the working group is going to meet two times between
8 now and the next meeting, which will be in early March
9 and if necessary one or two times again between that
10 meeting and the next meeting two months later on.

11 So that's sort of a rough summary of where we
12 are. I think it's important to just note a couple of
13 things that the Secretary said about this process.
14 First, to reemphasize that he is not wedded to a
15 particular outcome. Second, that he has stressed the
16 reliance on science. And third, that he believes that
17 farmers should have the right to decide what it is that
18 they want to plant, but also that in these discussions
19 it's very important as he put it to lead from the
20 middle. And he said that you get a lot of attacks from
21 both sides when you do that, but that is his opinion.

22 So with that summary, I'll be happy to

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1 answers any questions that you may have. And I'll
2 also, since we have one committee member there, Greg
3 can correct me if I've skipped anything or emphasize
4 things in a final way.

5 MR. JAFFE: Great job as usual, Michael.

6 MR. SCHECTMAN: That's great.

7 MR. JAFFE: I didn't plan it that way.

8 MR. WHALEN: Dave Whalen, Forage Genetics. I
9 was wondering when any of that new gene flow on Roundup
10 Ready alfalfa might be published.

11 MR. SCHECTMAN: Well, actually I think the
12 grant was just funded relatively recently, and I think
13 the grant goes for a couple of years, so I don't know
14 -- as far as I know, they were collecting data from
15 fields, and I don't remember them getting all the
16 details of the experiment. They were collecting
17 samples this past summer, and there will be analysis
18 during the summer, fall and winter months. I don't
19 know exactly how long that will take, and how long it
20 takes to get from there to publication, but certainly,
21 it's a priority.

22 MR. WHALEN: Thank you.

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1 MR. GEORGE: I want to then thank Mike for
2 taking the time to share with us. I have to say having
3 had the opportunity now to attend both two-day meetings
4 over the AC21 as sort of an observer I had to say it
5 was a great experience. We have a front seat in place
6 to observe the dynamics of this entire group. And one
7 of the things that Secretary Vilsack emphasizes is that
8 -- and I think he's absolutely right about this -- that
9 this is very strong group of people, and if you sit
10 there and listen, as I did, to all of the interchanges
11 between these folks, you'll realize that there is a
12 very diverse, experienced, and a very deep knowledge in
13 that group and that if anybody is going to solve this
14 very difficult, challenging problem that these are the
15 folks that will do it.

16 And the other thing I would like to add to
17 Michael's comments is that it requires, I think, a rare
18 talent to pull all of this together and to bring out
19 the best in people around the table when they have
20 disagreements, different viewpoints, and different ways
21 of looking at things. And I have to say that we've got
22 (indiscernible) in the back right over here.

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1 will be walking you through in a little more detail the
2 petition process improvement project that by now most
3 of you have heard about. We had a big press release
4 and rollout at least at a very high level about three
5 weeks ago where we introduced some of the changes that
6 we're going to making to the petition process, and in
7 this morning's session I'm going to step back a little
8 bit to give you more detail about how we arrived at the
9 conclusions that we arrived at, how we decided to make
10 some of the changes that we're making, and also to kind
11 of give you a sense of how we intend to be implementing
12 these things over the coming months.

13 As we all know very well, APHIS has a process
14 by which developers of genetic engineering organisms --
15 starting to get a lot of feedback. Is that better?
16 Can everybody still hear me in the back?

17 Okay. I'll try to turn it down a little.
18 Let me know if I get some feedback then.

19 As I was saying, we have as part of our APHIS
20 biotechnology regulations the process by which the
21 developers of genetically engineering organisms can
22 petition us for a determination of the nonregulated

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1 status. Now until you get to that point in our
2 process, things are presumed to be regulated, and
3 you're required to have authorization from us for field
4 trials, for the partition in the United States, and for
5 interstate movement. So later after several years in
6 development, you can come to us with a petition to
7 evaluate whether this organisms should pertain to our
8 regulation. We've had this process in our regulations
9 since about 1992, and since that time, we've reached I
10 think 80 now different genetically engineered
11 organisms, different petitions anyway.

12 In the early 1990s when the process first
13 began, our average time for completing a determination
14 was about 178 days; but in the last few years, our
15 average is now closer to three years and in some cases
16 it may reach upwards of five years or longer. And we
17 currently have as a result of the backlog of -- well,
18 when I made the slides week, it was 22 petitions, but
19 now we're back up to 23 petitions in the backlog. So
20 we're getting farther and farther behind.

21 The slide illustrates I think pretty
22 dramatically just how the timeline in the process has

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1 changed over the years. What I wanted to show you show
2 you. If you can't see this on the slide you -- well,
3 you probably can't see them on the handout either. I
4 apologize. But this is the beginning of the process
5 when it was first put into the regulations in 1992 all
6 the way up to about 2009, and each point here is a
7 different petition to termination, and the height is
8 how many days it took APHIS to reach a decision, to
9 reach a determination.

10 So what we can see is throughout the 1990s we
11 were hitting steadily at maybe 200 days or less. And
12 then very dramatically and clearly, some happened
13 around 1999 that makes the process begin to get longer
14 and longer but also more highly varied more. So it's
15 not just that the length of time is getting longer, but
16 it's also the spread the timeline is getting a lot
17 longer. Also, I'll point out you notice the graph here
18 stops around 2009 because we have yet reached any
19 possible determinations of petitions that we've
20 received since 2009.

21 As a result of the clear slowdown and
22 variability, we certainly heard from all the

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1 developers; we've heard from stakeholders who wished
2 they would grow these crops, from our own Secretary of
3 Agriculture, from Congress. The situation of the
4 increased timeline and high variability needed to be
5 addressed and solved. This is an issue that the
6 Secretary of Agriculture himself has taken as a very
7 high priority, and he has put a lot of pressure on us
8 to figure out what's a different process to make it
9 become more timely and more predictable. This is just
10 a quote that he gave in at speech to the American Farm
11 Bureau Federation about a year ago. So certainly those
12 of us here in APHIS's Biotechnology Regulatory
13 Services are very personally pressured to figure this
14 out and to making real progress at improving the
15 system.

16 So to do this, about a year ago, we formed a
17 team composed of in-house staff who are expert in the
18 petition process. It was composed of our biotechnology
19 regulatory specialists, people from our regulatory
20 program that publish our documents, and other folks in
21 APHIS who actually worked on the petition on a day-to-
22 day basis. And we were tasked to tackle this problem.

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1 "What's taking you so long?" "Why is it so variable?"

2 "And what can we do to improve that."

3 We have worked very closely over the year
4 with Longevity and Associates, who are some
5 consultants who have been helping us deal with our Lean
6 Six Sigma process improvement techniques, which I'll
7 talk about a little bit more in just a moment. And we
8 formally launched this project in December of last
9 year, so we're about to summarize sort of a year's
10 worth of work.

11 Explicitly from the beginning, the goal that
12 we established for the process was to identify and
13 implement solutions to significantly and measurably
14 improve the speed and predictability of the petition
15 process without affecting the quality of the
16 decisionmaking because that's really something
17 important in how we structured the beginning. This
18 process improvement project was focusing very
19 specifically from the timeliness and the efficiency of
20 how the process was conducted. What we very explicitly
21 from the beginning determined is that we would not be
22 doing anything that would affect the quality of the

1 documents that we were preparing, cutting the wires on
2 how we do our risk assessment and so forth. This is
3 just focused entirely on the efficiency of the process
4 itself and not so much on the quality of output in all
5 this and so forth.

6 So the set of techniques that we used are
7 commonly known as Lean Six Sigma. This is a series of
8 business process improvement techniques, a package of
9 tools that the Secretary of Agriculture himself used
10 very successfully when he was the governor of Iowa.
11 This was originally developed for things like the
12 manufacturing industries to find way to streamline your
13 automobile manufacturing plants and so forth. But it's
14 also been utilized with success in service industries
15 like ours and issuance of welfare checks and those
16 types of things to really take a hard look at the way
17 they do business and to improve the efficiency of the
18 process.

19 In a jargonny (ph) sense, to give you a sense
20 of kind of what it is that we're doing behind the
21 scenes, Lean refers to examining your process where
22 you're cutting out all of the steps that aren't really

1 contributing to the final value of the process. By
2 value, we mean the quality of our decisionmaking
3 documents. So we're focusing all the parts that are
4 adding up to that that we're just sort of doing the
5 unnecessary handoffs, the delays caused by our
6 redundant reviews and those types of thing. If there
7 are ways that we can reduce those or eliminate them to
8 make the process more efficiently that's kind of what
9 we will focus on.

10 Another big part of Lean is focusing on the
11 differences in time between the elapsed time and the
12 actual work time to get a particular step done. This
13 is very often what we'll find in Lean Six Sigma is that
14 a person may be assigned a task and a lot of time pass
15 it forward and doesn't complete the task but because
16 the person isn't working on it that whole time.
17 There's a big difference in time between how long it
18 actually takes to get the work done and how long it
19 takes before they're actually finished to understand
20 the difference.

21 So then Six Sigma without being told the
22 details, this is basically referring to the normal

1 distribution of the quality at the end. And the idea
2 is that you're building a process to reduce the
3 variability, so in addition to making things shorter
4 and trying to find ways to make it more sort of
5 standardized and less variable in terms of the
6 timeline.

7 And finally, another thing that we're
8 considering is not just the timeliness of a single
9 petition going through the process, but our ability to
10 handle lots of petitions at once and how that may
11 affect the timeliness of the petitions, so it's a
12 capacity issue in addition to how long it takes for a
13 single one to go through the process.

14 And this is the last jargonny slide about
15 Lean Six Sigma, and I (indiscernible). One of the cool
16 things about Lean Six Sigma is it's different than the
17 way that we've done processing petitions in the past,
18 and so it's very methodically, that we're forced to
19 kind of slow down and not make any assumptions about
20 what needs to be improved and how to not just making
21 changes without really the data about whether it's
22 going to fix the problem or not. Instead, it kinds of

1 slows us down a little bit to say sort of "What exactly
2 is the problem that you're trying to fix?" And the
3 next step is to gather data about the current operation
4 of the process to figure out what's really causing the
5 process to go slowly to be kind of variable.

6 And then once you select those root causes to
7 the problem, then you develop solutions that are
8 specifically targeted to fix those problems. And of
9 course, the next phase is to implement them but also to
10 monitor those changes to make sure that they're working
11 the way that you expected them to work.

12 So in terms of just basically where we are
13 right now is that we have identified the solutions that
14 we want to implement. We've announced those solutions
15 to the public, but we'll start changing gears now and
16 working out all of the details of when they'll be
17 implemented and how and how we're going to monitor them
18 so that we make sure that they work correctly.

19 So now the process. This is where we're
20 getting into the data of exactly sort of lifting the
21 hood up on the biotech engine, see how things are
22 running, why things are going slow and variable.

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1 To do this analysis, we took a hard look at
2 all the petitions that have ever come into APHIS. This
3 includes 131 petitions in all that we've received since
4 1992 when the process was first built into the
5 regulatory system, and we looked at public data and
6 some of our internal databases about the variables for
7 how the whole steps that each of the petitions go
8 through.

9 And then to get a better sense of what's
10 happening right now with our petitions, we looked at
11 the most recent 30 petitions that have gone through our
12 system and are currently in house. That include all
13 the petitions that we received since 2005. And for
14 those, we really did an exhaustive analysis of what it
15 was that took those petitions so long to make it
16 through the system, what caused the variability.

17 And to do that, we really sat down that in
18 addition to our internal databases we walked through
19 and talked to the biotech and staff who actually did
20 each of the steps for each of those petitions and tried
21 to collect from their personal recollections, from
22 their emails, and so forth exactly what was going on at

1 the time that they were doing each of those steps to
2 get a better idea of really what was truly causing some
3 of those variabilities and the length of time.

4 The other thing that we gathered for this
5 detailed analysis is how long the work actually takes
6 to do. This may sort of seem sort of not intuitive,
7 but as I said before, there's often a very large
8 difference in the amount of time it takes for a step to
9 be completed versus how much work time it would
10 actually take if a staff member was allowed to work on
11 it full-time because they're doing lot of other things;
12 they're not necessarily doing it from start to stop
13 with no distractions. So we tried to estimate how long
14 would it take you to do this per step if you were
15 allowed to do just that step and nothing else.

16 One of the things that we found from slowing
17 down and taking a look at our data and sort of setting
18 aside any assumptions about what might actually be
19 causing the slowdown is that we found pretty quickly
20 that a lot of our assumptions about what was causing
21 the slowdown aren't actually true.

22 Now I apologize because this is probably very

1 difficult to see in your handout because you're seeing
2 it in black and white, but it also is a little
3 difficult to see here on the slide, so I'll walk you
4 through it slowly. What I got here in this graph is
5 these are all the years in the petition process from
6 1992 when it was first put into place until today. And
7 this blue line, which I'll kind of trace with my marker
8 here so you can tell what I'm highlighting, the blue
9 line represents the number of petitions that we
10 received in any given calendar year. So you can see
11 that there was a big peak in the number of petitions
12 that we have in the 1990s, and that peak declined over
13 time, so that we actually have fewer petitions coming
14 in now than we did in the 1990s.

15 So very often one of the stories that I think
16 we've repeated and we've heard other repeat is that we
17 have more petitions now than we've ever had. And it
18 turns out that's actually not true.

19 Another thing I want to point out too, if you
20 look at this red line, these are determinations of
21 (indiscernible) status in a given year, and I think as
22 Michael alluded to earlier we were actually making more

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1 determinations in the 1990s then we have been recently,
2 so you can see this as sort of the baseline currently,
3 roughly around maybe three or so per year for the last
4 several years, whereas in the 1990s we were doing more
5 something like 12 in one year at the peak. So receiving
6 more, making determinations on more back in the 1990s
7 than we are currently.

8 Another big difference to point out is the
9 number of petitions that have been withdrawn; that is,
10 at some point in the process the developer decided they
11 don't want to take the petition any further and
12 actually withdraw the petition before the determination
13 is reached. This is the green line here down at the
14 bottom. So you notice that actually there were more
15 petitions withdrawn in the 1990s also, so that
16 particular aspect of our regulatory system was used
17 differently back in the 1990s than it was now; at least
18 the ones that have been more recently.

19 So the difference in all of these is sort of
20 our accumulating total of the things that we haven't
21 yet reached a determination on. And what you can see
22 is that the purple line, this line right here, starting

1 around the late 1990s or early 2000s, our backlog goes
2 up and up and up. So right now we're actually more
3 like 23 total petitions in the backlog.

4 Another cause or assumption that we had was
5 that petitions could be much slower because they were
6 more complicated; the crop-trait combinations are more
7 difficult and so far, that that maybe somehow slowing
8 down the process. But what we found when we looked at
9 our data is that all of the crop-trait combinations are
10 slowing down even sort of the more common ones. In
11 this slide what I've done shows you -- oops.

12 So what I've got here is the number of days
13 required to make a determination for some of the common
14 crop-trait combinations. So here we've got herbicide-
15 tolerant corn, insect-resistant corn, and here's sort
16 of stacked insect and herbicide tolerant corn. Here's
17 the same things for cotton, all three combinations, and
18 the same for soy.

19 So what I think you can see I think pretty
20 dramatically is that even for these common crop-trait
21 combinations everything is slowing down. They're all
22 getting gradually slower over time.

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1 I should also point out too in this that we
2 get the lines that are cross-hatched are the ones that
3 are in house but have not yet reached the final
4 determination. So this is how many days and counting
5 as of the amount of time that they (indiscernible). So
6 basically everything is slowing down, not just a
7 certain number of things.

8 Another one that's a simple way of affecting
9 this, one of the ideas that we kind of tossed around is
10 whether petitions are getting more complicated over
11 time and more difficult to analyze. This is just a
12 very simple process to illustrate that. This just the
13 number of pages long a petition is for a petition, and
14 they're aligned by when we got them in the door. So
15 you see that even on the graph there might be just a
16 slight increase in the length of petitions over time,
17 but when we do the staff analysis, those were valued as
18 not significant. So while there is a slight increase
19 in the length of petitions in terms of pages over time,
20 even that's not really very supportive in terms of what
21 might be slowing us down.

22 When we looked at sort of behind the scenes

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1 what's going on and we looked at the petition process
2 over time, I've broken the timeframe in the last 20
3 years or so up into three chunks. This is sort of what
4 the timeline looks like leading up to that sort of
5 1999-2000 slowdown, so this is what it looked like
6 basically for the first 10 years of the process. Then
7 I broke out the rest of the process into the five-year
8 chunks.

9 So the way things worked in the early days is
10 that we would take about 50 days to review the petition
11 for completeness. Then almost immediately after that,
12 we would publish the petition for public comment; for a
13 60-day public comment period. And during that whole
14 time is when we would be preparing our environmental
15 analysis, and we would publish our environmental
16 analysis and our decision or our determination at the
17 very end, like I said before, an average time of about
18 180 days.

19 So one big change to the process from the
20 olden days is that we would publish the petition for
21 comment also as soon as it would be completed, and we
22 were doing our analysis at the same time in the

1 background, and we would publish our determination at
2 the end with our analysis.

3 So sometime around 2000, you'll notice that
4 all of the bars in the petition process gradually begin
5 to increase in length. The time it took for us to deem
6 a petition complete has gone from 48 days to 186 days
7 on average within about five years, and the variability
8 has also increased significantly. So it's 186 days
9 plus or minus a month and a half. The time that it's
10 taken us to actually publish the petition for public
11 comment has increased dramatically, and then the time
12 it takes to publish our final determination is now up
13 to about 500 days on average from the 2000-2005 period.
14 So something around 2000 and 2005 had dramatically made
15 all the petitions slow down and become more variable.

16 One of the big changes that happened around
17 this time is that we began publishing our environment
18 documents for comment earlier in the process. We
19 essentially waited to publish the petition for comment
20 until we had finished our graph analysis and then
21 publish the two of those together, so that's the big
22 change that happened in the early 2000s.

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1 So what you're seeing out here at this point
2 is that we're publishing the petition itself and our
3 analysis for public comment together; then after this,
4 we would revise our document and so forth and then
5 publish a final determination after that.

6 Then in the most recent five years, you can
7 see that it slowed down even more. All the steps have
8 slowed down. We've gone now from 186 days to 288 days
9 plus or minus three months to deem a petition complete,
10 a dramatically longer time to complete our risk
11 analysis and our NEPA analysis and then the -- I think
12 this is a little inverse -- even our 60-day public
13 comment period, it doesn't increase over time.

14 MR. NESBITT: But the average for a 60-day
15 comment period is now 82 days over the last five years.
16 That's because we have more frequently increased on our
17 reopened portion of the comment periods and so forth,
18 so even that time has been increasing recently. To the
19 point now of the final decisions over the last five
20 years is approaching three years. But the other thing
21 to note too is three years and plus or minus 363 days.
22 So not only has some reports been getting longer and

1 longer, it's becoming far more variable in terms of
2 when the determinations will be finalized.

3 In terms of the summary of what we see from
4 our data, first obviously is there has been a very
5 larger slowdown and increased variation of all of the
6 major process steps over time since about 1999. It's
7 not that any one particular part has gotten longer and
8 more difficult. They all seem to be slowing down over
9 time.

10 There have been a few process changes in the
11 history of the BRS petition process, and one of the big
12 one is, of course, the timing of our petition relative
13 to our analysis, which switched around 2002. As I
14 pointed out before, more petitions were withdrawn in
15 the early days of the process than there are now. And
16 another thing that I didn't mention before is that we
17 make more frequent use of the extension process in the
18 2000s than we did now. Extensions are a shortened
19 version of the petition process where instead of in a
20 petition where we compare the GE organism to other
21 conventional crops, with an extension process, we're
22 basically comparing the new GE crops to one that we've

1 already looked at, so it's sort of a shortened review.
2 But we did that much more frequently in the first
3 decade than we have recently.

4 Another thing too that I had better point out
5 is that we reopened comment period is a lot more longer
6 in the last five years a bit more.

7 The other thing that we found sort of behind
8 the scenes is that even though all of the petitions
9 more or less follow the same process in the background,
10 when you really get down into the detail level of which
11 staff is working on what in what order we found that
12 there is a great deal of variability, that the process
13 isn't always exactly the same behind the scene in terms
14 of who writes which section, who does the reviews and
15 so forth. We found a lot of variability behind the
16 scenes.

17 And the other thing we identified was
18 actually work time; the amount of time it takes for our
19 staff, and other staff, to do a particular step is
20 relatively small compared to the actual amount of the
21 elapsed time to complete that step. And the reason for
22 that is that typically, especially in the biotech group

1 and our scientist group, they're working on a lot of
2 other things at the same time. So their only function
3 isn't working the petitions.

4 In addition to doing petition review, they're
5 issuing permits and notifications; they're helping us
6 work on rule revisions; they're helping us prepare
7 administrative records; they're going to meetings like
8 this. So they're juggling a lot of different and other
9 competing priorities with their time.

10 So what we found is that a big difference
11 between work time and elapsed time is more related to
12 how we're managing our staff's time relative to other
13 priorities rather than the fact that the work itself is
14 taking more of our time.

15 So then this kind of gets down to the causes.
16 What is actually causing the slowdown and the
17 variability and timing? And what we found is that some
18 of the common explanations really are not supported by
19 our data. It really does not appear to be true that
20 things are slowing down because we're getting more
21 petitions. Things like petition complexity, petition
22 length, and so forth really don't appear to be the main

1 causes of slowing things down. And that, I think is
2 not maybe surprising to say that publicly, but this is
3 really not a very surprising finding for everything
4 (indiscernible) Six Sigma (indiscernible) that affects
5 the business processes. But really at heart, it's more
6 about the efficiency of the process, how we do the
7 steps, how we manage our staff resources, and less
8 about the substance of the work exception.

9 So what we found is just that. The primary
10 root causes of the slowdowns were more related to how
11 we're managing the process, that we have unclear or
12 variable process steps, that we don't have deadlines
13 for most of the steps behind the scene, and we've had
14 some difficulty in tracking work in progress to sort of
15 find who's working on what and how far along they are.

16 And the other thing that I kind of mention
17 before too is that there are a lot of competing
18 priorities for our staff who are doing all the work on
19 the petitions.

20 So in order to fix this and to really fix it
21 and not just sort of (indiscernible), we really have to
22 focus on addressing what's causing the slowdown and

1 make improvements that will get at that and not some
2 sort of guess of what we think might be slowing things
3 down.

4 So that's where we changed gears then and
5 have really now focus on building a better mousetrap.
6 What can we do to make the process become more
7 efficient, more timely, and more predictable, more
8 proficient really, without sacrificing any of the
9 quality of that analysis that's an important part of
10 the process?

11 So in general, here are some of the types of
12 things that we're implementing. Most of the type of
13 things that we're talking about are the unglamorous,
14 behind-the-scene kind of changes where we're really
15 just streamlining the process; we're eliminating steps
16 that are redundant or unnecessary or that aren't really
17 adding value to the decisionmaking at the end, and
18 we're building in sort of standard timelines and
19 deadlines for staff. So the vast majority of the
20 improvements that you're going to see are those kinds
21 of behind-the-scene, under-the-hood kind of adjustments
22 to the process.

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1 We're also developing some resources
2 management tracking tools to help our supervisors
3 better manage their staff's time especially as they
4 relate to other priorities that our staff are having to
5 work on.

6 Another feature that you'll see be a common
7 theme is that we'll be more clearly separated the test
8 risk assessment functions of the petition process from
9 the new work-related functions. And I think most of
10 you are familiar with the terminology, but basically to
11 kind of recap, the fact-test risk assessment is the
12 basis of our regulatory determination: Is the organism
13 more than likely to pose a plant pest risk or not. So
14 that's the analysis that our scientists prepare to be
15 the basis of our determination.

16 We do an additional analysis on top of that
17 to comply with the National Environment Policy Act.
18 These are the things that we call environment analyses
19 or environmental impact statements. And that then will
20 evaluate the potential impacts on the human environment
21 of our regulatory determinations. So we do both of
22 those. But historically, we've had a lot of overlap

1 between the two of those and which staff doing which
2 motion. So one of the things that we're going to build
3 into the new process is more critically separate those
4 two activities because if anything it helps us manage
5 our staff's time a little bit better.

6 And finally, one of the biggest public
7 changes, most visible changes that you're going to see
8 to the process going forward is that we're going to
9 change the way that we seek stakeholder's input, public
10 input, on a petition process. And I'll give you a
11 little bit more details of what that means here next.

12 Now what I'm going to do is walk you through
13 step by step -- why won't that not go backwards. It's
14 stuck. It's no longer able to. I bet that's why
15 it's...

16 MR. NESBITT: Yes, this is the kind of thing
17 process improvements (indiscernible).

18 MR. NESBITT: So everyone check the handouts,
19 and I've got a copy up here as well. So I'll just
20 continue to walk you through the slides without my
21 PowerPoint presentation, and we'll see if it comes back
22 on at some point. Unfortunately, I can't use my fancy

1 laser pointer or anything, so I think it'll be a little
2 more challenging.

3 In the next slide, I've got the first few
4 steps of the new petition process, and I'm going to
5 walk you through some of the key new changes in terms
6 of the order that they come in the process.

7 With the new process, basically what will
8 happen is that when we receive a new petition we will
9 very quickly mobilize the team scientists to basically
10 work on completing this review full-time. One of the
11 things that we found that's a big sort of time
12 constraints on the old process is that the team of
13 scientists who were reviewing your petitions were
14 working on lots of other things at the same time
15 they're reviewing petitions. So to help speed that up,
16 we're basically going to task people to petitions that
17 they have all of their other work responsibilities
18 cleared or largely cleared at that particular moment,
19 so they really can just focus on the petition itself.

20 So one big change that you'll be seeing
21 pretty quickly is that the amount of time that it takes
22 us to either deem the petition complete or to get a

1 deficiency letter back to the petitioner will be
2 greatly shortened. And we're not doing anything in
3 that step to truncate the way we do the completeness
4 review or to cut corner in the actual review itself.
5 It really is just more giving the scientists more time,
6 full-time, to focus on it.

7 So this first step, like I was saying, the
8 completeness review will be greatly shortened. We
9 think that we will be setting aside staff for about a
10 month to work full-time or less so that from the time
11 you submit your petition until the time that you hear
12 back from us our target goal will be about a month. So
13 that's dramatically faster than it has been in the
14 past.

15 The other thing that will be a different
16 feature of our completeness review is we'll be focusing
17 entirely on the requirements from 7 C.F.R. 340.6. That
18 is the what you are required to submit under
19 regulations, the data that we need to drive our plans
20 for first assessment. We will not be at this point
21 reviewing additional data we might want have to
22 complete our NEPA analysis. It really will be, just at

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1 the beginning, what do we need to draft our plant pest
2 risk assessment.

3 So within a month, if there are deficiencies,
4 you will get a letter back from APHIS -- Greg, my
5 (indiscernible) doesn't work.

6 MALE SPEAKER: Oh, man.

7 MR. NESBITT: So you'll learn about it from
8 APHIS in about a month. And in this case, another good
9 change that we'll be adding to system is that there
10 will actually be sort of a timeframe within which we
11 will ask the companies to respond to our deficiency
12 letter. What we found over time is that when we're
13 waiting on companies to give us data back again that
14 basically it's very bimodal, fall into two puddles.

15 One are the sort of superficial changes that
16 we need the company to clarify whether they conducted
17 this experiment or answer a few sort of technical
18 questions that we may not have understood. Those
19 responses that will come back fairly quickly, but in
20 cases where we're actually asking a company to redo
21 some analyses or conduct additional tests that they
22 hadn't conducted it didn't take much longer for

1 products that are a year or more.

2 And unfortunately, the way we've been keeping
3 of things is that that time that it's with the
4 companies sort of counts it in the process in terms of
5 this whole timeline, so that helped administratively
6 keep track of that better. Basically, what we are
7 going to do is that if there are deficiencies we'll ask
8 the companies to come back to us within 30 days. If
9 you do respond at that time, then we'll continue with
10 the timeline for us the way that we described. But if
11 we don't hear back from the companies within 30 days,
12 we'll basically treat the petition as incomplete, and
13 then you are free to come back in at any time whenever
14 you want to just like you normally would, but we'll
15 basically be treating it as a new petition when it
16 comes back in the second time.

17 From the perspective of the developers, you
18 really shouldn't see any difference because when you
19 come back in in all likelihood you'll still have the
20 same team of biotechs; you probably will not have a
21 review that will take any longer because of previously
22 petition because we're already looked at it once

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1 before. But otherwise, this gives us the opportunity
2 to kind of drop the ones from our books that we're just
3 sort of waiting on, but it also allows us to free up
4 our resources to go work on other petitions instead of
5 sort of keeping a standing team waiting until that day
6 who knows when when we'll get more data back.

7 So like I said before, most of these
8 petitions fall into two camps. The median time is
9 currently about 50 days, so we think that for those
10 quick-turnaround things, different petitions, having
11 problems getting back to us, for the longer term things
12 we'll treat them as a new petition when they come back
13 in later.

14 So then when it comes back in, if there are
15 deficiencies, then we will very quickly give the
16 petition another final review; and assuming that you
17 have met the deficiencies that we've asked to be met,
18 then the big new change is that we will immediately
19 publish the petitions in the Federal Register for 60-
20 days public comment. This is going back to the way we
21 used to do things in the 1990s, and it's actually
22 consistent with the way that our regulations describe

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1 how the process should be that when we have deemed the
2 petition complete we publish the petition for 60-days
3 public comment.

4 There are a couple of different reasons why
5 this is a big improvement. First, it gets the petition
6 in the hands of the public much earlier. And in
7 effect, we can use this now as scoping for our
8 analysis. So in the Federal Register notice when we
9 publish the petition, we'll basically be saying,
10 "Company X has come to us and proposes to grant us to
11 determine nonregulated status. We're thinking about
12 it. Here are the types of issues that we will be
13 analyzing in our environmental analysis," and we can
14 solicit additional feedback from the public at the
15 beginning in what types of issues that we should be
16 analyzing in our NEPA analysis. Greg, actually I think
17 it was working -- no, it's the latest requirements, but
18 I think I can do it without that, unless you want to
19 stand up and do it.

20 MR. NESBITT: I can make do without
21 (indiscernible).

22 MALE SPEAKER: Oh, that's fine.

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1 MR. NESBITT: So anyway, one of the
2 advantages of putting practice early is that, first,
3 we'll get better -- we can make better use of public
4 input; that is, that instead of waiting until the very
5 end until we've done all our analysis and then our
6 concern with the position of reacting to public input,
7 instead, we get public input early and can take that
8 and make considerations in what it is we analyze. So
9 we're basically using it much more effectively now.

10 The other thing I'll mention of doing the
11 public comment period early us that -- and by early I
12 just to find out the timeline they were looking at. So
13 from the time that we get the petition in the door
14 until it's published in the Federal Register, we'll
15 looking at total of a little more than three months.
16 So from receipt of the petition, if the company can get
17 the data back to us within a month if there are
18 deficiencies, the petition would be published in the
19 Federal Register in just a matter of months. So it's
20 dramatically earlier than it has been in the past.

21 As I was saying, in addition to using public
22 input more effectively, we can -- Okay. So during the

1 60-day comment period by closing the comment period
2 earlier, there's actually more work that we can be
3 doing in parallel so that we don't have to wait for
4 everything in series.

5 While the petition is being published for a
6 60-day comment, we can begin preparing our plant risk
7 assessments, so that's the basis for our determination.
8 And if we will be using contractors to prepare our NEPA
9 analysis, which is becoming a little more common these
10 days, we can actually start lining up or contractors
11 during that 60-day comment period so that by the end of
12 the comment period, we have this package of nine things
13 that we can hand off to either our NEPA staff or to
14 contractors who would be helping us prepare the NEPA
15 analysis. We can give them this draft risk assessment.
16 We can -- we've obviously got the contractor lined up
17 lined up -- but we can also hand off those public
18 comment to our NEPA staff to actually begin doing the
19 environment analysis, so that it sort of informs our
20 analysis.

21 The standard timeframe that we're building in
22 right now to prepare that environmental analysis is

1 about six months. That's the current timeline that
2 we've been using over the last year at least for
3 contractors, and we think it takes about the same
4 amount of time to prepare in house. But as we'll talk
5 about a little bit later, we also have this NEPA Pilot
6 going on. Isn't looking at ways of making the six-
7 months steps effective or more efficient. So at least
8 for purposes of the overall process improvement, we're
9 setting aside about six months to get our NEPA analysis
10 done.

11 The other thing I should point out too is
12 this, of course, presumes that we will be preparing
13 internal analysis. Now it's very possible that what
14 will happen is that doing the 60-day comment period,
15 which we now get at the beginning, that comment period
16 may inform a decision to prepare an environmental
17 impact statements, which could now happen much earlier
18 in the process. So it's very possible, or conceivable
19 anyway, that public comment would lead us to not
20 preparing either right away, but instead switch and
21 prepare our normal impact statements from then on.

22 So even though the rest of my slides here

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1 talk about environmental assessments, I'm just assuming
2 it's an environmental assessment because that's what we
3 typically do. But if we do switch at this point to
4 prepare an EIS, all bets are off in terms of those
5 timelines because we haven't read that many, and we
6 really don't have and a good sense of how long it
7 takes, but I think reasonably it may be in a year or
8 two if we go down the EIS path.

9 If we do prepare an environmental assessment,
10 then we would go through the normal agency clearance to
11 publish something. But the other new addition to the
12 public engagement process is that the path would have
13 one or two forks now at the end.

14 So the first path -- and this is a little bit
15 different than the way we've been doing it -- for those
16 petitions that represent fairly common crop-trait
17 combinations, this is sort yet another Bt corn, another
18 Roundup Ready soybean, sort of the same things that we
19 see repeatedly, in those cases we would publish the EA
20 as a final EA with a preliminary determination. So
21 basically what we would say in that notice is that we
22 have reached a preliminary determination that this

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1 should be given nonregulated status and that if we
2 don't get any new information that would cause us to
3 change our determination or our analysis in 30 days
4 then that determination would automatically go into
5 effect.

6 So this is sort of a public review period.
7 This is published in the Federal Register. At the end
8 of that 30 days, we would review any information we got
9 if any, and then the final determination would go into
10 effect. We haven't quite worked out how we would
11 publish that, but basically at minimum, we would issue
12 a press release and publish it on our Web site, and we
13 would notify the petitioner. But, nonetheless, this
14 wouldn't be a third Federal Register notice. It would
15 just sort of go into effect the end of the 30-day
16 period.

17 We have two, and this is for petitions that
18 raise new issues that we haven't considered in the
19 past. Typically, we think they would new crop-trait
20 combinations, things that raise new issues. Then we
21 would continue the process more or less the way we have
22 done in the past. We would publish our draft

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1 environmental analysis as a draft for 30-days public
2 comment. At the end of the 30-day comment period, we
3 would then require an environmental assessment as
4 needed. We would prepare a determination; then there
5 will be a third Federal Register notice that publishes
6 our final EA and our determination.

7 Now, again, this presumes that we can
8 actually reach an FONSI, which is sort of the way that
9 the legal process ends for NPA. If we're unable to
10 reach at this point a conclusion that there are other
11 significant effects on the environment, then another
12 fork in the path will take place here, and we'll
13 prepare our old impact statement. So this, again,
14 kinds of presumes that we can reach a FONSI, and we may
15 not be able to in every instance.

16 So in total, this path now takes a little
17 over 13 months; and for the slightly longer path, we're
18 expecting a little over 16 months. So you can see,
19 it's a dramatic improvement in the timeline relative to
20 what we have been doing when we were taking two and a
21 half years or often significantly longer.

22 In regards to how this overlaps with our NEPA

1 Pilot, we'll have another presentation I think
2 immediately following me to talk in a little bit more
3 detail. But basically, the gist of the NEPA Pilot is
4 that we're exploring two new mechanisms that makes the
5 preparation of NEPA documents more efficient, the
6 quality and the time invested, and so forth. And the
7 two mechanisms are using a petitioner-provider
8 environmental report. So basically, the petitioner is
9 preparing their own kind of sort of NEPA analysis that
10 we would then use to help to form our own NEPA
11 analysis, and we'll give you more details about that
12 later.

13 And the other mechanism is that the
14 petitioner is funded us to use a contractor to prepare
15 a NEPA document, so it's sort of a three parties and
16 stuff. Again, I won't get into the details there, but
17 those are the new mechanisms that we're at least
18 evaluating as a pilot.

19 As I mentioned before, of course, we've had
20 this ongoing NEPA Pilot in parallel to the overall
21 petition process and request. We're basically counting
22 around six months for preparation of an environmental

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1 assessment because those are the sort of standard
2 timeframe we're getting now, but that could change
3 given the outcome of the pilot if we find other time
4 savings.

5 So we've gotten, said this first of all,
6 there are some question about for those companies or
7 developers who are preparing environmental reports in
8 the pilot, how does that sort of line up with the
9 timing of the new process. And while I think there
10 remains a little bit to seen, we're still kind of
11 working out the details about how it works, the best
12 way of doing that. I would say that definitely in
13 order for your environmental reports to be helpful to
14 us we should get them before we start our environmental
15 analysis so it can make sense. But now our
16 environmental analysis starts at the end of that 60-day
17 comment period on the petition, so that means if you
18 want to send and ER to help us do our NEPA analysis,
19 you will have to get it in by then.

20 The other thing is that some people have
21 asked would the ER be published if at all. Then again,
22 we haven't figure out how that would work; but,

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1 noneththeless, I think that it's fair to say any document
2 that is submitted by developers will be made available
3 to the public whether they're published with the
4 petition, again, or they're published later with our
5 environmental analysis as supporting documents. At
6 some point in the process, they will be published. I
7 think what we're leaning towards at this point is that
8 it comes in with a petition we would publish our
9 comment with the petition, but we're basically only
10 asking for comment on the petition itself. We're not
11 soliciting input on the petitioner's environmental
12 documents. So that's kind of the basis gist of our
13 thinking like on how that would play out. But,
14 noneththeless, the bottom line is that it will be
15 available to the public at some point in the process.

16 So finally, I'm going to talk a little bit
17 about our current thinking on how this will be
18 implemented so you all get a sense of the timing over
19 the next few months. First, I would say with the
20 behind-the-scenes improvements that would relate to the
21 process are taking place right now, so we're already
22 changing the way we manage our staff time. We're

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1 building some new tools to track things differently
2 than we have in the past and so forth, setting up
3 deadlines, and those kinds of behind-the-scenes things.
4 Those are already being implemented now.

5 In terms of those bigger, more public changes
6 that I was talking about particularly in regard to how
7 we engage the public and public input on our petition
8 process, we're not going to implement those changes
9 until we publish our Federal Register notice that more
10 clearly lays out what that process is going to look
11 like, our criteria for deciding if it's going to be
12 path 1 or path 2 at the end and so forth. And that FR
13 list is being developed now, so I think you can expect
14 to see that probably about the first of the New Year or
15 so, early in the New Year.

16 But, again, I want to stress we're not going
17 to make those changes until we've given a public notice
18 that we're changing that part of the process, which
19 really is a significant enough change in the way that
20 we engage the public that we want to make sure that
21 people really do understand how there are opportunities
22 for participating in the process that is going to

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1 change in the near future.

2 So then once that notice is published, that
3 will help inform which petitions will be going down
4 which path, whether it's the new path or the old path.
5 Here's a little bit better idea of what I mean by that.

6 So here is the sort of summary of where all
7 of our 22 petitions are in house. This number actually
8 I think should be seven now. It was initially 12, and
9 now we have more petitions, so this number should be
10 seven. And this also doesn't include the two EISs that
11 were prepared, so it doesn't count sugar beets, and it
12 doesn't count (indiscernible) grass. Nonetheless,
13 these should add up to 21.

14 Basically, what will happen or what we think
15 we'll use as sort of a schema for how we're going to
16 transition things to the new process is it really
17 depends on where they are currently when the Federal
18 Register notice is published.

19 So, for example, we have two petitions that
20 are currently in house for which a draft environmental
21 analysis has already been published. We already have
22 public comments on those, and we're preparing our EIA

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1 and determination now. For those, it doesn't make any
2 sense to switch to the new process because they're
3 basically already done. So we expect that those
4 petitions will sort of play out in the current process.

5 Now if we switch gears and look at things in
6 the front, so things that we're currently reviewing for
7 completeness, it's very likely that those petitions
8 would then be transitioned fully into the new process.
9 So once we've deemed them complete, then we would begin
10 publishing those petitions for comment at the
11 beginning, and then follow the rest of the process the
12 new way for those.

13 The same is probably true for those for which
14 we've already began preparation of the plant pest risk
15 assessment. In all likelihood, those would also have
16 the petition published because it's still not too late
17 to have public input on the petition to inform the
18 development of our NEPA documents.

19 Now for these that are in the middle, for
20 which we've already deemed them complete, we've already
21 finished our plant pest risk assessment, and we have
22 already began to prepare our environmental analysis,

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1 the switch to the new process, or the old process, will
2 really depend on how far along the EA is in
3 development. For example, some of these EAs in house
4 may be almost finished, so it really is not efficient
5 to backtrack, publish the petition for comment, and
6 then go back forward to the new process again.
7 Instead, for those that are almost done, we would
8 probably follow the old process. They would go out for
9 60-days public comment with the petition, and they
10 would follow sort of the old path.

11 For those that we are just beginning, then
12 we're thinking that we would probably switch them to
13 the new process if we would still have some benefit
14 from publishing the petition; it's not too late to make
15 use of the public scoping basically, and those are very
16 complicated. Again, we're not going to make decisions
17 petition by petition until we're ready to pull the
18 switch.

19 But when that happens, we will publish on our
20 Web site; we'll communicate with all the companies, and
21 let you know sort of which path your petition will be
22 in, and it will be steered to where it's fully

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1 implemented. But, nonetheless, that gives you a general
2 idea of what we're thinking.

3 Now the other thing to keep in mind too is
4 look at how quickly we're going to have a logjam. If
5 we have actually seven petitions now that are under
6 review for completeness and now the new process will
7 take a matter of months, assuming that the companies
8 come back to us with the completed data, we have PPRAs,
9 which will be completed within a matter of months. And
10 we already have seven NEPA documents in preparation, so
11 what will happen is as these accelerate over the next
12 few months, we're going to have a huge logjam of these
13 10, actually 12 now, catching up with the other seven.
14 Do you follow that?

15 So what's going to happen is next spring
16 basically almost all of our petitions will be sitting
17 with our poor, small NEPA branch. So they will have a
18 huge backlog next spring of analyzing the environmental
19 effects of a very large number of petitions all at
20 once.

21 So the point that I want to make is that
22 despite the fact that we're implementing all these

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1 process improvements and we designed a process that
2 will go much faster, the process still will not be
3 fully up to speed until we have cleared out a big part
4 of the backlog. I don't want to give anybody the
5 impression that it would work if you were to withdraw
6 your petition and then resubmit.

7 MR. NESBITT: Because it really is like
8 everything is in the same pipeline. It really will not
9 speed things up if you try to (indiscernible) on these
10 lines. We've got to get all of them moving again in
11 order to catch things up.

12 Our current estimates are that we will be
13 able to clear out the backlog -- I mean with all the
14 additional caveats of whether to do an EIS and so
15 forth, but we'll be able to clear out much of the
16 things that are in the backlog within about a year. So
17 we think that we're going to be fully operating at
18 normal speed roughly in a year or so from now. So
19 petitions that come in tomorrow, you probably shouldn't
20 expect them to take 13 to 16 months; but petitions that
21 come in a year from now maybe they'll run into that
22 speed.

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1 And again, we haven't tried all these things.
2 We did our best to make them based upon the data that
3 we've got on hand, our best guess about how long the
4 work takes, reasonable timeframe, and so forth. So as
5 we go forward implementing changes, it will be a
6 learning experience, and we may find that some of these
7 things don't work or that we can do things faster than
8 we thought we could.

9 I should emphasize too that these are our
10 best guess for how long thing will take, but we expect
11 to learn a lot more as we go forward.

12 So, finally, stay tuned. As I said, we're
13 transitioning from the phase of identifying the changes
14 that we want to make to figuring out how to implement
15 them. So in the very near future, as I said, shortly
16 after the first of the New Year, you should see a
17 Federal Register, you should see from us giving more
18 details about the changes in the stakeholder's input
19 part of the process. And then shortly after that,
20 we'll begin making decisions about which petitions will
21 go down which paths at the end.

22 We will also keep posting additional

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1 information as it develops on our Web site. We'll send
2 stakeholders emails to everyone on our listserv, so be
3 sure to get signed up for that stakeholders register if
4 you're not. And once we make decisions about specific
5 petitions, we will, of course, engage with each of the
6 petitioner to let them know about the specifics or
7 advances of their petition.

8 So I think with that, we have plenty of time
9 for comments and questions. As I said early, I should
10 just warn you, that we still working out some of the
11 details of how they will be implemented. But if I'm
12 not able to answer those now, we've got this marker
13 board here, and I do want to capture your question so
14 that we can get them resolved and get back to everybody
15 else if I'm not able to answer them now. Got any
16 questions? Yes.

17 MR. JENKINS: Thank you for the presentation.
18 I'm Dan Jenkins from Monsanto

19 MR. NESBITT: Okay.

20 MR. JENKINS: Yes. And a question for you on
21 the process we have Path 1 and Path 2 laid out --

22 MR. NESBITT: Yes.

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1 MR. JENKINS: -- and under Path 1, you said
2 that there would not be a posting in the Federal
3 Register at the end of that process --

4 MR. NESBITT: Correct.

5 MR. JENKINS: -- to communicate that a final
6 determination had been made. So do you see that a
7 letter would be coming from the -- something that would
8 be used to show official --

9 MR. NESBITT: Absolutely.

10 MR. JENKINS: Okay.

11 MR. NESBITT: Absolutely. Because if we're
12 saying basically after a 30-day review period if we
13 don't get any new information that would cause us to
14 change our determination that the decision would go
15 into effect. But, nonetheless, we'll do something to
16 confirm that it went into effect and that we didn't get
17 any information. So we do envision sending letters to
18 the petitioner, posting online in the Web site, press
19 release, those types of things. But we're not
20 envisioning going through another whole Federal
21 Register notice.

22 MR. JENKINS: Okay. Thank you. And in terms

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1 of -- thank you. And in terms of what you would
2 publish on the Web for public comment, how do you see
3 the agency dealing with things that are confidential
4 business information in a petition?

5 MR. NESBITT: Well, if it is confidential
6 business information, we can't publish it. So there is
7 a tradeoff, in terms of claims of confidential business
8 information in petitions, I think that our standing
9 practice has been to discourage to the extent possible
10 of making claims about CBI in petitions. And
11 certainly, we don't have to publish the CBI after the
12 active version of the petition to the public.

13 But there are consequences of that happening;
14 we're basically in the petition as scoping; if there
15 are parts of that petition that are blanked out, the
16 public can't comment on the scoping because that may
17 limit our ability as how we would analyze those and
18 forth in the future. But generally speaking, we've
19 been trying to discourage people from putting CBI in
20 petitions because it will have some effects on how we
21 make analysis and public engage us.

22 MR. JENKINS: Thank you.

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1 MR. WHITE: My name is Jim White, and my
2 comments are for people that just left.

3 MR. WHITE: Mr. Gregoire and Dr. Firko. I'm
4 an AG plant pathologist, and I'm retired, but I was
5 either manager or comanager of the biotech group from
6 1991 to 2002 when it became BRS, so much of that is the
7 time that Clint was talking about in the previous
8 process. I'm going to withhold judgment on this
9 reinvention because basically it's going back to --
10 some of it's going back the 1990s, and we evolved to
11 these changes in 2000 based on lawsuits and general
12 counsel. But, here's the dead elephant in the room.
13 Back in that time, we had about four or five scientist,
14 biotechnologist, per policy person, and that
15 distribution is quite different in BRS.

16 I don't see -- and I predict that there won't
17 be any great change in the review process because John
18 Turner's staff is basically the same size as it was
19 before. And until you put more effort on the
20 scientific part, that's the way that you can move the
21 process forward.

22 MR. NESBITT: Mike, would you like to

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1 respond?

2 MR. GREGOIRE: I believe the changes will
3 have an impact, and as I pointed out this morning, we
4 received a \$5-million increase in our appropriations
5 this fiscal year; and as I pointed out, that increase
6 was proposed in large part to put more resources into
7 this process, and that where I see a lot of these new
8 resources going into staff that works on the petitions
9 and on the NEPA analysis that inform those decisions as
10 well.

11 So we are in fact putting more resources into
12 this effort to accompany the actual process changes
13 that are being made.

14 MR. WHITE: So that mean you're hiring for
15 scientists?

16 MR. GREGOIRE: We expect to, yes.

17 MALE SPEAKER: (off mic) And our legal staff
18 has grown by three in the past year, maybe year and a
19 half, so it's grown significantly, and there is just a
20 lag on the (indiscernible).

21 MR. MENCHEY: Hey, Cliff. Keith Menchey of
22 the Cotton Council. Could you give me an idea of what

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1 volume of comments that you get on these, the Federal
2 Register notice, in term of volume and perhaps a feel
3 for who it is that is responding?

4 MR. NESBITT: Who it is that's responding to
5 the comments or responding from -- who's making
6 comments?

7 MR. MENCHEY: Yes. What portion of the
8 public are making comments, if you could generalize?

9 MR. NESBITT: The proportion of the public
10 making comments is very small, but I would say that
11 generally it's extremely bimodal. Most petitions have
12 extremely small number of comments, and sometimes in
13 order of 4 or 5, 10, 12, something like that. But then
14 there are a few petitions that go through that have
15 tens of thousands; there's sometimes even hundreds of
16 thousands of comments. (Indiscernible) if it was a
17 company's document that get more comment than other.

18 But it does appear -- it's extremely bimodal
19 that a lot of them go through with very few comments
20 from the public and others just get hammered. I think
21 it's fair to say that most of those really have some
22 volume tends to be write-in campaigns from a few

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1 groups, typically those in biotechnology. I don't
2 recall having any sort of write-in campaigns from
3 people like the other side, which is the pro-biotech
4 groups. But by and large, when we get the
5 (indiscernible) comments they tend to be more
6 (indiscernible) in favor of the particular company and
7 so forth.

8 Actually, also there's another important
9 caveat that we do have to go through and analyze the
10 issues that are raised in all those comments; so when
11 we do get slammed with 10,000 or 100,000 or so
12 comments, that can slow down the process. So I think
13 that the timeline that you saw assumes a fairly normal,
14 reasonable amount of comments that our staff can review
15 in a timely way. I would say roughly a hundred or so,
16 couple of hundred comments.

17 But beyond that, we're really looking at
18 thousands and thousands of comments, especially if
19 there's a substantially different -- I mean we're just
20 sort of (indiscernible) then that's one thing, but if
21 they're different comments that each raise different
22 substantive issues, then it does take longer to

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1 analyze.

2 MS. CAVATO: Tracy Cavato from Monsanto. Two
3 questions for you, Clint. The first one is in the
4 improved process when would you envision petitioners
5 getting a completeness letter? So it is before it goes
6 out for public comment or after?

7 MR. NESBITT: Yes, that would be before it
8 goes out --

9 MS. CAVATO: Okay.

10 MR. NESBITT: -- for public comment.

11 MS. CAVATO: And then --

12 MR. NESBITT: Basically, if you look at my
13 little graph where final review, we expect a letter to
14 go out at the end of that final review box.

15 MS. CAVATO: Okay.

16 MR. NESBITT: So we'd send the letter to the
17 petitioner at the same time we'll be preparing the
18 clearance for publication.

19 MS. CAVATO: Okay. Then my second question
20 is I was intrigued by the comment when you said that if
21 the petitioner doesn't come back within 30 days it'll
22 be incomplete and it goes back. So it almost sounds

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1 like a first-in/first-out queue the way you've
2 described it. So I was wondering if you could?

3 MR. NESBITT: It's not literally first in
4 first out because when we've got a team of
5 (indiscernible) scientists that are all working on
6 petitions in various aspects, so to some degree if
7 they're busy working on other petitions, then obviously
8 they can't work on the new ones.

9 But I think part of what we're doing that
10 will help that process is by really concentrating the
11 amount of time that they're working on any one given
12 petition they'll be more quickly freed up to work on eh
13 next one until then. So by compressing it, we're
14 expecting that they'll be less likely to have petitions
15 that are stacked up on top of each other with a single
16 group of people.

17 But you're right, to some extent it is more
18 or less first in first out. We're not going to -- the
19 ones that are programmed in the queue aren't going to
20 -- they're eventually will go further ahead than the
21 ones coming (indiscernible).

22 MS. CAVATO: Thank you.

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1 MR. JAFFE: Greg Jaffe, Center for Science in
2 the Public Interest, Clint. So my question is I was
3 trying to follow your flow diagrams, and I'm trying to
4 figure out where the PPRA comes back into the process.
5 So right now, today, the PPRA's usual publish with the
6 draft EIS at the same time for public comment.

7 MR. NESBITT: Right.

8 MR. JAFFE: I understand here you're going to
9 do a public comment on the petition process while the
10 staff is working on the PPRA, and I wanted to find out
11 so when you get to Path 1 and Path 2 will the PPRA
12 somehow at some point when you do those other sort of
13 public review or public comments will it be published
14 then or will --

15 MR. NESBITT: Yes.

16 MR. JAFFE: -- it only come out the final
17 determination?

18 MR. NESBITT: Yes. No, the PPRA will be
19 published with the EA. So whenever the EA is published
20 and I do one or two processes, the PPRA will be with
21 it.

22 MR. JAFFE: And so if the public got comment

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1 on the PPRA, that's when they would make comment on
2 that --

3 MR. NESBITT: Yes.

4 MR. JAFFE: -- that document --

5 MR. NESBITT: Right --

6 MR. JAFFE: -- the public --

7 MR. NESBITT: -- so if it doesn't have, one
8 for example, we push with the EA as final, and so the
9 public will have the opportunity to give us the
10 information that might cause us to change the
11 conclusion in the PPRA or the NEPA document. And if we
12 have to change it, then we would change the path.
13 There'll be a formal comment period that you're going
14 to have too, and that's includes the PPRA as well.

15 MR. JAFFE: Okay. It'll be helpful I think
16 in the --

17 MR. NESBITT: Yes.

18 MR. JAFFE: -- future to include that in the
19 flow chart because it sort of gets lost there. You're
20 not really sure where that document --

21 MR. NESBITT: And that's a good point --

22 MR. JAFFE: -- is going coming back out.

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1 MR. NESBITT: -- yes, you're absolutely
2 right.

3 MS. REED: Hi, Genna Reed from Food & Water
4 Watch. I was just wondering -- I know there's been
5 estimate of how much the petition process actually
6 costs USDA Vilsack, and that quote that you had
7 mentioned that it cost millions of dollars. And I was
8 wondering if you actually have an estimate of how much
9 USDA spends and that if the change in the petition
10 process will actually have cost saving for USDA?

11 MR. NESBITT: No. I don't have a cost for
12 that. I think to some extent -- first I should clarify
13 that companies aren't paying their fees, so they're not
14 being formally charged anything. The companies do have
15 to conduct experiments that provide the data to us, so
16 that's a cost to them, but I don't think that we have
17 estimates that accounts for how that cost to them.

18 But I think the other thing in terms of your
19 question of the cost saving to USDA we do think that it
20 will be a big cost savings because it cuts out a lot of
21 all the sort of unnecessary staff and wasted staff and
22 so forth. I don't have an estimate off the top of my

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1 head how much exactly dollars-wise that would save.
2 But our scientists are typically they have, what, GS-
3 13/GS-14 level scientists that are getting those spend
4 half the amount of time that they had to spend with, it
5 means a big savings for the taxpayers.

6 MS. WEBER: Natalie Weber, Pioneer/DuPont I
7 have two questions. One is regarding those petitions
8 that are currently pending and you guys coming back to
9 us with any -- what path your petition will go down,
10 whether it'll follow the new process or not. Will
11 petitioners have a choice in that?

12 MR. NESBITT: I don't know. I don't think
13 so. I think we will certainly take your opinion in
14 consideration, but we don't want to kind of make a
15 standard set of rules for how we would decide which
16 petitions that are (indiscernible).

17 MS. WEBER: My second question is around the
18 comments that have been historically received. What
19 proportion of those in the current process are actually
20 on the petitions themselves?

21 MR. NESBITT: Do we have anybody who could
22 weigh in on that? Maybe follow up that question when

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1 we talk about the NEPA staff. I think generally it's
2 fairly informal. There tend to be more comment in
3 general upon the technology, on the trade, and how they
4 feel it is, if they like it or they don't like it; and
5 we'll often include additional scientific information
6 on the things we've already considered, but I think
7 because we've been publishing all at once -- so we've
8 been publishing the decision and the NEPA document and
9 the PPRA all at the same time. It's hard to tell
10 exactly what it is that they're commenting on.

11 So one of the advantages of splitting it up
12 is so the public understands a little better exactly
13 what it that we want them to be making comment on; that
14 they do one comment on the substance of the petition
15 that we got from Company X, or do we want comments on
16 the substantive of our analysis of that determination.
17 There's something that's to splitting it up that's
18 (indiscernible).

19 MR. PEARSON: Hey, Clint, over here. Les
20 Pearson with ArborGen.

21 MR. NESBITT: Okay.

22 MR. PEARSON: On a couple of these things,

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1 you've got agency clearance on your flow chart. I
2 wonder if that's the part of the process that these
3 would go through legal review with OGC? And if so,
4 have you factored that into the timelines you have on
5 there?

6 MR. NESBITT: Absolutely. That does include
7 OGC review. One of the process changes that I did
8 mention that we've already implemented that's actually
9 been ongoing absolutely is that we have already
10 implemented a fairly streamlined review with the
11 Office of the General Counsel.

12 Basically the way that we've done that is
13 that we've worked with them ahead of time to sort of
14 work out standard legal language that we need to
15 include in all of our notices and all our dockets, and
16 sort of the agreement is if we included that particular
17 language, phrases certain ways they would basically
18 have a shortened review of the petitions. But we have
19 the option at any time if we think that it's a petition
20 that raises new legal issues that we would ask them for
21 a longer (indiscernible) of review and let the analysis
22 expand the length of the process. But that three weeks

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1 does include a sort of new streamlined kind of
2 (indiscernible) review.

3 MR. JENKINS: Dan Jenkins with Monsanto. For
4 the teams that initially review the PPRA part of the
5 petition for completeness, once you move through that
6 process and then the PPRNLs can go on, do any of those
7 folks follow that petition? Or are they done with it
8 and a reeducation process begin within BRS with wholly
9 new people looking at petitions for the first time?

10 MR. NESBITT: The way we going to be handling
11 this it is largely separating the two groups of people
12 so that the biotechnologists that review it
13 completeness are the same that would focus on drafting
14 the ERA and doing activities related to our
15 determination. But shortly at the end of that process
16 around the time that the comment period begins, there
17 will be a handoff between the biotechnologists that are
18 in the staff and that kind of handoff briefing that
19 will set up -- that's when they all sort of talk
20 through together what are the issues that the biotech
21 scientists to see whether the petition may raise NEPA
22 issues. So there is a kind of formal handoff, and the

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1 NEPA team won't have to go through and review the
2 entire petition all at once.

3 MR. JENKINS: But there's continuity within
4 the people that are --

5 MR. NESBITT: There's definitely continuity.

6 MR. JENKINS: Yes. Okay. Thank you.

7 MS. COATS: Isabelle Coats from Bayer
8 CropScience. How or what will determine Path 1 versus
9 Path 2?

10 MR. NESBITT: Generally, as I said, it's more
11 related to whether or not the crop raises new issues or
12 not. But in the Federal Register notice that we're
13 going to be posting in the near future we'll spell out
14 those criteria more clearly, so you can know you
15 advance what they'll be.

16 MS. COATS: Is there any opportunity for the
17 petitioner to explain which --

18 MR. NESBITT: Which path they're on?

19 MS. COATS: -- well, which path --

20 MR. NESBITT: (indiscernible) --

21 MS. COATS: -- or why one would seem more
22 suitable than the other?

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1 MR. NESBITT: We had considered that. I
2 would guess that we want to keep the same consistent
3 pattern across petitions.

4 MR. WHITE: It's Jim White again. This is a
5 comment for Mr. Gregoire. Based on my personal
6 experience in the 1990s with virus-resistant squash and
7 the first Bt commercial with APHIS, publishing the
8 petition when it's received puts the agency on quite a
9 defensive posture in the sense that critics of the
10 technology can put stuff out there. And on the virus
11 resistance, a lot that can all be FOIA-ed; and with Bt
12 crops, for example, insect-resistant management,
13 without any internal review and anything written down,
14 APHIS was on the defensive for that. That's why the
15 process changed that the draft EA would be available
16 with the deemed-complete petition. It gave the agency
17 a better way of dealing with critics of the petition
18 process and its environmental assessment.

19 MS. FITZPATRICK: Hello, this is Sherry
20 Fitzpatrick with Metabolix. I just had a question
21 regarding, gain, the Path 1, Path 2 choice. It has
22 some similarities with an extension that you said that

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1 had been used previously. Is there any encouragement
2 of the use of extensions or efficiencies that might be
3 built into the extension?

4 MR. NESBITT: Those particular process review
5 did not consider a way of how to use the extension
6 process more efficiently or ways to encourage people to
7 move toward extensions. But I guess that we thing that
8 we did find is that the way that the extension process
9 was used in the 1990s is very different than the way
10 we're using it more recently. Typically though, it was
11 very quick. The company who had already been grant
12 nonregulated status for (indiscernible) would come back
13 in and would say "Now we got these five additional
14 constructs that we wanted deregulated." And the
15 analysis would be certainly shorter but the
16 (indiscernible) analysis for the petition.

17 Since then, around 2000 or so, it's sort of
18 grown that the analysis for extension was more or less
19 just as complex as the analysis for the petition. But
20 we haven't really yet explored whether and how we might
21 sort of change the use of extensions. I think we do
22 have one extension currently in house, but still, I

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1 think fairly similar to the way we did petitions in
2 summarizing the different process.

3 Any other questions? We got plenty of time.

4 MS. GUTSCHE: Annie Gutsche from DuPont. Can
5 you hear me?

6 MS. GUTSCHE: Annie Gutsche from DuPont, and
7 a follow-up question on the open comment periods. The
8 current comment period for petitioners tends to be 60
9 days unless they get extended, and with the new
10 petition process, it looks like a total of 90 days.
11 Could you walk us through the agency's thinking and why
12 you didn't do 30/30 or why you decided to do 90 days
13 total now?

14 MR. NESBITT: Sure. Absolutely. Our
15 regulations for the (indiscernible) process since the
16 beginning describes a 60-day comment period on the
17 petition. So it builds into our regs and says that
18 once we deem a petition complete we'll publish the
19 petition for 60 days over time.

20 For NEPA comment periods, in other parts of
21 the Federal Government it's been more to a 30-day
22 public comment period on perhaps environmental

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1 assessments and so forth. But some were in the past,
2 as I think Jim was alluding to, we just had to combine
3 both of those. So they were basically making -- for
4 expanding the EA analysis comment periods to match the
5 60-day comment period on petitions, so that they're
6 both out at once for 60 days.

7 So by splitting them up, we're going back to
8 keeping the petition comment period the way we've
9 already described, and then we'll take a 30-day comment
10 period on the EA in most circumstances, more consistent
11 with what we have with other Federal programs, take
12 comments on NEPA documents. So yes, because that why
13 we (indiscernible) those two numbers.

14 I should point out also that there are other
15 Federal agencies that use this other type process where
16 they'll publish concerning preliminary determinations
17 with the final analysis, and then it would go into
18 effect after a 30-day review period, putting it out
19 (indiscernible). Just trying to make it the way
20 (indiscernible) with some other Federal agencies.

21 MR. PIERCE: Clint, it's Les Pierce from
22 ArborGen again. You talked about getting a Federal

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1 Register notice out early in the new EA. Do you
2 anticipate that a lot of the petitions that have had to
3 complete this review are in the plant-pest risk
4 assessment process will be published at the same time
5 or very soon after? Or should we expect a lag between
6 when the first of these become available?

7 MR. NESBITT: That's a good question. I
8 don't think we've determined that because it really
9 will have to depend on where everything is at the time
10 that that notice goes in effect sort of when we going
11 to flip the switch. But I think it's very possible
12 that we would see quite a few of them coming out more
13 or less at once shortly after that.

14 All right. Very good. Thank you for your
15 time. Oh, I'm sorry. Mike.

16 MR. GREGOIRE: I just want to be clear on one
17 point. We have had questions on this. Path 1 and Path
18 2 the agency will make that decision, and I expect we
19 will have input on that from developers and
20 stakeholders whether we ask for it or not. But I'm
21 going to be really clear that that will be the agency's
22 decision, and it's a decision that we would make at the

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1 end of the comment period on the petition. And again,
2 the criteria that we would use for making that decision
3 will be described in the Federal Register notice that
4 will be out in a few weeks, and we want to be
5 consistent in how we apply that.

6 The other thing I would just mention is that
7 one of the things that we are experiencing and when we
8 get new petitions we do put information on the Web
9 sites and general information about new petitions when
10 they come in, but we are routinely getting FOIA
11 requests for new petitions when they come in, so
12 they're ending up being out there in the public domain
13 fairly quickly anyway. So we think the new process
14 will also save us some time in the FOIA process.

15 MR. NESBITT: Thank you very much.

16 MR. GEORGE: Thank you, Clint. Wanted to
17 mention the preparation of environmental documents is
18 an important part of what we do at BRS, and the NEPA
19 Pilot Project was launched last year in an effort to
20 find better ways for preparing those documents.

21 Here to tell us more about the NEPA Pilot
22 Project Senior Protection Specialist Rebecca

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1 Stankiewicz Gabel.

2 MS. STANKIEWICZ GABEL: See if I can operate
3 this thing.

4 MS. STANKIEWICZ GABEL: I think you need a
5 degree in this thing. It's very bizarre. I'm going to
6 talk a little bit about the NEPA Pilot Project today.
7 And it was just about this time last year that I stood
8 up and introduced NEPA Pilot Project to you, and just
9 like last year, I got to stand up here and talk to you
10 as they were readying the lunch in the back of the
11 room. So I'll try to stick to schedule and to the high
12 points and not keep you from your lunch. I don't know
13 why I always get this spot.

14 NEPA Pilot Project we actually implemented in
15 April of last year along with publish the Federal
16 Register notice, but as I mentioned at this
17 stakeholders meeting last year, we had introduced the
18 idea of doing this pilot project to you.

19 It is a voluntary program. The timeframe is
20 two years, and the goal is to evaluate petitioners-
21 submitted environmental reports and using cooperative
22 agreements to spawn environmental documents. We're

1 looking at this in the context of to increase our
2 efficiencies within house in terms of timeliness and
3 resources. The important thing is there is no
4 limitation on participants, so we're inviting all of
5 you to join our pilot project because the more
6 information we have as we go through the pilot project
7 the better we'll be able to look at what types of
8 things that we're doing to actually improve our
9 process.

10 The goal is to test new approaches to develop
11 the environmental analyses and documents and determine
12 to what extent these approaches improve the quality,
13 timeliness, and cost effectiveness of our NEPA
14 documents. So we're looking at ways to improve our
15 NEPA analysis in terms of efficiency, cost,
16 (indiscernible), and timeliness.

17 As Clint mentioned in the petition
18 improvement process, we have several environmental
19 analyses that will be coming our way, coming down the
20 spring, and so we're using these tools to look at how
21 the staff approach all of those analyses that we have
22 and the (indiscernible).

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1 We mentioned two things that we're looking
2 at. One is the environment reports, and the other one
3 is a cooperative agreement. Environment reports are --
4 I feel that this is so loud -- environmental reports
5 are really a report that's provided by a petitioner,
6 and it describes the subjectivity of the petition. It
7 compares the current agricultural ecosystem to one that
8 contain (indiscernible), and it is supported by
9 specific scientific data.

10 We've put guidance for environmental reports
11 on our Web site, and in that guidance, we describe
12 basically the outline of the types of information we're
13 looking to gather from you in this report. We are
14 looking for information on the (indiscernible)
15 organism? Why it was developed? What market is it
16 addressing? What issues it's addressing? What you're
17 asking us for? Are you asking us to grant nonregulated
18 status to the organism? Where is this organism
19 typically grown? So corn is typically can grown
20 throughout the Corn Belt but is also grown within 49 of
21 the 50 states. So pilots are typically used with those
22 various area.

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1 Whereas another crops like sugar beets, for
2 example, is really only grown in certain states, so you
3 don't need to talk about sugar beet production in
4 Alabama. People just don't grow it there. So it's
5 defining those regions.

6 We talk about the affected environment,
7 alternatives. Usually, the alternatives are in the
8 case of an environmental report you're describing what
9 you're asking us for compared to the current state of
10 environmental action alternative. So if you're asking
11 for a petition for nonregulated status, that's one
12 alternative. The other alternative is for us to not
13 approve the petition for nonregulated status, and we'll
14 be comparing those to two state.

15 In the comparing of the environmental
16 consequences, we compare the alternatives, and you're
17 looking at various environmental resources programs.
18 And the other thing we ask for and we have
19 (indiscernible) is (indiscernible).

20 As I mentioned, we have guidance for
21 environmental reports, and they're on our Web site, and
22 I list our new URL (indiscernible) -- you don't need to

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1 copy them don't. If you go to our Web site, you can
2 find the page. We have a page that's dedicated to the
3 NEPA Pilot Project, so in addition to guidance on
4 environmental reports, we have some information from a
5 workshop that we held this summer and also information
6 on cooperative agreements as well.

7 So that brings us to what are the cooperative
8 agreements. A cooperative agreement is based on a
9 contract between the petitioner and the agency, and in
10 that agreement, the petitioner is agreeing to supply
11 funds for the preparation of environmental analysis.
12 The agency then take those funds and contract
13 environmental analysis, so we're using the funds that
14 you placed into an account to pay for the work, the
15 preparation for hiring an environmental contractor. We
16 hire the contractor. We supervise the contractors. We
17 approve the work of the contractor. We're responsible
18 for the analysis.

19 The role really of the petitioner in this is
20 to just supply the funds, and this is to help us hire
21 contractors; because as Mike pointed out, even though
22 we have a budget increase, we're -- the funds are

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1 limited, so we would use funds supplied by the
2 cooperators in order to hire the contractor. And
3 there's information about that as well on our Web site,
4 so you can get information about how to go about
5 initiating a cooperative agreement and the types of
6 information that we need in order to implement that
7 agreement.

8 Currently, in the pilot project, we have nine
9 participants, and eight of the participants are from
10 industry, and one is from academia. I want to mention
11 that I know some of you are not currently participating
12 in the pilot project, but you've asked about it or have
13 expressed some interest. If you're interested in
14 participating in the pilot project, we ask that you
15 send a letter -- it can be an email or a letter -- to
16 the agency formally stating that you'd like to join the
17 pilot project. We'll be looking for your letters.

18 Currently, we got one more petition last
19 week, so the fives already out of date. There are 22
20 petitions in house, and of those 22 petitions, we have
21 8 that have environmental reported that's updated with
22 them and three that have cooperative agreements. And

1 of the remaining 12, there are some of those petitions
2 that people have expressed interest in preparing the
3 environment report that have submitted the
4 (indiscernible) or have expressed an interest in
5 turning it into a cooperative agreement, but those
6 (indiscernible).

7 For the project, what we're actually doing is
8 we're looking at the effectiveness of using these tools
9 on our overall process, and we want to understand is
10 this really helping us in the agency, is it improving
11 our efficiency, is it improving our timeliness, is it
12 cost effective to use these two tools to help us to
13 prepare or NEPA analyses.

14 So we've developed a group of metrics that
15 we're going to use to measure better throughout this
16 process. What we're really measuring when it all comes
17 down to it is employee time. We're looking at the
18 total amount of time it takes for our analysis, so
19 start with an issue that Clint was talking about
20 earlier, the time it takes from start to finish, but
21 there's also the time it takes the people who are
22 working on it to actually prepare it. So those are the

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1 two metrics that we're measuring, and they're both
2 time.

3 And we're looking at agency resource. We're
4 looking at our time and how we spend it in different
5 way, whether we have environmental report or
6 cooperative agreement in place, whether we're preparing
7 our own analysis in house. And we're really looking at
8 does it take less agency resources to do it one way
9 versus another.

10 We've divided up our petition process into
11 three phases for our analysis. We have the phase which
12 is preparing the draft environmental assessment,
13 response to comments. So after the comment period, we
14 get comments; we analyze those comments; we respond to
15 them; and we incorporate any changes into our final
16 document; and then the preparation of the final
17 document based on those comments.

18 So as we've been going through and developing
19 the NEPA Pilot Project, petitions have still been
20 moving through the process. We have some petitions
21 that are entering the process in the draft phase and
22 are going all the way through. We have some that are

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1 entering the process -- this is in terms of collecting
2 data on time -- the response to comment, and some for
3 the final.

4 We also have petitions that had a cooperative
5 agreement in the preparation of the draft but not to
6 respond to comment or the final document, and we have
7 some that have cooperative agreements for the end of
8 the process but not the beginning. So we're looking at
9 all of those variables as well when we're analyzing the
10 amount of agency resources it takes.

11 Our next step. As I mentioned earlier, we
12 did have a workshop this summer. We've prepared some
13 draft guidance. We've put it up on the Web. We're
14 going to call it guidance D1, and we're still looking
15 for comment on that. So if any of you have any
16 comments on our guidance, would like to see guidance on
17 other topics or expand the guidance, we ask you to give
18 us that information.

19 We also will be hosting a series of webinars
20 and calls related to development of environmental
21 report, and if anyone is interested, we can also do
22 more related to cooperative agreements. We talked

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1 about both of these things this summer, but we'd like
2 to do some followup calls to address your specific
3 questions.

4 And again, you just heard about the new
5 petition process, so we're working through our data
6 collection with respect to the new petition process.
7 One of the things that is important in the new petition
8 process is we do have that 60-day public comment
9 period. If you're interested in entering into a
10 cooperative agreement for the preparation of an
11 environmental document, we need to know early on that
12 you want to enter into that agreement because it's
13 going to be a comment period that we would be
14 soliciting for a contractor. So if you're interested
15 in actually participating in that, we would need to
16 know that with your petition.

17 Likewise for your environmental report, as
18 Clint mentioned, the environmental reports we'll need
19 it so that we have it before we initiate preparation of
20 our NEPA analysis, so we would ask that you submit that
21 before the end of the 60-day comment period.

22 We will be posting environmental reports that

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1 we produced into the pilot project. We typically will
2 publish that with the EA and supporting documentation.
3 However, we will put it out when we have it to put out.

4 In addition to that, I lost my slides, but I
5 wanted to introduce someone to you. Shelley, can you
6 come on up? I want people to be able to see you, so if
7 they have any questions, they can talk to you.

8 Shelley Gray is joining us on the NEPA Pilot
9 Project. She is an -- you're an environmental
10 protection specialist, correct? She's an environmental
11 protection specialist with the ERAF (ph) staff, which
12 is in our PDE program (indiscernible) on acronyms I use
13 because I don't know what they all mean. They do most
14 of the environmental documentation, ESA compliance
15 Historic Preservation Act for the agency on agency
16 action. o come on up, Shelley.

17 MS. STANKIEWICZ GABEL: Just wanted you to be
18 able to find her during lunch if you have any questions
19 for her.

20 FEMALE SPEAKER: Can I take (indiscernible)
21 questions or comments?

22 MS. STANKIEWICZ GABEL: Oh, yes, they found

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1 it. Okay. Maybe. And there's Shelley's contact
2 information.

3 MS. GRAY: Simply send us a tape and send me
4 an email or give me a phone all if you have any
5 questions about the process.

6 MS. STANKIEWICZ GABEL: We invited Shelley to
7 join on the project because we felt we really need a
8 project manager to interact with you guys to keep tabs
9 on what's going on, make sure that all of our metrics
10 and measures are getting tracked and analyzed in a
11 timely fashion because this product is basically
12 generated from the NEPA team. And as you've heard, the
13 NEPA team has doubled in the last year, so it's now six
14 of us, so we're a very busy group, so Shelley is
15 joining us and giving us a hand.

16 So does anyone have any questions?

17 MR. WERNER: This is Michael Werner.
18 Rebecca, I want to ask to what extent do you balance
19 the ER with EAs that you prepare to make sure that you
20 can demonstrate that APHIS has conducted the critical
21 objective hard look, which is going to be the first
22 entry for litigants to bring claims against you for

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1 failure to fulfill your lease obligations?

2 MS. STANKIEWICZ GABEL: Be that the ER has,
3 we'll call it a basis or starting point for an EA, but
4 every statement in it, every reference used we check.
5 We evaluate -- we do our own literature search to
6 validate the information that's in the document, and
7 we'll use that information to develop our environmental
8 assessment, but we have to validate every statement
9 that's made before we include it in our document.

10 MS. COLLINGE: Rebecca, the way you've
11 described it it almost looks like you did an ER -- I'm
12 Susan Collinge, J.R. Simplot Company -- but it almost
13 looked you did an ER or a cooperative agreement? It
14 sounds to me like you might do both. Could you
15 clarify?

16 MS. STANKIEWICZ GABEL: Yes. You can do
17 both. As a petitioner, if you wanted to prepare an ER
18 and then enter into a cooperative agreement, have us
19 hire an outside contractor to prepare our NEPA
20 documentation, you can have it both ways, yes. It's
21 not necessarily one of the other.

22 MS. COLLINGE: Thank you.

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1 MS. STANKIEWICZ GABEL: Anyone else have any
2 questions? If not, I will keep -- oh, we do. Okay.
3 I'm sorry. I didn't see you.

4 MR. REDDY: This is Srinu Reddy from Forage
5 Genetics. What is the criteria on how do you select
6 the contractor?

7 MS. STANKIEWICZ GABEL: The Federal
8 Acquisition Regulations describes the process by which
9 contractors are hired, and basically what we do is we
10 as the agency write what's called the statement of
11 work, and our contracting office at APHIS solicits
12 contracts typically from the GSA, which is the General
13 Services Administration; and they have a precollected
14 list of environmental contractors that meet certain
15 criteria. We go out and we solicit to people on that
16 list, and we describe what we need; they prepare
17 proposals; they send them to us, and then we evaluate
18 those proposals.

19 Typically, when we are looking for a
20 contract, we will look at criteria such as past
21 performance and technical expertise and the ability to
22 basically do the project that we're proposing and then

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1 price. So we have those two criteria.

2 When we evaluate these things in house, we
3 typically get the proposals without the price list with
4 them. We do a technical evaluation, rank them, and
5 then after that, price weighs in. And what we'd like
6 to be able to do -- let's say a contract for
7 preparation of EA or EIS -- we'd like to be able to
8 send out with that proposal as much information as
9 possible. Because we'll get the best proposals back if
10 these contractors know what they're actually bidding
11 on. So one of the things that will be nice about this
12 project running in with the new petition process is
13 that the petition will be out for public comment while
14 soliciting our contractors, so everything will be out
15 there for them to look at and see, and they will even
16 be able to see where the beginning of the public
17 comments are.

18 Does anyone else have any questions?

19 Okay. So don't let me stand between you and
20 your lunch. It's in the back of the room. Oh, wait.
21 He wants to say something first.

22 MR. GEORGE: Yes, she's correct. Right,

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1 lunch is in the back of the room, and we will not stand
2 in your way, but I did want to mention I know some of
3 you will probably be leaving and most likely will not
4 attend the afternoon session. Would you please fill
5 out the evaluation form. It's the last page in your
6 handout. So obviously, we would love to have your
7 input so anything we can do better in the future.
8 Also, will remind you if you're are looking at the
9 getting e-authenticated in order to get access to
10 ePermits. Steve Bennett is at the table, and he is
11 ready, willing, and able to help with that.

12 And with that, since we're running a little
13 bit ahead of schedule, why don't we take our lunch
14 break, and reconvene at 1 p.m., 1 o'clock be back here.
15 Thank you.

16 (Off the record)

17 (On the record)

18 MR. GEORGE: I would encourage you all,
19 because apparently the crowd has thinned out a bit, to
20 please move forward if you would. There are seats up
21 here these first four tables. I would encourage you to
22 take them once you move forward. It would make it a

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1 lot easier for you to hear and make it easier for our
2 speakers to sort of connect.

3 MR. GEORGE: Hope everyone enjoyed their
4 chicken tonan (ph) subs. I will tell you that last
5 year my first experience with BRS was when I came to
6 this meeting, which was about a week before I actually
7 started working. They had these tonan subs, and I was
8 like "You know I like this organization."

9 MR. GEORGE: "These are some good subs." I'm
10 going to get started, it's sort of (indiscernible) it's
11 part of the waiting process for our first speaker
12 (indiscernible). Hold just second.

13 MR. GEORGE: We got to change the schedule a
14 little bit. We were going to reconvene at 1:30 on the
15 original schedules. Even though we announced it,
16 apparently it wasn't (indiscernible) to everyone, so we
17 have a minute or two (indiscernible), our speaker
18 (indiscernible).

19 MR. GEORGE: I think we're good to go. As we
20 mentioned this morning, we designed the day into two
21 parts. The morning session was more about sort of high
22 level look at BRS activities, and the afternoon is time

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1 look and detail some of our process and procedures, so
2 that's exactly what we're going to do.

3 This afternoon will be devoted to permitting
4 and notification trends, updates to ePermits,
5 confidential business information, and compliance and
6 training. And there will be time at the end of the day
7 for your questions. We would ask that you hold you
8 questions until the end of the day. We have an hour to
9 take from about 2:30 to 3:30 for any questions you
10 have. Also, I will also at that time remind you that
11 we do have an evaluation form in your handouts, so I'm
12 going to mention them because we would like you to fill
13 that out and leave that with us to help us plan future
14 meetings.

15 And with that, we'll turn the podium over to
16 John Turner, Division Director of our Environmental
17 Risk Analysis Program.

18 MR. TURNER: Thanks, Dick. And with that
19 introduction, I really don't have much to add. I want
20 to welcome you all here. I'm glad to see for this
21 afternoon session. As he said, the morning is an
22 opportunity to look at some of the big picture things

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1 going on in BRS. The afternoon that's the nuts and
2 bolts. That's for the people who use ePermits, who
3 write reports, and do notifications, who file
4 petitions, and we hope to have a great session; and at
5 the end when we have time for questions and answers, it
6 will be a brief give and take. So with that's, I'm
7 going to turn it over to our first speaker. This is
8 Margaret Jones. She'll be talking about permit and
9 notification, specifically guidance documents,
10 amendments, states, and tribes. Margaret.

11 MS. JONES: Good afternoon everyone. Thanks,
12 John. This afternoon, I'd like to -- how does this
13 sounds? It sounds awfully loud. Is it too loud or?

14 It's good? Okay. I want to start talking --
15 in the trenches, we're talking about what we do permits
16 and notifications, and we're going cover guidance
17 documents, permits amendments, states and tribes, and
18 update the database, changes to the APHIS database.

19 In 2007, the notification guidance was first
20 published; and since that time, there have been a
21 number of periodic updates, and these are covering the
22 updates that have been in place since the last

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1 stakeholders meeting.

2 The guidance clarifies that when you're
3 providing anuia (ph) shipment that you should indicate
4 the combined totals of all the movements that are
5 carried out under that permit or notification. This
6 for the second one for the fizher (ph) release. This
7 for release sites that are planted more than one time
8 that you indicate the largest area that you're going to
9 plant. It clarifies the term termination, what that
10 means, and it clarifies when the regulated article is
11 harvested or destroyed.

12 And then for planting reports, and this,
13 again, is for release sites that are planted over the
14 course of time. When you're submitting planting
15 reports, you usually submit one report, and it just
16 gives you greater flexibility in submitting more than
17 one report if you plant within 30 days.

18 Lastly, if APHIS has reached a determination
19 of nonregulated status for a line, we request that you
20 submit a change of status notice, and the method for
21 doing that is outlined in the notification guidance.

22 We have a new guidance document that is

1 currently under final agency clearance. It address
2 permits, and the overall organization of is to guide a
3 person through the permits process, so it walks you
4 step by step through the permits submission.

5 Currently, we have a pharma, industrial, and
6 pharma abbreviation guidance document, and that
7 document is a standalone document, and what we've done
8 is taken everything specific to pharmas and taken that
9 in made that into appendix. It will be an appendix of
10 this new guidance document.

11 We're going to have various appendices, and
12 hopefully, this will help us keep everything up to
13 date, so it will be published like a PDF portfolio with
14 multiples appendices, among which are example permits
15 including the list, which will be a CBI, a CBI deleted
16 version for multiple species, a release for corn, and a
17 release and movement, which is the CBI, and it's
18 represented to multiple year grade.

19 I'd like to move on and talk about amendment.
20 There have been many questions raised about the
21 amendment process, so, first, I'd like to walk through
22 things that you can use amendments for, that you can't

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1 use amendments for, and, the final, the whole amendment
2 process.

3 You can use permit amendments. You can use
4 amendments after a permit has been issued and you want
5 to make modifications to that amendment but before the
6 permit has expired. You can add many constructs. You
7 can add field locations in states that are listed in
8 the permit, or new states. You can change disposal
9 methods. You can add or modify SOPs or design
10 protocols, and you can add containment facilities, and
11 you can increase the size of shipments or acreage.

12 You cannot use amendments to change the
13 effective or the expiration date on a permit. You
14 cannot add new plantings that extend the permit beyond
15 the expiration date. So everything that's done in
16 regards to a field release excluding the voluntary
17 monitoring has to be done within the timeframe of the
18 duration of the permit.

19 You cannot add new recipient organism. There
20 is really no need to remove a release site or location
21 because that information will be reflected in the
22 planting report. And lastly, you can change the

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1 responsible person on a permit or notification, but you
2 can't do it through the amendment process, and we
3 request that you address any changes in a responsible
4 ownership to the site that's listed on your slide, BRS
5 permit.

6 In terms of the amendment process, please
7 keep in mind that an amendment it can take as long as a
8 permit, a full permit, whether it's a movement or 60
9 day or release for 120 days. And that's because an
10 amendment goes through all the same steps as any permit
11 that's submitted to us. It doesn't always take that
12 long, but recall that during our busy season, late
13 winter, late spring, we're awfully busy, so try and get
14 in as early as you can your amendments. In the
15 amendment, provide a description of the amendment.

16 And lastly, for multiyear movements and
17 releases, the movement part cannot be amended greater
18 than one year because according to the regulations, the
19 movements are restricted to one year. So if you have a
20 multiyear lease, you'll note that the movement portion
21 of it is only for one year even though the release may
22 extend up to three years.

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1 I'll just have to walk you through the state
2 review slides. Our state review liaison is Gwen
3 Burnett, who is right here to help you on any of your
4 questions, and she is here to help resolve issues and
5 concern relating to any concerns for permits and
6 notifications, and she can provide the contacts for
7 state reviewers if applicants have questions or
8 concerns about state requirements or comments or
9 (indiscernible) timing.

10 Another issue about state review is that when
11 notifications and permit applications contain CBIs, you
12 should be aware that the presence of CBI impacts
13 processing. So to help facilitate this review, we
14 request that you provide if you can and if you're not
15 CBI, a portion of the permit provides in lay terms the
16 nature of the expressed product and its intended use
17 and if possible a total cumulative acreage of all the
18 release sites. This facilitates the state review.

19 In terms of the timeframe, there are a number
20 of issues that are contributing to slow turnaround time
21 for a state review. Some of them are many states have
22 furloughs and hiring freezes, and in addition, many of

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1 the state regulatory officials are near to retirement,
2 leading to a loss of expertise. To address this last
3 concern, last summer in June BRS partnered with the
4 National Plant Board and held a training to help bring
5 the state reviewers up to speed.

6 Not tribal consultations. There are
7 currently 556 tribal nations across the United States,
8 and the Federal Government has a unique and political
9 relationship with tribes that requires the Federal
10 Government to consider agency actions that might impact
11 Federal tribe, tribal nations, and protected rights of
12 treaties.

13 We want to raise you awareness to the fact of
14 this obligation of the Federal Government because it
15 may impact your site selection, and currently, BRS is
16 assessing the proximity of its field releases to any
17 Federally recognized tribal lands. And in cases where
18 it may impact tribal lands, BRS will need to
19 communicate and consult with those tribes. We do
20 anticipate that this will affect a minimum number of
21 permits and notifications because most of them are not
22 located near tribes.

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1 To facilitate your finding out information
2 about tribes, we've provided you with a couple of Web
3 sites here. The first is the Bureau of Indian Affairs,
4 which has a list of all Federally recognized tribes.
5 The second one is the National Congress of American
6 Indians, and they maintain a site as well as contacts
7 for tribal leaders, and they have also contact
8 information for those tribal leaders.

9 And lastly, the Census Bureau has a map file
10 that you can download if you're interested in
11 determining if your release site is located in close
12 proximity to Federal tribal lands.

13 Moving on to some of the changes in our
14 public database made available. There have been a
15 number of changes, and I just want to kind of walk you
16 through a couple of them.

17 This is the APHIS database for notifications,
18 permits, and petitions, and here is the URL here. All
19 permits and notifications you can see the status is
20 they're pending or issued. The first change that we
21 have relates to -- leaves a greater understanding of
22 what are the timeframes and what activities can be

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1 carried out under a permit or notification. It used to
2 be that all of these fields were present, and where
3 these dates come from, there's a beginning and the end,
4 and the beginning and end of a release, beginning and
5 end of any movement; and then we have the effective
6 expiration date. These dates come from information
7 that you give us when you provide a proposed release or
8 proposed movement, when it begins and when it ends.
9 And then after a permit is issued, the permit or
10 notification comes with an effective date and an
11 expiration date.

12 And there's been some confusion about whether
13 or not if you carry out a movement or release outside
14 of the timeframe that you had proposed in the permit
15 but, nevertheless, within the timeframe during the
16 duration of the permit. It is okay to carry it out
17 outside of these proposed dates, so to help communicate
18 this, we no longer show these dates to show that the
19 activities are authorized between these two timeframes.

20 The second change is that we now make
21 available acreage. This information has previously
22 been available on the Virginia Tech database, but you

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1 had to query one notification and one permit at a time,
2 and this allow you -- you can see all of them if you
3 print out the entire spreadsheet.

4 The last slide that I have relates to what we
5 formally the status page. This is accessible from the
6 status page on the BRS Web site, and if you pull up the
7 data -- here is sort of a screenshot of pulling up data
8 for a movement permit.

9 The summary of what I'm going to tell you for
10 this is that this information used to be available for
11 notifications, but now it's available for permits, and
12 the information that's now available for permits are
13 two things. The first is you can now see the progress
14 and whether or not a state has responded, so you can
15 look up state by state also for permits, so they'll
16 note if it'll be pending, and if they have responded,
17 then it'll give you the date.

18 Here's an example of a regulated article,
19 Pomance fly, and then you can see the type of
20 introduction that's occurred by import, when it was
21 received and issues, and then after that tech review.
22 And what that is the date at which the biotech first

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1 does the first step. So you can kind of see if it's in
2 the door and being looked at, and that's what that data
3 is. And so those are now available for permits as well
4 as notifications.

5 And that's all I have, and the next speaker
6 is Lee Handley. We call him our ePermits guru because
7 he was instrumental setting up our ePermits for
8 notifications and permits, and he's going to talk to
9 you today about ePermits.

10 MR. HANDLEY: Okay. Everybody's favorite
11 topic: ePermits. What I'm going to do today is cover
12 some reminders about issues of ePermits and the ways to
13 do things with ePermits; talk a little bit about the
14 reports and notice module, the e-modules that we
15 launched early this year, and the age-old issue of size
16 limitation for applications.

17 As a ruling with renewal to your permits, any
18 planting that's been in the ground for more than a year
19 must be under a permit, we changed I guess about four
20 or five years ago. We no longer allow multiyear
21 notifications, so if you have a perennial, it must be
22 under a permit, and you can lay it to the ground for

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1 more than a year.

2 Multiyear permits are typically issued in
3 three-year intervals, so submit your multiyear permit,
4 and then once a year, you submit an annual report; and
5 then at the end of the three-year period, you submit
6 your final field test report. They also lessened the
7 review to keep the plants in ground for a longer period
8 of time. So people who have the three-year permits are
9 typically renewing the permit at least 120 days before
10 the permit is going to expire.

11 That's really, really important because a lot
12 of times we have to do another 30-day species analysis
13 because things might have changed during that three-
14 year period, so make sure that you get your renewals in
15 at least 120 days before.

16 The reports are not -- this is NATRAL (ph).
17 Some of you are aware that we launched that back in
18 February of 2011. It was pretty successful. We did
19 have some early glitches for the XML upload schema.
20 There were some problems with data matches, and some of
21 you folks have been dealing with that. I think there
22 may be one or two issues that still have to be fixed.

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1 As far as I know, the only problem we got is people
2 can't put zero in the number of volunteers that were
3 monitored once you've done your volunteer monitor and
4 testing that equal zero. That should be fixed probably
5 in a couple of days.

6 One of the questions that I got a lot is how
7 do we do planting reports; we've already planted them;
8 we've submitted some paperwork for it, but now we want
9 to submit electronically. One of the things we're
10 saying is you can just keep doing that on the paper if
11 you want to or you can backfill the planting reports
12 that you've already planted.

13 The other thing about planting reports is
14 that they're dynamic. You can submit one, but you can
15 also resubmit it and overwrite what you've submitted
16 previously. So, for example, in the initial planting
17 report, we don't require that you submit on the strokes
18 or lines. Subsequently though, before you submit your
19 final field test report, you need to include the
20 construct. So this lets you go back in after the fact
21 after you've submitted your first planting report and
22 fill in all information right before you submit your

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1 final field test. That was because you guys had told
2 us that it was really hard for you guys to report all
3 of the constructs that you planted within that window
4 of time that you have to submit. So we just need to
5 know that the field test is planted; then, you can fill
6 in all the pertinent construct information.

7 Also with planting reports, if you haven't
8 reported a planting, we are assuming that that's not a
9 planted side. So if compliance goes in to schedule an
10 inspection, they will look and they will say, "Well,
11 I'm not going to schedule and inspection for this
12 location because ePermits is telling me it hasn't been
13 placed. So that helps compliance know what you have
14 and haven't planted.

15 The final field test report all locations in
16 the permit or notification have to be accounted for
17 before you can submit that final field test report.

18 So what ePermits will do is when you go into
19 that last part of the reporting module to start
20 submitting the final field test report it's going to
21 look to test every single location that it came in for,
22 even with a planting or a no planting. So if you

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1 submitted a notification or a permit and you decide not
2 to plant there, you still have to report to us that
3 they didn't plant.

4 And the other things that it will do is it
5 will check to make sure that at least one construct is
6 in each planting report. So right before you submit
7 the final field test report, it's going to check and
8 make sure that you've accounted for at least one of the
9 constructs. It also does validation to look to make
10 sure that the construct that you have sent and that you
11 have in the application and in the final sort of
12 matches what you have uploaded in your final report.

13 And I've got the question about do we need to
14 submit land reports electronically or field test
15 reports. No, it's not mandatory for permits and
16 notifications, but a lot of people are doing this for
17 practice, testing your XML uploading schemas and stuff
18 like that.

19 Some of you who have the multiyear permits
20 and renewed permits are discovering that it's a little
21 bit more complicated for planting reports. In some
22 cases, for example, with some of the tree permits, we

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1 have plantings that were planted six years ago. So you
2 have to go back and you have to account for all those
3 planting before you can submit the final field test
4 report.

5 There are easier ways to do that. You can
6 lump the plantings together, and I've talked to a
7 couple of you guys about how to do that. If you have
8 questions about how to do backfilling and a lump
9 planting report, which I won't get into the details
10 here, just call me, and we can talk about the best way
11 to do that.

12 For the multiyear permits also, as I
13 mentioned, there's a requirement that you submit an
14 annual report at the one-year anniversary. It's not
15 going to check to see if all locations are accounted
16 for because obviously you might have a site that you
17 submitted for a permit, and you don't intend to plant
18 until the second or third year. So it's not going to
19 do any check to make sure that you've got all sites in
20 the form.

21 But if you did have plantings and you didn't
22 report it, it would say as missing, but you wouldn't

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1 really have to worry about that if you had submitted a
2 paper planting report. That would be in the ePermits
3 file, so the compliance staff can pull it up and see
4 it.

5 The issue with the size limitations for
6 permits and notifications. As a few of you guys know,
7 we've had some particular problems with the PDFs
8 getting bigger and bigger and bigger, and I think part
9 of the reason for that is that ePermits has been so
10 successful that people are packing more and more stuff
11 into fewer and fewer applications.

12 The problem with the very large PDFs is it
13 takes a long time for the system to generate the PDF.
14 In some cases, it will just completely timeout, and it
15 won't finish generating the PDF, or it will finally
16 open the PDF, but we can't edit it or you can't edit
17 it, so that if we need to fix a mistake or make a
18 change, if you decide you want to add something or take
19 something away while it's still in the review process,
20 in some of the cases when it's really, really big, it
21 just won't let us make any changes.

22 And the other issue is that even if we can

1 open it, sometimes the states can't open it; for
2 whatever reason, their computer systems won't let them
3 open very large PDFs. In that case, what we wind up
4 having to do is we have to send the state a CBI-related
5 copy of the PDF in email. So we like to try to avoid
6 these problems.

7 One of the things that I wanted to point out
8 here is just showing the number of notifications and
9 permits with over 100 constructs. You can see that
10 since we launched ePermits in 2006 and 2007 this was
11 the number of constructs, and then that significantly
12 increased over time. And again, I think part of that
13 is because the ePermits system was very successful, and
14 the other thing is that we've asked you guys not to
15 attach Excel files and things like that in the ePermits
16 with the constructs that actually need to be entered
17 into the system. That lets us search the data. It
18 makes it a much more robust system.

19 So that's the other thing that happened is
20 that you guys are just packing more and more construct
21 information into the notifications and permits.

22 And this shows the number of constructs by

1 year issued. Again, you can see we've had a
2 significant increase in the number of constructs that
3 we're reviewing. In this case, what I mean by
4 constructs is what in ePermits is called a designation.
5 A designation can be on average three constructs, six
6 constructs, and you have the promoter, and you have the
7 gene terminator, the gene mentrest (ph); you may have a
8 selectable worker. So this counts designations. So
9 you can see that we're getting a lot of designations,
10 just not individual components but more and more
11 designations.

12 This also shows the number of notification
13 that we're seeing, so you can see we're getting more
14 and more locations that we're having to review. So
15 it's not just more genes, it's a lot more field test
16 sites that we're looking at.

17 The other thing I wanted to point out here --
18 and I know I talked to a couple of you folk about this
19 -- is what winds up happening is if you have the same
20 location in five or six different notifications, a
21 separate biotech is looking at that location every time
22 we do a review. So in some cases, one biotech will see

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1 a location; another notification will come in, the same
2 location, take a look at this same location.

3 We've talked about a way of using the
4 location-unique ID that's in an ePermit if there a way
5 that we can think about having as system so you can
6 tell us, "Hey, you've seen that before. You don't need
7 to look at that same location." Kind of like what
8 we've with genes, that same kind of concept. We don't
9 know how it would work, but it's something that we'd
10 like to explore particularly with these really, really,
11 bit applications; if there's a way that we could come
12 up with a system that you could say, "Yes, you've seen
13 this location," and maybe tell us what notification
14 this is, what permit, that kind of thing. I know that
15 could be a lot of work, but it's just something we'd
16 like to explore. Okay.

17 Rough guidelines for how you know you're
18 going to get yourself in trouble if it's getting too
19 big. If it look like a system starts to fails when a
20 PDF gets to about 500 pages just based on experience,
21 based on the times that we've seen the system hiccup,
22 it's like when you're getting close to the 500-page

1 limit. On average, and this is really rough, there's
2 about one construct per PDF page. That depends on
3 who's submitting the information. Some people pack a
4 lot of information into a construct that can take up a
5 lot of space; other people don't have that much
6 information, so you might get two constructs per page.
7 And again, I'm talking about designations. But if you
8 want to do some rough math, that's how you can figure
9 this out.

10 But release location, that's about three
11 locations per page because based on the location you
12 need to probably use the description of those
13 locations, the critical habitat, maybe the contact
14 person. When we look at all of them across the board,
15 that's about what we see.

16 Origin and destination is about four or five
17 locations per page. So, again, it's depending on how
18 much you enter into the construct and location
19 information; but if you want to do some rough math to
20 figure out when you might get yourself in trouble, this
21 is a good guide.

22 If you think that you're going to submit an

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1 application with 500 or more constructs or 500 and more
2 locations, please check with us first. Let us know
3 that you're getting ready to do this because we can
4 alert the contractor to say, "Okay, you know, Company X
5 is getting ready to upload a very large application."
6 They can look to see what's happening behind the scenes
7 and let us know if it looks like it's going to be a
8 problem because what'll happen you guys will see that
9 you may or may not get an error, you may submit it, and
10 you walk away from your desk, and three hours later,
11 you're still wondering did it submit or not. So if you
12 can let us know when you're getting ready to submit, it
13 would be a really big help for us.

14 And if you're getting close to that 500-page
15 limit, we may have to ask you to split it into two or
16 three different pieces. And some of us have all worked
17 together trying to figure out the best way to skin a
18 cat: Do you put more constructs in fewer locations,
19 more locations fewer construct, that kind of thing.
20 But it depends really on how it works best for you to
21 split it up.

22 One last thing is the ePermits setup desk is

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1 going to be moving. The contractor isn't going to be
2 the first person to get the phone call. It's going to
3 be USDA help desk, and then they will route all
4 internally to the different programs, and if it has to
5 be escalated, if it truly is a broken system, then it
6 get escalated to a contractor. That probably means
7 that the 800 number is going to change, and the help
8 desk email may change. And as soon as that happens,
9 we'll let everybody know.

10 So that's it. Okay. Next up is Cindy Eck,
11 and Cindy is our Document Control Officer, and Cindy is
12 going to give an update on CBI issues and how to deal
13 with CBI.

14 MS. ECK: Good afternoon. I always talk to a
15 lot of you on the phone, so it's nice to put a face to
16 a voice. I am going to talk about confidential
17 business information. One of the thing, well, several
18 things I'm going to hit on is we're going to talk about
19 a definition of how define CBI; talk about your
20 justification statements; current guidances out there;
21 getting it right the first time, meaning getting your
22 justification statement right with us the first time;

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1 and release of that information. When we get to the
2 end of the presentation, we'll actually talk about
3 coming to our Web site where we have some proactive
4 release and what is not available through the eFOIA
5 reading room.

6 Before we actually talk about defining CBI, I
7 think it's important to understand that CBI taken
8 through in the Freedom of Information Act is
9 approximately like 44 years ago on July 6, 1966, Lyndon
10 B. Johnson is the one that signed the Freedom of
11 Information Act into place. The purpose of the act, of
12 course, is to provide access to Federal agency records
13 to any person for any reason. This includes paper
14 documents, tapes, photos, and electronic records.

15 What does this mean to you? It means that
16 you can expect that APHIS stakeholders will request
17 information about you and your business. They'll be
18 asking for any records that APHIS's employees may
19 generate, maintain in their custody or in their
20 control. And it is our responsibility to make sure
21 that these records are available either through a FOIA
22 request response or by proactively making records

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1 available to our APHIS electronic Web pages.

2 The FOIA does set standards, however, for
3 determining when government records must be made
4 available and which records may be withheld. The FOIA
5 gives requesters specific rights and provides
6 administrative and judicial remedies when access to
7 records or portions of records are denied. The FOIA
8 statute requires that Federal agencies provide access
9 to and disclosure of information pertaining to the
10 government's business to the fullest extent possible.

11 But under FOIA, certain records may be
12 withheld in whole or in part from the requester if they
13 fall within one of the nine exemptions of the FOIA.
14 And the exemption that we deal with mainly in BRS is
15 exemption 4, which is confidential business
16 information.

17 So when we see CBI, again, it's defined by
18 Section (b) (4) of the Freedom of Information Act, which
19 protect trade secrets and confidential, commercial, or
20 financial information. So when we say trade secrets,
21 we want you to think about your production process. We
22 want you to tell us -- you need to know that it must be

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1 commercially valuable, the information you want to
2 protect, used in one's business, and maintained in
3 secrecy. Is it commercial or financial information?
4 Yes, I'm sure a lot of it is. But is it really CBI?
5 Are you facing active competition? And typically where
6 we see CBI is in your safety data, efficacy, or potency
7 data, or environmental data.

8 Confidential business information must be
9 justified, competitive, or financial harm due to
10 release, not protected just because. And in fact I had
11 a good conversation this morning with the Assistant
12 Director of the FOIA office, and she told me that if
13 your justification statements -- and we're going to get
14 to that -- are good and clean and tight and
15 justifiable, that if there's a FOIA request that comes
16 in, without making you go through the process again of
17 justifying what's CBI, they will write a letter to you,
18 which they're required to, and tell you that they agree
19 with our argument. So that's why it's some important
20 that we get this right the first time.

21 So you must include a statement, and each
22 claim must be detailed and meeting definition of

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1 exemption 4. If you want some guidance on preparing
2 your documents, of course, we have our BRS document
3 prep guidance document on the Web.

4 You must send us both a CBI marked document
5 and a CBI-deleted version document. I highly recommend
6 that you date your version to control your documents
7 that you send us. Remember this includes but it's not
8 limited to applications, (indiscernible), and
9 supporting documents.

10 So, again, prepare your justifications as if
11 we had received a FOIA request and you're now trying to
12 prepare an justification for the FOIA office. Tell us
13 what each category of information reveals about your
14 organization's business. Tell us how a competitor
15 could use this information to cause your company
16 competitive harm. Tell us specific competitive harm
17 that could result if the information is released; for
18 example, financial, research, and development,
19 etcetera. And then do what the FOIA office does:
20 Consult current case law about exemption 4. There's a
21 Web link here, and it's in your fine handout. Go and
22 look at what is currently being claimed as CBI.

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1 When I look at BRS application and the
2 biotechs come in and go, "Oh, Cindy, I think we may
3 have a problem here. Look at this justification
4 statement. It's like a paragraph." That's when you'll
5 get a phone call from me. So when I take a look a
6 justification statement, it's more than a paragraph;
7 it's usually at least a page and has several sections.

8 So this is what I'm looking for. I'm looking
9 for a legal background section. I want you to explain
10 how through FOIA exemption 4 information on gene
11 description and commercial development falls within the
12 definition of CBI. I want to see a section on gene
13 description; explain the essence of the commercial
14 value of your product is the particular genetic
15 information that confers desired properties on the
16 planned product; explain how this is unique or nominal
17 information; explain how the particular combination of
18 genetic component and vectors are unique; explain how
19 revealing this could cause replication by a competitor;
20 the money lost in developing your technology. Let's
21 see a section on name and the information on gene
22 promoters, terminators, and expressed traits; explain

1 how revealing the genetic sequence could cause
2 competitive harm.

3 I'd like to see a section on new or unique
4 identities and characteristics and donor organisms;
5 explain how this would cause you competitive harm if
6 released.

7 And then this is the biggest area that
8 everybody always wants to claims as CBI, and honestly,
9 it is a legitimate claim. It's identification of
10 physical site and release location. You ought to here
11 explain how you've invested monies to obtain these
12 cooperators and how revealing that would lead to you
13 losing a contract.

14 In the past and we currently see you all
15 making claims about threat to site locations. So,
16 again, in that conversation that I had with the
17 assistant director this morning, she verified with me
18 that if you can point to an actual or verifiable
19 threat, not a perceived one, but a threat, and you can
20 tell us how you've been threatened, they will accept a
21 CBI claim on your site location even if -- and this a
22 new thing -- even if it is your own site location and

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1 not a contractual one with a cooperator. So that's a
2 big plus, but it's got to be verifiable, and give us
3 details, explain. Okay.

4 So we do, we are required, to make
5 information available on the Web. We're encouraged.
6 Our current administration strongly encourages us to be
7 proactive. So if you go to our APHIS/BRS main Web
8 site, you will see that we have some inspection letters
9 that are redacted, confidential business information,
10 and personally identifiable information is also removed
11 -- that's another topic -- from our Pharma, industrial,
12 and priority mediation inspection letters. We also
13 have a lot of sugar beets, the Roundup Ready sugar
14 beets, information that we've made publicly available,
15 and we've redacted out the CBI information. I think
16 Rebecca SG talked about the BRS NEPA Pilot Project.
17 That's there, and of course, we've got a link to BRS
18 news and information.

19 And then finally, we have our eFOIA Reading
20 Room. And this is where if there's a FOIA request that
21 comes in and it's related to BRS documents that I
22 supplied and they redact out the information, the CBI,

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1 PII, and any of the nine exemptions of the FOIA, they
2 are then going to post the response of records, the
3 request and the response of records, on the eFOIA
4 reading room site.

5 So what we have here is a list from 2011 of
6 all the FOIA requests that you can click on and see the
7 redacted response of records.

8 And then finally, if you still don't
9 understand what's CBI, or you need some help in doing
10 your justification letter, please don't hesitate to
11 contact me. Questions? No. We're doing questions at
12 the end?

13 Okay. I do not. Thank you. The next person
14 up is my boss, our new Director of Regulatory
15 Operations Programs, Dr. Ed Jhee.

16 MR. JHEE: Good afternoon, everyone. You
17 guys hear me okay back there?

18 All right. What I'm going to provide to you
19 guys today to close out the day before we move on to a
20 question-and-answer session is an overview of
21 Regulatory Operations Programs, kind of where we've
22 been within the last year, what our current priorities

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1 were, and then moving forward to this fiscal year what
2 your primary focus is going to be.

3 As Mike mentioned this morning when he
4 provided his opening statements, we had a very
5 successful year regarding BRS's activities. I think
6 especially within Regulatory Operations we also had a
7 very tremendous year meeting many of the goals set out
8 for us.

9 We were intimately involved in many of those
10 high-priority performance goals set forth by the
11 Secretary's Office including those that Mike had
12 mentioned regarding the inspection programs, the
13 operation of the BQMS program as well as its expansion,
14 in addition to managing the overall compliance program.

15 Just to recap some of those numbers and some
16 of the data there, Mike had mention that the inspection
17 program was targeted for about 628 inspections. Going
18 back to 2010, we typically covered historically about
19 500 inspections on an annual basis. And last year, we
20 were met with an unprecedented close to 800
21 inspections, almost doubling the tremendous amount of
22 work that our team had done.

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1 In addition, Mike had mentioned that we did
2 greatly expand the BQMS program. I think we've seen
3 the evolution of that program rate since 2007 and 2008
4 when the concept was first developed to where we are
5 today with a very large rate of adoption within the
6 industry.

7 And in addition to that, our overall
8 compliance rate has been maintained at a very high
9 rate, and we applaud the industry for your efforts, for
10 you due diligence in meeting the compliance
11 requirements.

12 In addition, ROP was actively involved as
13 well as all of BRS in a lot of the emerging challenges
14 we faced including some of the litigation challenges
15 and other operational process improvement projects.

16 That moves us to 2012. So moving forward
17 after last year's success, what do want to accomplish
18 now?

19 Well, we wanted to take a step back and
20 continue to take a look at our operations, where can we
21 determine opportunities for realized efficiencies,
22 added value, especially within the inspection program.

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1 Challenging times face us especially regarding the
2 budget climate this year as well as moving forward. So
3 we want to move make sure that we're going to be
4 utilizing taxpayer funds to be able to be more
5 efficient as much as being operationally effective in
6 the way we approach the inspection program.

7 In addition, we're also going to be expanding
8 the compliance assistance branch. Rather than just
9 focusing as we have over the last few years on just the
10 BQMS program, we have an opportunity now to leverage
11 the resources and the partnerships we've established to
12 focus on services activities as well as more
13 partnerships on moving forward with this concept of
14 compliance assistance. I'll get to that in a little
15 bit more detail after this.

16 In addition, we are going to be focusing more
17 on program metrics as well as the analyses. We want to
18 determine really based on data where are those
19 opportunities for added value for operational
20 efficiencies.

21 So what are the actionable event? Compliance
22 assistance, and just a couple of slides on the

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1 expansion of this branch. As I mentioned, we've been
2 very successful in the implementation of the BQMS
3 program, but that's not all about compliance
4 assistance. What we want to do is focus on additional
5 activities that we can provide a regulated entity.
6 Some of these are in the current works or working stage
7 right now: Planning and conducting regulatory
8 compliance, regulatory permitting and compliance
9 workshops.

10 These workshops are actually going to be
11 targeted for the public sector. Many of you in this
12 room are well aware of what compliance requirements are
13 and how to navigate the permits conundrum as well as
14 other challenges. A lot of the public sector still
15 needs this type of education, and so we have been
16 actively engaged in working with some key partners in
17 the industry as well as the academic community to be
18 able to have hosted workshops where both the risk
19 assessment staff as well as the Regulatory Operations
20 Programs can provide this face-to-face type of training
21 too.

22 The focus of these workshops will be on

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1 raising their awareness and the education process and
2 really what are their responsibilities, what are their
3 regulatory obligations.

4 In terms of those operational activities,
5 these workshops are going to be covering four main
6 points: The permitting, the notification process. As
7 I mentioned, many of you are very experienced in using
8 ePermits or even the paper-based process. A lot of
9 these academic and public institutions are just now
10 getting into this, or in some cases, they may need some
11 refresher training. This is an opportunity for us to
12 provide some outreach to them as well.

13 In addition, one of the components will be
14 about the inspection program, what to expect when an
15 APHIS inspector comes to your site. We believe that is
16 going to be a very transparent way for the entities,
17 for those permit applicants to understand really what
18 they're about to get themselves into.

19 In addition, the Evaluation and Enforcement
20 Program, we're also going to provides some insight on
21 what the repercussions are for failing to abide by the
22 regulations.

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1 these four. We have other experts. We have our branch
2 chiefs Susan Koehler and John Cordts. We still got
3 Gwen Burnett, our state and tribal liaison, and Linda
4 Pardoe, our IT specialist. We have a lot of experts to
5 answer your questions. I guess we'll have a roving
6 microphone again.

7 FEMALE SPEAKER: Yes.

8 MR. TURNER: Yes, Colleen is ready for that,
9 so whenever you guys are ready, raise your hand, and
10 we'll take your questions.

11 MR. BOTTOMS: Jeff Bottoms with Syngenta.
12 Actually, I have a couple of questions. In the permits,
13 the multiyear permits are currently issued for three
14 year. Is there any plans or any investigation into
15 having longer time periods for some of the GE crops?

16 MR. HANDLEY: At this point, no, we picked
17 three years. We thought that was a good number. It
18 seemed to work well. We talked about five years, but I
19 lot can happen in five years, so I think we're going to
20 stick with the three-year time period for now.

21 MR. BOTTOMS: And my second question goes
22 around the company application IDs.

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1 MR. HANDLEY: The organizational applicant?
2 We would love to implement that. I believe the problem
3 at this point is a blanket problem. It's a major
4 development for the ePermits system, so I don't know if
5 I am supposed to talk about current ePermits system,
6 but we're basically going into maintenance mode at this
7 point. So as I understand it, we won't be making
8 significant changes in the system at this point.

9 MR. FIRKO: I can make a brief comment on
10 that. Besides being the Acting Associate Executive
11 Administrator for BRS, the APHIS sponsor ePermits.
12 EPermits is very expensive right now, primarily because
13 it was originally envisioned in about 2001, 2002, so
14 the technology that we use to build ePermits is feeling
15 its age. So we need to move to a different platform,
16 and we've reached that point in ePermits when we've
17 decided to quit sinking money into it to enhance it and
18 create new capabilities in ePermits. And we've started
19 a business process analysis of the existing permit
20 policies and ePermits as an IT solution, and we hope to
21 have a new system within a few years.

22 As we did last time -- I don't know who all

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1 in this room participated, but we had a set of
2 stakeholders meetings where we had folks come in when
3 we were part way through the build, showed them what we
4 had, and said, "What do you think? What would you like
5 to see as we go forward?" And I hope to do that again
6 this time, so keep your eyes open for the next build of
7 electronic permitting system.

8 MR. BOTTOMS: One more thing to sort of
9 followup. As part of this overhaul of the current
10 system into a new platform, is there anything that the
11 industry could do to help fund this particular
12 enhancement as part of this build, something similar to
13 the cooperative agreement where we're actually helping
14 to fund the NEPA analysis being outsourced?

15 MR. FIRKO: The person who is managing this
16 transition has spent a little time looking into the
17 possibility of getting outside support for creation of
18 a system. I know that many of the companies out there,
19 the biotech companies, actually spend a lot of money on
20 their own system so that they can interface well with
21 ePermits, so they certainly have an interest in doing
22 that. I would be happy to give you the contact of the

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1 person who is managing this new contracting effort, and
2 you can get in touch with her and talk about
3 possibilities. Is that fair enough?

4 MR. BOTTOMS: Sounds good.

5 MR. FIRKO: All right.

6 MR. MUNDELL: Scott Mundell with DuPont. One
7 of the numbers that was shown was the sheer volume of
8 permits and notifications sites constructs that your
9 agency deals with. To your credit, they far outstrip
10 anything else anybody in the world is doing. And I was
11 curious if your agency in your international outreach,
12 regulatory, was sharing those kinds of numbers with
13 other regulating bodies throughout the world as an
14 example of what can be done, what is possible to do
15 with an eye toward the environment with safety in mind
16 effectively and efficiently?

17 MR. TURNER: We've certainly shared the
18 numbers in terms of the number of field techs, the
19 number of permits, the number of notifications over the
20 years. I'm not sure it was correctly targeted. It
21 seems like from my experience that a lot of the
22 international capacity-building efforts centered around

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1 the approval process; those terms loosely are
2 deregulation process. So I don't know.

3 MR. MUNDELL: You're sharing the numbers
4 though?

5 MR. TURNER: I've shared the numbers. I know
6 common (indiscernible) will at least have the numbers
7 that our field task force (indiscernible). There
8 should be an awareness. It's very common with
9 (indiscernible).

10 MR. MUNDELL: Okay.

11 MR. PEARSON: Les Pearson with ArborGen.
12 Question for you, Lee. You talked about there were 14
13 ePermits has not yet required, but from now that they
14 will be required at some point. Is there some timeline
15 that you guys are thinking about for that?

16 MR. JHEE: There was a couple, a lot of, many
17 considerations that went into this timeline question
18 that you're raising. The first one was the question
19 raised again about the organizational applicants. We
20 realized that there were multiple factors that would
21 lead to the success of using ePermits for reporting the
22 mechanism, and one of them being the flexibility of an

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1 organization applicant was really necessary. In light
2 of the budget situation and the explanation Mike
3 provided, we all understand that that's not going to
4 happen at least in the near future.

5 So we had to make an assessment of really is
6 this a policy to mandate the use of ePermits? No. We
7 cannot mandate you by law to use ePermits, but we can
8 strongly encourage you to out of best practices. How
9 is that?

10 MR. PEARSON: So I have a question for
11 Margaret too about the tribal land information, and you
12 talked about looking at the sites and the proximity to
13 tribal land. So the first question is how close is
14 close? And then gave us a Web site to map these things
15 out. It's still make a little like TES that's dynamic.
16 We have to check that every time we do a new permit or
17 whatever. I'm assuming the tribal lands sites are
18 pretty static, so once we've done that analysis to
19 check our proximity to sites that that should be fairly
20 standard for that point forward. Does that make sense?

21 MS. JONES: All it does -- Gwen, I'll take
22 the first part, and you can take the second part. In

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1 terms of proximity, it is case by case if anything. It
2 depends the biology of the organisms, the release, and
3 the action area that are potential for a safety flow,
4 and that distance is determined based on whether or not
5 it's within the action area. At this point, we have
6 had one where it was actually located in a tribal
7 reservation land, and it resulted with the successful
8 communication with them, and they authorized the field
9 test, but we do always check to see if the proximity is
10 in any way close to the action area. We're going to
11 err on the side of contacting the tribes.

12 MS. BURNETT: And I can answer that second
13 question, Les. Can you hear me? I'm sorry. My name
14 is Gwen Burnett. I'm the state and tribal liaison for
15 BRS -- and everybody can hear me, right? In terms of
16 the lands for tribal lands, the Census Bureau updates
17 that maps but not really -- not the super-regular
18 basis. It's not once a year; it's once every two years
19 I think on the data they have.

20 The BIA does publish one a year with
21 supplemental information, Federal Register notices of
22 the list of all the Federally recognized tribes, and

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1 that's not real dynamic. I think we've had one new
2 tribe in the last year, and that's an unusual
3 occurrence.

4 MR. WEGENER: My name is Randy Wegener from
5 Bayer. Ed, I got a question for you on your, looks
6 like your workshops. You're going to be outreaching
7 mostly to the public, such as universities?

8 MR. JHEE: Right.

9 MR. WEGENER: I just want to make sure that
10 I'm not confused. This is not going to be a training
11 that's somebody could say that they've taken, and they
12 wouldn't have to take an industry compliance training?

13 MR. JHEE: No, no, no, no. I think there is
14 -- we're going to make a clear difference I think from
15 an operational aspect of our you guys train our
16 collaborators versus really the higher level type of
17 training of (indiscernible) and permit; what are the
18 fundamental requirements for compliance if you are the
19 owner of this permit or the responsible party. So in
20 terms of that type of outreach and education, that's
21 our focus. Does that help?

22 MR. WEGENER: Yes. Second question. I think

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1 I know the answers. You've politely uninvited industry
2 to these correct, because we already know what we're
3 doing?

4 MR. WEGENER: I wouldn't -- if I see
5 something come up online, I'm going to want to jump,
6 any kind of education in compliance that I can get...

7 MR. JHEE: We actually welcome that because I
8 think -- and also it's depending on the host.
9 Oftentimes, some of the host institutions they may want
10 to keep it within their entities. Oftentimes -- we've
11 talked with the BIO. We've also talked with the ETS
12 folks. We've also had some discussion with the
13 American Seed Trade Association on how from an
14 organizational standpoint they may be able to leverage
15 some of their members and organizations to participate
16 as partners as well.

17 I think it would be a modular approach to
18 also provide the industry perspective on how they
19 collaborate with the public sector and keep a lot of
20 the research and development priorities. That's
21 another opportunity as well.

22 MR. BOTTOMS: One more question. Jeff

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1 Bottoms from Syngenta again. One issue that I've
2 notice when working with BRS and submitting permits
3 it's not very clear who the biotechs are that are
4 reviewing the permits. Are there any plans in the
5 future of trying to make that a little more obvious
6 from our viewpoint?

7 MS. JONES: I don't know about the future,
8 but if you send an email to biotechquery@aphis.usa.gov,
9 they'll be able to supply you with the biotechnologist
10 who is working on any given permit or notification.

11 MR. BENNETT: Also could add that within the
12 environment of ePermits, we have the ability to
13 messaging, so you could do messaging right from
14 ePermits, and what you may find out is there could be
15 more than one person who may be working on that permit.
16 It depends on what workflow step you're at will
17 determine on who you might be corresponding with your
18 messaging. That is some other function I'll get into.

19 MR. BOTTOMS: Can we instigate instant
20 messaging?

21 MR. BENNETT: Yes. What I was asking is I
22 don't think we can instigate instant messaging. We

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1 have to wait until we're contacted.

2 MS. FITZPATRICK: This is Sharie Fitzpatrick
3 of Metabolix. I just had a question specifically on
4 the state liaisons. Is there a -- do you have a
5 Federal Web page of states that have specific
6 requirements or sort of any across index?

7 MS. BURNETT: We don't have a Federal Web
8 page that has that, but a couple of years ago we did
9 partner with the National Plant Board, and they look at
10 state requirements dealing with biotech matters or
11 regular (indiscernible) they might have, and they did
12 post that on their Web site or their laws and
13 regulations site. And if you're interested, I'd be
14 happy to show you where that is?

15 MS. FITZPATRICK: Has it been updated?

16 MS. BURNETT: I don't think it's been updated
17 this year, no.

18 MS. MASSEY: Hey, Adrienne Massey with BIO.
19 Lee, back to the question about the company
20 identification. Last year there was some discussion
21 about this being an agency-wide policy that you put in
22 this security reasons. And Sid has said that he was

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1 going to talk about maybe trying to make some changes
2 agency-wide as a policy. At that point in time, that
3 was actually the easier route, which seemed amazing,
4 but I was willing to take anything we could get. Do
5 you know how that conversation went and --

6 MR. HANDLEY: You're talking about --

7 MS. MASSEY: -- is it still in process?

8 MR. HANDLEY: That was the having a
9 corporation e-authentication account?

10 MS. MASSEY: Yes.

11 MR. HANDLEY: And as far as I know, and maybe
12 Sid could correct me, that didn't go anywhere. We
13 tried really hard. Because you're right, that would've
14 solved a lot of problems.

15 MS. MASSEY: It did seem like it was a lot to
16 hope for but --

17 MS. MASSEY: -- it was appreciated.

18 MR. FIRKO: If I heard the question right,
19 part of the problems that that required new
20 development, and we're just not doing new development
21 enhancements in ePermits right now.

22 MR. HANDLEY: No, this is an e-

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1 authentication. This was a change in the e-
2 authentication, how you can only have an e-
3 authentication ID for a person and not for a
4 corporation. So the idea was if you could have a
5 corporate account for e-authentication, then anybody
6 using the e-authentication, companies could share
7 (indiscernible).

8 MR. FIRKO: Sorry, I missed that. We should
9 bring in some of our security people. E-authentication
10 is a USDA application. It's not a APHIS application,
11 and the whole thing is based on an identity proofing.
12 And if it's a corporate account, you can't identify to
13 a particular individual. Did you hear all this last
14 year?

15 MS. MASSEY: Not in this detail. Well --

16 MR. FIRKO: Okay.

17 MS. MASSEY: -- I couldn't, but somebody
18 else.

19 MR. FIRKO: And from a USDA security point of
20 view -- and there's a USDA other policy that says
21 whenever there is two-way information flow in a USDA
22 system, USDA must know exactly who they're dealing

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1 with. So with a corporate account, you lose that
2 identity, right. So that's the reason it's difficult
3 because it wouldn't be just a matter of BRS changing a
4 policy, it wouldn't be just APHIS changing a policy, it
5 would affect all USDA.

6 MR. TURNER: Mike, would you just please
7 identify yourself in the mic for the --

8 MR. FIRKO: Oh --

9 MR. TURNER: -- sake of our court reporter?

10 MR. FIRKO: Sorry. Mike Firko with BRS.

11 MR. TURNER: If you could all just try to
12 remember --

13 MR. FIRKO: Right.

14 MR. TURNER: -- to do that, it would help a
15 lot including BRS folks.

16 MR. TURNER: It looks like you guys are going
17 to beat the traffic.

18 MR. TURNER: (Indiscernible), going one,
19 going twice --

20 MR. GEORGE: Actually, I just wanted to say a
21 couple of things before we close.

22 Again, thank you all for being here today. I

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1 hope you found it productive. I lot of work went into
2 pulling this stuff together, and the whole idea was the
3 interchange of ideas and (indiscernible) that's the
4 kind of information that you would find useful, and I
5 hope that you did.

6 I just want to ask you please to be sure to
7 fill out your evaluation forms, which I believe are in
8 the handouts. And I was just reminded of the
9 PowerPoint presentation. It'll be on our Web site
10 along with the complete transcript of most
11 (indiscernible), which be within a few weeks.

12 Thank you all for coming out and for being
13 here today, and drive safely.

14 (Applause)

15 (Whereupon, BRS/APHIS Public
16 Stakeholders Meeting was concluded.)

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Capital Reporting Company
Biotechnology Regulatory Services: Public Stakeholder Meeting 12-13-2011

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1 CERTIFICATE OF NOTARY PUBLIC

2 I, NATASHA THOMAS, the officer before whom the
3 foregoing hearing was taken, do hereby certify that the
4 testimony appearing in the foregoing hearing was taken
5 by me in audio recording and thereafter reduced to
6 typewriting under my supervision; that said
7 transcription is a true record of the proceedings; that
8 I am neither counsel for, related to, nor employed by
9 any of the parties to the action in which this was
10 taken; and, further, that I am not a relative or
11 employee of any counsel or attorney employed by the
12 parties hereto, nor financially or otherwise interested
13 in the outcome of this action.

14

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NATASHA THOMAS
Notary Public in and for the
State of Maryland

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