

Capital Reporting Company
Stakeholder's Meeting 11-20-2013

1

USDA
BIOTECH REGULATORY SERVICES
ANTI-INFECTIVE DRUGS
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
(APHIS)

Wednesday, November 20, 2013

Location:
Department of Agriculture
Animal and Plant Health Inspection Service
4700 River Road
Riverdale, MD 20737

Reported by: Bryan Young
Capital Reporting Company

Capital Reporting Company Stakeholder's Meeting 11-20-2013

<p style="text-align: right;">6</p> <p>1 the back of the room. Down the hall, out this door 2 and to the right, and then the first left, is a 3 cafeteria if you'd like a different beverage or 4 something to eat during the break. 5 Also, during the break and after the 6 meeting, our Permits and Program Services Branch 7 Chief, Steve Bennett, is here to help anyone who may 8 need help to get authenticated in order to access our 9 e-permit system. There's Steve at the back. Give him 10 a wave. If you need help, Steve is your guy. 11 Today's presentations are available as 12 printed handouts that are on the sign in table. So if 13 you'd like to follow along and take notes on the 14 handouts, be sure to pick up a set if you haven't 15 already. If you'd like a set of the handout, just 16 give us a wave and we'll get a set to you. So if 17 there's anybody needing some, just let us know, and 18 Gail will get a set over to you. All of the 19 PowerPoint presentations today will also be available 20 on our website within the next day or two. 21 Today we're webcasting this meeting. This 22 has become a popular option and this year we actually</p>	<p style="text-align: right;">8</p> <p>1 please come to this microphone to ask them so that 2 everybody online will be able to hear and also see 3 you. I will also have a stick mic so if it gets 4 problematic over the long trip from the back of the 5 room or something, we can move that around as well. 6 Also when you ask your questions, please 7 identify yourself and your organization. Also, after 8 we're done today, many BRS staffers will hang around 9 after the meeting to take questions individually if 10 you prefer or if you just want to say hello. 11 Those of you online, there are two ways to 12 ask a question, either in written or spoken form. 13 First, once you're in live meeting, you can click on 14 the Q&A button at the top of your screen. This will 15 bring up a text box. Type in your question then click 16 on the ask button. We'll pick up your question, read 17 it aloud here, and try to answer it. If you prefer to 18 speak your question, on your telephone keypad hit 1 19 then 0. This will alert our webcast moderator that 20 you'd like to speak and we will unmute you and invite 21 you to ask a question. 22 So again, please note there are two ways to</p>
<p style="text-align: right;">7</p> <p>1 have more people registered for the webcast than to 2 attend in person. So our challenge today is to be 3 mindful that in addition to those who are here in 4 person, we have a sizable contingent who are not 5 visible but still in attendance. Those of you online 6 should be able to see the presenters and presentations 7 and to ask questions. We're glad to make the meeting 8 available via webcast to stakeholders who could not 9 attend in person, and that so many are able to join us 10 this way. 11 We have a court reporter here today, Bryan 12 Young, who is up here in the corner. He'll produce a 13 complete transcript of this meeting, and that will be 14 posted on our website as well within a couple weeks. 15 So if you hear something today, you want to go back 16 later and double check to see if you got it right in 17 your notes, look for the transcript on our website. 18 We would ask that you please hold your 19 questions until each speaker has completed their 20 presentation. We've allowed time for questions at the 21 end of each presentation. Then for those of you in 22 the room, I'm going to ask if you have questions to</p>	<p style="text-align: right;">9</p> <p>1 ask an online question. Click on the Q&A button on 2 the top of your screen, type your question in the text 3 box and hit ask. Or hit 1 then 0 on your telephone 4 keypad and we'll let you know when it's your turn to 5 speak. We'll repeat these instructions along the way. 6 Today for the first time we've scheduled 7 some time for what we're calling a listening session, 8 in which you're free to make any comment you choose on 9 biotechnology and related subjects. This is intended 10 not as a question and answer period but rather as a 11 chance for you to make a comment on any biotechnology 12 related subject. 13 We scheduled it in response to comments in 14 the past that our communications in these meetings 15 tend to be one way, with us delivering several hours 16 of nonstop outgoing information with little chance for 17 incoming. So we've allowed some time for that. 18 We do have at least three people who have 19 signed up to comment who are attending the meeting. If 20 you'd like to comment and have not signed up in 21 advance, it's not too late. You can sign up at the 22 registration desk and you will have a turn. Also, if</p>

Capital Reporting Company Stakeholder's Meeting 11-20-2013

<p style="text-align: right;">10</p> <p>1 you prefer a written comment, that's also fine, and 2 you can put it in the comment box which is in the back 3 of the room. We'll be sure to read it. If you're 4 online and would comment during our listening session, 5 use the Q&A button, bring up the text box, write your 6 comment and we'll read it aloud, or hit 1 then 0 and 7 we'll let you know when it's your turn to speak. 8 Not knowing how many commenters we might 9 have, we have not created time limits. When we get to 10 that part of the agenda we'll repeat these 11 instructions and try to allot time so that everyone 12 who wants to speak has the opportunity. This 13 listening session is not part of any official public 14 comment period of the sort that often accompany our 15 regulatory actions, but more simply a way for you to 16 provide feedback or input that you'd like to share 17 with us. So that's how it's going to work. 18 One last thing, after the meeting you will 19 receive an email survey. We would ask that you please 20 take a couple of minutes to fill it out. It will help 21 us make these meetings better in the future. 22 So at this time I would like to introduce</p>	<p style="text-align: right;">12</p> <p>1 As Mike indicated, I became the 2 administrator of APHIS in June. And one of the first 3 things I did was set up some goals, things I'd like to 4 see accomplished over the next three or four years. 5 And one of those things, very high on that list, is 6 that we will carry out our regulatory role with 7 genetically engineered organisms in an efficient and 8 effective way. As you probably all know, we've looked 9 very hard at our system to see what we could do 10 better. 11 We have a very specific role. Our role is 12 to simply make sure that we don't put plant pest and 13 diseases into the environment. In that way we protect 14 American agriculture and the environment. Now that's 15 our role. The courts have told us that's our role. 16 The law says that's our role. And that's the one we 17 intend to carry out. 18 And we are fully aware that over time our 19 role is taking too long. And we looked at this very 20 hard. We used a very exhaustive business process 21 improvement method to look at how we move things to 22 deregulation. And we did that with no intention to</p>
<p style="text-align: right;">11</p> <p>1 the BRS Acting Deputy Administrator, Mike Firko. 2 MR. FIRKO: Thank you, Dick. I've got my 3 traveling mic on. I tend to be more comfortable 4 wandering around so I have a white line that I'm not 5 supposed to go past. It's my great pleasure this 6 morning to introduce the APHIS administrator, Kevin 7 Shea, who will open our meeting with a few comments. 8 Biotechnology and USDA 9 MR. SHEA: You want me here so I can be seen 10 here, correct? Good morning. A pleasure to have 11 everyone with us here today. And I do need to open up 12 by expressing Max Holtzman's regrets that he could not 13 be here today. Max was taken ill overnight so we're 14 certainly hoping Max will feel better as the day goes 15 on, but he wasn't feeling too well this morning so he 16 wasn't able to join us. 17 Max, of course, is our Acting Deputy Under 18 Secretary and also the senior advisor to the 19 Secretary, and most of you probably met with Max 20 somewhere along the line. Know that he is very, very 21 interested in this entire subject matter and follows 22 it very closely, as does the Secretary.</p>	<p style="text-align: right;">13</p> <p>1 making our regulatory system any less rigorous or make 2 the protections any less good. We did it to make sure 3 that we were doing it efficiently and so that we 4 weren't holding things up, holding new technologies 5 from market unnecessarily. 6 We recognize that healthy and profitable 7 agriculture is good for America and anything we can do 8 to help make that happen, we want to do. So we have 9 looked at the system. We've made some great 10 improvements we think. There's been some progress. 11 We're not where we need to be yet and where we expect 12 to get within the next year or two, but we're making 13 great progress. And things that used to take three to 14 five years we think are going to take less than 18 15 months. We've already done that on a few petitions, 16 and we're making great progress on the others. 17 Now I mentioned that this was one of my 18 personal goals as Administrator of APHIS, and it 19 wasn't any great legal courage for me to make that one 20 of our goals because it's one of the Secretary's 21 goals. And Secretary Vilsack has had as one of his 22 goals from the day he took office was to increase our</p>

Capital Reporting Company Stakeholder's Meeting 11-20-2013

<p style="text-align: right;">14</p> <p>1 ability to export biotechnology products and to bring 2 new technology to bear for the American farmers and 3 ranchers.</p> <p>4 So that's our pledge is to continue doing 5 that. You'll hear a lot more about it in detail today 6 and we hope that we can continue to work with you to 7 make that process more efficient so that we are doing 8 our job well without impeding your job and your 9 ability to do what you need to do.</p> <p>10 As Mike indicated, at the end of 11 presentations today, there will be an opportunity for 12 you to say anything you would like. And this is 13 something else that we've been doing over the last few 14 months, is having a series of meetings with all the 15 sectors of agriculture.</p> <p>16 Now we've had stakeholder meetings where we 17 bring all of our stakeholders in, but if you're 18 familiar with APHIS you know our stakeholders are a 19 pretty varied bunch and when we bring them in to talk 20 about the fact that we need to find what the most 21 important things are, they tend to say, we're the most 22 important thing, it must not be those other guys so</p>	<p style="text-align: right;">16</p> <p>1 some increases and I think that we can do better with 2 that additional support and funding we receive and we 3 appreciate that support.</p> <p>4 I mentioned earlier that we want to get 5 through the deregulation processes faster, but I also 6 said we won't cut corners on the science, and we 7 won't. And in fact we also have built in an extra 8 opportunity for the public to comment on the work we 9 do. But I think we're trying to efficiently do the 10 best of all worlds here, move things to market 11 quickly, but safely, and give the public the 12 opportunity to comment, which is certainly their 13 right, and we welcome all your comments.</p> <p>14 I also mentioned something I want to 15 emphasize. We regulate for plant pests. That's our 16 role. There are lots of other interests, as we all 17 know, in biotechnology. There are other agencies that 18 have roles that are of public interest. We have a 19 pretty narrow role but we need to carry it out 20 effectively and efficiently and we intend to that.</p> <p>21 So again I want to thank you all for being 22 here, and again express Max's best wishes to all of</p>
<p style="text-align: right;">15</p> <p>1 take your budget cuts from the other guys.</p> <p>2 Well that's not really the way it could 3 work, so we've decided to kind of work with you sector 4 by sector. And we met with the seed sector last week, 5 and of course they're very tightly intertwined with 6 the biotech sector, and we've met with others as well.</p> <p>7 And so this is another opportunity for you as a sector 8 to give us your feedback, because we need to make sure 9 we're doing the right things.</p> <p>10 APHIS-wide, we lost a quarter of a billion 11 dollars, that was a B not an M, we lost a quarter of a 12 billion dollars in appropriations in three years from 13 fiscal year '10 to fiscal year '13. Now that's kind 14 of the bad news overall for APHIS. The good news for 15 the biotech sector is that the appropriation for 16 biotech work's actually gone up over that time. And I 17 think that reflects the fact that the Congress and the 18 appropriators see the importance of this, see the 19 importance of developing these markets and this 20 technology.</p> <p>21 So although we have seen great budget cuts 22 over all for APHIS, biotechnology we've seen actually</p>	<p style="text-align: right;">17</p> <p>1 you. He certainly enjoys working with you and is a 2 big proponent of an effective biotech regulatory 3 system within APHIS, and one that is efficient and 4 works for everybody. So thanks very much for being 5 here and we will welcome all your comments as the day 6 goes on. I'll turn it back to Mike.</p> <p>7 Reflections on FY13 and a Look Forward to FY14</p> <p>8 MR. FIRKO: Thank you, Kevin. I was pleased 9 to introduce Kevin because over the years, working 10 with Kevin for the past 15 or so years, he's been a 11 personal mentor to me and I'd like to thank you for 12 that.</p> <p>13 Before I get started, I also wanted to get a 14 wave from Melinda Sepp over here. That was a pretty 15 low wave. Melinda is from our Under Secretary's 16 office. She is senior advisor to Under Secretary 17 Edward Avalos. Within marketing and regulatory 18 programs, USDA oversees not only the biotechnology 19 regulatory program, but also the national organic 20 program. So you might have some interesting 21 conversations with Melinda while you're here.</p> <p>22 Okay, clicker. The clicker has an on off</p>

Capital Reporting Company Stakeholder's Meeting 11-20-2013

<p style="text-align: right;">18</p> <p>1 switch. So for Biotechnology Regulatory Services, and 2 I say that the long way this time, BRS because I'll 3 probably be saying BRS a few times. That's our 4 Biotechnology Regulatory Services program. In 2013 5 challenges were opportunities, and we took advantage 6 of several opportunities this year to improve our 7 program, and we'll be describing that; I'll be talking 8 about that.</p> <p>9 One of our challenges has been IT issues. 10 Actually it's more of an operator problem it looks 11 like, me. One of the first things I'm going to talk 12 about when -- here we go. So I introduced Kevin, and 13 although Kevin was here at our stakeholder meeting 14 last year, he was here as Acting Administrator. This 15 year he is here as permanent administrator of APHIS. 16 And we are all very pleased to be working with Kevin.</p> <p>17 APHIS has now gone back to a model that's 18 been used in past years. We have two acting associate 19 administrators in the administrator's office. One is 20 Dr. Jere Dick, who was recently from APHIS's 21 Veterinary Services program. And the second acting 22 associate administrator is Michael Gregoire, who was</p>	<p style="text-align: right;">20</p> <p>1 Management System, our BQMS. And you'll be hearing 2 more about that, and that's an example of a non- 3 regulatory solution. We are going to be looking for 4 opportunities like that across APHIS and across the 5 BRS program.</p> <p>6 So I don't want you to read all this 7 necessarily. You notice I've highlighted some things. 8 These are APHIS's top ten, and these can be 9 characterized not necessarily as the most important 10 things that APHIS is doing. They are all very 11 important things that we feel that we can make 12 significant progress on over the next few years.</p> <p>13 And I show you the entire list to remind you 14 of what APHIS stands for. It's an animal and plant 15 health organization, and so a lot of the items here 16 you see deal with animal or plant health. I've 17 highlighted 7 and 8 because those are the two of the 18 top ten that BRS is involved with. You can look at 19 the full list in greater detail if you have a copy of 20 the presentation or if you pick one up later.</p> <p>21 So number 7, obviously we are heavily 22 involved in that. It has two different parts to it.</p>
<p style="text-align: right;">19</p> <p>1 here last year at this meeting as BRS Deputy 2 Administrator. And do you want to talk about your 3 core beliefs, Kevin?</p> <p>4 MR. SHEA: I want to see what they are. 5 MR. FIRKO: Okay. A healthy America. 6 Healthy and profitable agriculture is good for 7 America. And consistent with the Secretary's vision, 8 that means all sectors of agriculture, all types of 9 agriculture. The government's role is to do 10 collectively what no individual can do for themselves.</p> <p>11 There's a lot of information in that 12 sentence, and it means that we, in APHIS,+ are looking 13 very closely at what we do as public servants and ask 14 ourselves the question, are they things that we should 15 continue to do as public servants, and are there other 16 things we should be doing as public servants. And a 17 very strong interest in this current APHIS 18 administration is taking a hard look at what we're 19 referring to as non-regulatory solutions.</p> <p>20 I think most of the folks in this room are 21 familiar with one of our most obvious non-regulatory 22 solutions, and that is the Biotechnology Quality</p>	<p style="text-align: right;">21</p> <p>1 The business process improvement that BRS implemented 2 we started in November of '11, formally implemented 3 and became clear on how we were going to do that in 4 March of 2012. You'll be hearing much more about the 5 business process improvement throughout the day. The 6 other part of this is our Center for Veterinary 7 Biologics who went through a similar business process 8 improvement effort, but BRS owns half of number 7.</p> <p>9 I mentioned number 8 because although that 10 is a top ten program primarily for our plant 11 protection and quarantine program in APHIS, BRS has an 12 important role there. It has been recognized by the 13 citrus industry that what may ultimately save the 14 citrus industry in the United States are some biotech 15 solutions.</p> <p>16 There was a wonderful article in the New 17 York Times several months ago which laid out the 18 approaches that are being taken in Florida to find 19 some resistance to citrus greening in Florida. And 20 our interest here is to make sure that the same damage 21 to the citrus industry in Florida does not spread to 22 California.</p>

Capital Reporting Company Stakeholder's Meeting 11-20-2013

22	<p>1 BRS's role is that, as with all</p> <p>2 biotechnology initiatives in plants, we are working</p> <p>3 with these developers and we are being very careful to</p> <p>4 make sure that we safely facilitate the work that</p> <p>5 they're doing to find solutions to citrus greening</p> <p>6 disease.</p> <p>7 So opportunities and challenges. We were</p> <p>8 out of business in BRS for 16 working days, and of</p> <p>9 course that means a few days ahead and a few days</p> <p>10 after as we prepared and recovered from not being in</p> <p>11 our offices. Several of us had withdrawal symptoms</p> <p>12 from our Crackberrys, which is now actually iPhone,</p> <p>13 but that was an interesting 16 days.</p> <p>14 Some of you who worked with, for example,</p> <p>15 the PBQ permitting unit may not have noticed any</p> <p>16 difference. Well that's because the PBQ permitting</p> <p>17 unit is funded by AQI user fees, Agriculture</p> <p>18 Quarantine Inspection user fees. That program and</p> <p>19 many programs in APHIS are not funded by appropriated</p> <p>20 dollars. BRS is funded by appropriated dollars, so we</p> <p>21 were affected by the shutdown.</p> <p>22 You may also know that one of our activities</p>	24
23	<p>1 that we kept open in BRS was our compliance hotline.</p> <p>2 So we certainly wanted to stay in touch with</p> <p>3 compliance issues as they came up throughout the</p> <p>4 country, so that service remained (inaudible).</p> <p>5 We are currently working under a continuing</p> <p>6 resolution until January. I'm sure everyone here</p> <p>7 watches CNN and has heard all about this. And then</p> <p>8 the debt ceiling situation will be coming up in</p> <p>9 February as well and we are optimistic that our</p> <p>10 program will continue to run, and very hopeful that it</p> <p>11 will continue to run without interruption as we get</p> <p>12 into January and February. Obviously, that makes long</p> <p>13 term challenging, long-term planning a little</p> <p>14 challenging, but we're very confident that our program</p> <p>15 will remain active and robust for the rest of the</p> <p>16 fiscal year.</p> <p>17 And as Kevin indicated, we have the</p> <p>18 resources we need to do our work. I can say something</p> <p>19 for BRS that most programs in APHIS cannot say; we've</p> <p>20 increased our staff over the last few years. And as</p> <p>21 we go through the talks today I think you'll see how</p> <p>22 that has led to improvements in our service delivery.</p>	25
24	<p>1 Your guess is as good as mine though what's going to</p> <p>2 happen in January and February.</p> <p>3 So last year I talked to you about our</p> <p>4 developing CARPOL system and there's the whole acronym</p> <p>5 spelled out for you. The part that BRS is primarily</p> <p>6 involved in of course is permitting. We have a</p> <p>7 permitting function that many of you are familiar</p> <p>8 with. And as I said last year, we are moving towards</p> <p>9 a new system.</p> <p>10 When the sequestration was applied to</p> <p>11 various federal agencies, this affected our ability to</p> <p>12 fund some of our initiatives on CARPOL, but under</p> <p>13 Kevin's leadership APHIS did such a great job at</p> <p>14 tightening its belt, it turned out towards the end of</p> <p>15 the year we had money to get going on CARPOL again. So</p> <p>16 before the end of last fiscal year, before the</p> <p>17 furlough, we had reinitiated our efforts in CARPOL</p> <p>18 So although there will be a slight delay in</p> <p>19 development of our new system, we are moving forward</p> <p>20 on that again. And as we're developing CARPOL, we</p> <p>21 will do what we did when we developed e-permit, we</p> <p>22 will be consulting with you and other of our</p>	26
25	<p>1 stakeholders in biotechnology to help us build our new</p> <p>2 system. We'll be asking for your input. We see e-</p> <p>3 permits and we see CARPOL not strictly as an internal</p> <p>4 tool and a workflow manager, but as a tool that you</p> <p>5 use every day to access our services. And permitting</p> <p>6 is the first function, is the first CARPOL function</p> <p>7 that will be addressed.</p> <p>8 So petition process improvements. Mea</p> <p>9 culpa, we've been admitting for the last couple of</p> <p>10 years that our process had gotten to be too long. As</p> <p>11 you probably know, Secretary Vilsack has been a strong</p> <p>12 proponent of Lean Six Sigma as business process</p> <p>13 improvement. As long as I've known Kevin, he's been a</p> <p>14 strong proponent of business process improvement.</p> <p>15 For many years we've been talking about do</p> <p>16 we have too many handoffs in our system, do we have</p> <p>17 too many steps in our system, and so we wanted to look</p> <p>18 at why the system was taking as long and what we could</p> <p>19 do to shorten those times. As recently as 2011 some</p> <p>20 of these petitions for non-regulated status were</p> <p>21 taking over three years. The average was over two-</p> <p>22 and-a-half years. It was just taking too long.</p>	27

Capital Reporting Company Stakeholder's Meeting 11-20-2013

<p style="text-align: right;">26</p> <p>1 It says here the backlog had reached 22 2 petitions. In fact it has been as high as 23 in the 3 last few years. Now we use the term backlog. We're 4 going to be transitioning away from the term backlog 5 because at this time, well at the time that we had 22, 6 many of those were brand new petitions that we had 7 just received. So it wasn't really a backlog. Some 8 of them we had for a few years, but some of them were 9 brand new.</p> <p>10 As I mentioned, the technique we use for 11 business process improvement was the Lean Six Sigma, 12 and you'll be hearing from Clint Nesbitt, our Lean Six 13 Sigma green belt a little while later. And those of 14 you familiar with Lean Six Sigma understand what that 15 means.</p> <p>16 So just a few of the general results that we 17 obtained, challenges that we turned into 18 opportunities. We have already significantly reduced 19 the time for reviewing petitions. As you've seen in 20 past years, and as you'll see in a little while, there 21 are a variety of steps that we go through in 22 addressing a petition for non-regulated status. One</p>	<p style="text-align: right;">28</p> <p>1 dealing with new petitions that are coming in, we're 2 going to be meeting our targets. I said that the 3 target that the number of petitions that we had in 4 house was at one point 23, it's now down to 15. We 5 had a big year. Not only did some petitions come in, 6 we cleared out a lot that had been here for a while.</p> <p>7 In '13 we completed nine petitions, 50 8 percent more than we had done in either of the 9 previous two years. We did that under some 10 interesting circumstances. I only have a single side 11 on GE wheat but you know that we had a significant 12 regulatory incident this year that we spent a lot of 13 time on. We were implementing a new process and we 14 made significant progress by doing 50 percent more 15 than we had done in previous years.</p> <p>16 Now I said that we completed one petition 17 start to finish. What this bullet indicates is that 18 there are three other petitions that were already here 19 when we implemented our new process that we moved into 20 our new process, and we have finished those three as 21 well. And in terms of internal working, we have 22 developed a new method for tracking our own progress</p>
<p style="text-align: right;">27</p> <p>1 of those first steps is to receive the petition, make 2 sure that the petition has the information we need, go 3 through a back and forth process with the petitioner, 4 review it for completeness, and that particular 5 process has been cut, with a sample size of about 6 seven so far, by 259 days. I consider that a very 7 significant improvement, and you'll see more details 8 about that.</p> <p>9 We reduced the time for conducting our plant 10 pest risk assessments. We have completed, from start 11 to finish, one petition. That means a petition that 12 has come in since we implemented the process, and we 13 have taken it all the way through to the point of 14 publishing the determination in the Federal Register 15 that that particular product has attained non- 16 regulated status. And that process took us 658 days, 17 it's still longer than we want it to be, but it's 364 18 days less than the average we started with.</p> <p>19 As Kevin said, although we're not meeting 20 all of our targets yet, we're making significant 21 progress towards those targets. And as we start 22 clearing out old petitions, and at the same time</p>	<p style="text-align: right;">29</p> <p>1 on the petitions we're working on.</p> <p>2 You know during our Lean Six Sigma process, 3 and for those of you who are not familiar with Lean 4 Six Sigma, it's not only about decreasing a time, or 5 decreasing steps, or decreasing handoffs, it's also 6 about reducing the variability. That's the Sigma part 7 of Lean Six Sigma. And we are making an effort to 8 make our process much more predictable.</p> <p>9 So this is a slide that Max was going to 10 show. Now I mentioned the interesting situation that 11 Max is in as Acting Deputy Under Secretary for 12 Marketing and Regulatory Programs, and Melinda deals 13 with this, the Secretary is very interested in a group 14 called AC21, Advisory Committee on Biotechnology for 15 21st Century Agriculture.</p> <p>16 And the Secretary has brought together a 17 very diverse group of stakeholders from biotech 18 developers, to organic farmers, and everything in 19 between, and the goal of this group is to figure out 20 ways to coexist. You may have heard this term 21 coexistence. USDA is interested in all forms of 22 agriculture. All forms of agriculture need to coexist</p>

Capital Reporting Company Stakeholder's Meeting 11-20-2013

30	<p>1 and we are trying to help the market and agriculture, 2 in general, find ways to work together and coexist. 3 There is currently a public comment period 4 that's open. I don't expect you to write down the URL 5 here, but please get a copy of the presentation and 6 make a comment on the AC21 activities. We'd greatly 7 appreciate it and your input would be greatly valued. 8 I often tell groups that public comments 9 that we receive are extremely powerful. I hope you 10 don't think of these as exercises. As public servants 11 we are accountable to read and acknowledge those 12 comments and respond to them. We take them all very 13 seriously. So I encourage you to access this website. 14 The comment period is open until January 3rd. 15 So some webcast firsts. As Kevin mentioned, 16 or Dick mentioned, you know last year we did our 17 webcast of this meeting for the first time, but we had 18 some other firsts this year. We conducted virtual 19 public meetings for some environmental impact 20 statements that we're working on. We had one meeting 21 that covered the eucalyptus environmental impact 22 statement that we're working on, and then we had</p>	32
31	<p>1 another meeting that covered the next two, both the 2, 2 4-D-tolerant crop EIS and the dicamba-tolerant crops. 3 There was a lot of interest in the webcasts. 4 We encourage everybody to participate in those in the 5 future. Those are good opportunities. We feel that 6 it gives us opportunities to hear from folks that 7 maybe we wouldn't otherwise hear from, and it makes 8 things a lot more convenient. It has obvious benefits 9 for folks who wish to participate. 10 So we are absolutely committed to continual 11 improvement. We don't think of our Lean Six Sigma 12 effort to improve the petition process as something 13 that we started and pretty soon we're going to finish 14 it and that's going to be that. As many of you know, 15 those of you who know Steve Bennett know that he's 16 constantly looking for businesses process improvement 17 opportunities in our permit and compliance operations. 18 His Director, Ed Jhee, came to us with a lot 19 of experience in business process improvement and is 20 committed to that. I've been involved in ISO for 21 about 15 years now, which is a quality management 22 system. So we think of this in all of our activities.</p>	33

Capital Reporting Company Stakeholder's Meeting 11-20-2013

<p style="text-align: right;">34</p> <p>1 by that result, that almost 98 percent of all field 2 trials that are being done are being done by folks who 3 subscribe to the BQMS program. I think that has been 4 very helpful in our communications between APHIS and 5 the regulating community, and I think they have had a 6 very positive impact on overall compliance. So thank 7 you all for your participation in that program. 8 We maintained our own internal ISO 9001:2008 9 registration for our implementation of BQMS. We do 10 our best to hold ourselves accountable. And as I said 11 before, that's an example of a non-regulatory solution 12 that many if not most of you are already familiar 13 with. Any input that you would like to provide us 14 about other non-regulatory solutions that you see as 15 opportunities, be happy to hear about that. 16 I have one slide on this GE wheat incident 17 that we had during 2013. We became aware, in USDA, at 18 the very beginning of May of this year and the 19 investigation is ongoing. There are still questions 20 we are trying to answer. Many questions have been 21 answered but we still have some questions we are 22 trying to answer. We hope to be wrapping up the</p>	<p style="text-align: right;">36</p> <p>1 regulation. 2 Most of you are also probably familiar with 3 what's referred to as the coordinated framework. USDA 4 APHIS works very closely with the Environmental 5 Protection Agency and the Food and Drug Administration 6 in the regulation of products with biotechnology. And 7 clearly we work very closely with USDA's Foreign 8 Agriculture Service, FAS, and together we all 9 participated in meetings with the Chinese government 10 during 2013. I think it's fair to say that we pushed 11 pretty hard on them to the point of annoyance on the 12 part of the Chinese. I considered that part of my 13 job. 14 It was nice to hear that we agreed with our 15 Chinese counterparts on many issues. Clearly the 16 political forces are different in China and the United 17 States but at the level of the regulatory agencies, we 18 were in agreement about our approaches in many 19 different areas, for example industrial pharmaceutical 20 crops. 21 We met with over 20 countries, here in 22 Riverdale or downtown in Washington DC, and shared</p>
<p style="text-align: right;">35</p> <p>1 investigation soon. I can't be more specific than 2 that because you go where the leads take you. 3 The good news is that after several months 4 of working and investigating, this remains a detection 5 of unapproved GE wheat in one field on one farm, and 6 that's it. And I think that's one of the primary 7 reasons why this appeared to be a difficult situation 8 that quickly attenuated and became something that did 9 not become a big problem for the United States. 10 I think the U.S. government and our partners 11 in industry did a great job of managing this 12 situation. We wanted to be very forthcoming with the 13 American public about the fact that an incident had 14 happened. We took a risk in doing that, but I think 15 together we managed the situation very well. Thank 16 you. 17 We also have an active international 18 engagement activity in BRS. We meet with many 19 countries. This year we met with a technical 20 trilateral working group, which is the three macro 21 countries, Canada, U.S. and Mexico, worked towards, 22 through several issues, harmonization and biotech</p>	<p style="text-align: right;">37</p> <p>1 information about our respective regulatory programs 2 for biotechnology products. And I think that's very 3 important. We are very proud of our regulatory 4 program in USDA. This gives us an opportunity to show 5 other countries how we do things. And we get to hear 6 about innovations that they may have used. And it 7 certainly fosters the development of smooth trade. 8 We're not there yet, as many of you know, but we work 9 at that every day in BRS. 10 So we've also -- one of the things we also 11 talk about with most of these countries is this 12 concept of low-level presence, LLP for short. And 13 we're working on that effort on several different 14 fronts. You'll be hearing from Sally McCammon in a 15 short while, our science advisor in BRS, about a 16 significant development that she accomplished this 17 year. There it is. It's projecting a little bit 18 there. That's the Organization for Economic 19 Cooperation and Development LLP document. Sally will 20 give you more details about that. 21 So looking ahead for 2014, we're already 22 there. Fiscal year 2014 we will continue to look for</p>

Capital Reporting Company Stakeholder's Meeting 11-20-2013

<p style="text-align: right;">38</p> <p>1 every opportunity to approve our permitting and 2 compliance programs. It was an interesting year. I 3 think we learned a lot about what we do well and where 4 we need to improve, and we'll take advantage of those 5 lessons.</p> <p>6 And as many of you know, we are in open 7 rulemaking on revising our regulations at 7 Code of 8 Regulations, Part 340. Although there hasn't been 9 much activity in the federal register or in the public 10 sphere regarding changes to these regulations, we're 11 very actively working on those and I hope that we can 12 improve our regulations in the near future.</p> <p>13 Some of you may have also noticed that the 14 information that is available on what was referred to 15 as the unified website has changed. We are now 16 working on providing some improvements to that. And 17 up now is some new information from USDA that shows 18 some of the information that's not been available over 19 the past few months.</p> <p>20 We will continue our work internationally on 21 LLP issues, low level presence. The primary concern 22 about low level presence is you may have seen in the</p>	<p style="text-align: right;">40</p> <p>1 an opportunity to ask your question. Seeing none, we 2 shall proceed.</p> <p>3 MR. FIRKO: Okay. I also have the pleasure 4 of introducing Dr. Sally McCammon who, although she 5 had to go to Paris to do it, I know poor Sally, will 6 tell us about some work that she has been doing in 7 Paris and what a great result she had this year. Thank 8 you.</p> <p>9 MR. GEORGE: Now I'm going to interrupt one 10 quick second before you start. We've had a request 11 that if you're listening at home, or in your office on 12 the phone, got a mute on it, please hit it because 13 there's a little interference apparently. Some people 14 can -- okay. Thank you. Sally?</p> <p>15 Working Group on Low Level Presence</p> <p>16 DR. MCCAMMON: All right, thank you very 17 much. Thanks for the very nice introduction, Mike. I 18 do want to acknowledge that there were a lot of folks 19 at BRS that contributed to the work on this document 20 as well as across the federal government.</p> <p>21 But (inaudible), as Mike said, we do a lot 22 of international work but there's one project that</p>
<p style="text-align: right;">39</p> <p>1 news this week that China rejected a shipment of corn 2 for something that had been approved in the exporting 3 country but not the importing, that's LLP. That's LLP 4 and we will continue to try to figure out ways -- and 5 this is USDA as a whole, this is not BRS only working 6 on this -- we will continue looking for solutions to 7 make sure that U.S. products move smoothly throughout 8 the world.</p> <p>9 And our petition process improvements, we 10 will be the first to admit we are not there yet to 11 where we want to be. We've made significant progress, 12 you'll hear about that, but this is an ongoing issue 13 for us. We will continue to work hard to make our 14 commitments, to reach our targets, and to finish the 15 petitions in a more timely fashion.</p> <p>16 Any questions? I've probably not left 17 myself a lot of time for questions have I? Okay, any 18 questions? Thank you, Kevin. So if there's anyone on 19 the webinar?</p> <p>20 MR. GEORGE: If there's anyone online who 21 has a question, if you'd like to hit 1 0 on your 22 telephone keypad, we'll pick that up and you'll have</p>	<p style="text-align: right;">41</p> <p>1 we've done under the auspices of the Organization for 2 Economic Cooperation and Development that was first 3 proposed in 2007 and then undertaken in 2009. So as 4 you can see, anything that happens internationally can 5 take a bit of time and a bit of patience, but I must 6 say I'm very glad Groundhog Day is over for this 7 particular project.</p> <p>8 The title of the document, it's now made 9 public, is Low Level Presence of Transgenic Plants in 10 Seed and Grain Commodities: Environmental 11 Risk/Safety Assessment, and Availability and Use of 12 Information. So the Organization for Economic 13 Cooperation and Development, it came out of the 14 administrative body for the Marshall Plan that was set 15 up in 1948. In 1961 it was consolidated into an 16 international body with, at that time, about 12 17 European countries and two foreign countries, U.S. and 18 Canada.</p> <p>19 Currently the organization now has 34 member 20 countries, and they coordinate and harmonize on a 21 variety of issues from trade, to scientific 22 innovation, to intellectual property rights, and OECD</p>

Capital Reporting Company Stakeholder's Meeting 11-20-2013

42	<p>1 seed schemes many of you are aware of, the pesticide 2 testing protocols under the Environment Directorate. 3 I chair a group called the OECD's Working 4 Group on the Harmonization of Regulatory Oversight in 5 Biotechnology, and we work to develop technical 6 documents that support environmental risk assessment 7 of transgenic organisms, particularly plants. But 8 we've also done work in the microbe area and are 9 initiating and doing some work in the animal area. We 10 have a sister body called the Task Force for the 11 Safety of Novel Food and Feed, and just by luck or 12 accident, Kathleen Jones of the FDA chairs that. 13 So this is our definition of low level 14 presence at this point. It's a little bit convoluted 15 but to come to any kind of agreement in an 16 international body is sometimes a little bit arduous, 17 but "Low level presence is where a seed contains low 18 levels of transgenic seed that have been reviewed for 19 environmental risk safety and received authorization 20 for commercial cultivation in one or more countries 21 but not in the country of import." 22 So the operative word is that it has</p>	44	<p>1 if you can in time. Or if you've planted a particular 2 field or fields with a particular crop and it needs to 3 be pulled up, then you have a real problem. So our 4 document tries to capture some of the experience that 5 different countries have had and how they've 6 approached it. 7 The document is for guidance for regulators 8 and risk assessors. It must be noted that when you're 9 doing a risk assessment in an LLP situation, the 10 ultimate goal is not to authorize the planting, but to 11 give you the relevant information as to whether the 12 problem is -- if there's a safety issue or risk issue, 13 and also to provide information for how to bring a 14 situation back into compliance. 15 So the issue in an LLP situation is you may 16 not have the information from an application. 17 Sometimes you do and you just kind of finish the 18 authorization process, but you can get the information 19 in a variety of other places, through databases, you 20 may have had it done through a feed safety assessment. 21 You may have reviewed something that's very similar to 22 what's been found in the LLP situation. And there's a</p>
43	<p>1 received authorization somewhere, and that the LLP 2 situation is in the importing country. It does not 3 cover research material in which no authorization has 4 been given, particularly for field tests, or where you 5 can't identify the event or the construct. However, 6 the document can be quite useful in dealing with those 7 kinds of situations. 8 So why was this an important topic? Mike 9 already indicated that this can cause millions of 10 dollars of time and effort. But the seed (inaudible), 11 as many of you know, is a multi-billion industry. To 12 develop any particular variety, increase seed can 13 involve five to seven countries. So when you have an 14 LLP situation you can be jeopardizing an economic 15 sector of your country. And increased cost for 16 compliance, both for industry as well as for 17 governments, is a big problem. 18 The other major problem is it can jeopardize 19 local food supplies in that if you've contracted and 20 received seed that needs to be planted within a 21 certain window, if that seed is rejected then you need 22 to figure out where to get your seed supply elsewhere,</p>	45	<p>1 variety of sources but the regulator or risk assessor 2 has to actively go out and find that information. So 3 the document tells you where you might do that. 4 One of the other major points is that we 5 verify that when you do a risk safety assessment for 6 an LLP you use the same principles as you would for a 7 full authorization in that you look at the trait, the 8 biology of the plant, and the environment in which the 9 situation has occurred. So as I said, the information 10 can be used for a variety of purposes to bring a 11 situation back into compliance. 12 The other major point that's covered is that 13 there are examples of how countries have dealt with 14 LLP situations from -- like in our country we've 15 developed some policies so people know what to expect. 16 Other countries have worked very hard, like Brazil, to 17 make their approvals as quickly as possible so they 18 don't have asynchronous situations. Countries like 19 Australia have worked with the industry to set up 20 management plans should an LLP situation occur. 21 So how does this fit in with other 22 international documents? As most of you know, there</p>

Capital Reporting Company
Stakeholder's Meeting 11-20-2013

<p style="text-align: right;">46</p> <p>1 are the three sisters under the World Trade 2 Organization. One of those is the Codex Alimentarius 3 and they have a standard for LLP. It's contained in 4 their annex to the plant guideline for food safety 5 assessment of transgenic plants. Now while the OECD 6 is not a standard setting body, this document does 7 complement that in that it treats the environmental 8 safety assessment or risk assessment aspect. 9 And finally, the document was released 10 September 18th of this year, and it can be found at 11 the OECD biotech BioTrack website. 12 So just to wrap up, this gives you a picture 13 of the 34 member countries of the OECD, many of them 14 European but now increasing numbers of countries from 15 the Americas and Asia. And finally we're also 16 actively courting some of the BRIC countries, Brazil, 17 India, China and others, but these countries are 18 participating very actively in our group. 19 So thank you very much. I guess questions. 20 All right. Are there any questions regarding this 21 particular document? Yes sir? 22 MR. GEORGE: (Inaudible).</p>	<p style="text-align: right;">48</p> <p>1 unauthorized release into the environment. Is that -- 2 MR. CORZINE: Well I just would hope, you 3 know we talk about synchronization and harmonization 4 of regulatory across the world, but we certainly 5 aren't there and it will be a while. But I see the 6 low level presence becoming an issue even in this 7 country. And I understand the extra issues going 8 towards grains, but I would hope that you would also 9 include some focus on those when we get to talking 10 about grain. 11 Very similar, you know we just had the issue 12 with China. Even though they're almost there, you 13 know they're not and it creates an issue. And I'm 14 also glad to see you've got the BRIC countries because 15 that was a question I had as well on including them. 16 DR. MCCAMMON: Okay, well as Mike indicated 17 earlier, we're very actively participating in some of 18 global initiatives, the global LLP initiative for 19 transport of grains, as well as the trends, the TTQ 20 initiative. And Canada has put out a variety of 21 proposals and we've been actively engaged in watching 22 their particular proposals very carefully to see how</p>
<p style="text-align: right;">47</p> <p>1 MR. CORZINE: Does this work? 2 MR. GEORGE: Yes. 3 MR. CORZINE: Okay. I'm Leon Corzine. I 4 farm in Central Illinois. The question is, I see 5 you're focusing on seeds and you need to start 6 somewhere but I would hope that you would -- there is 7 a plan to include grains because the low level 8 presence issue could become big, even in this country, 9 with Brazil getting ahead of us on some products as 10 far as things coming into the U.S. That was my first 11 question. 12 DR. MCCAMMON: Okay, there's two aspects to 13 that question. Of course anything that comes into 14 this country must comply with our laws and our 15 regulations. So with grains coming in, most of the 16 time there should be evaluation by our Food and Drug 17 Administration for food safety. 18 The other aspect is that if, just if during 19 transport of grain, if something falls off the truck 20 or off the train, then this document does also treat 21 that particular instance of -- particularly the 22 aspects of environmental risk assessment of</p>	<p style="text-align: right;">49</p> <p>1 they evolve and how well they are able to address some 2 of these issues. 3 So I can say we're in active discussion but 4 we don't have any specific policies at this particular 5 time except that anything that comes into this country 6 must comply with our rules and regulations. 7 MR. CORZINE: Well I understand we never get 8 there as quickly as we would like to. We would have 9 liked to have been there yesterday, but we have been 10 talking about this for a really long time and I do see 11 it as an issue in the U.S. because then it gets to 12 predictability of trade, if you get something that 13 everybody on the same page and understanding where 14 they're at. And I do see that as a growing issue not 15 a shrinking issue, so I encourage you to keep the 16 pressure on or whatever it takes to get everybody on 17 board and on the same page with this. Thanks. 18 DR. MCCAMMON: No, thank you very much. 19 MR. GEORGE: Do we have any phone calls? If 20 anyone online would like to ask a question, hit 1 then 21 0 on your telephone keypad and pause a moment. It 22 takes a moment but if you'd like to ask a question of</p>

Capital Reporting Company Stakeholder's Meeting 11-20-2013

<p style="text-align: right;">50</p> <p>1 Sally.</p> <p>2 MR. JENKINS: So Dan Jenkins.</p> <p>3 MR. GEORGE: Yeah? Let's get a microphone</p> <p>4 to Dan please.</p> <p>5 MR. JENKINS: Sorry it takes a while. We</p> <p>6 don't have a backup here, so --</p> <p>7 DR. MCCAMMON: It's okay. It's all right.</p> <p>8 MR. JENKINS: Dan Jenkins with Monsanto. My</p> <p>9 question is you've mentioned FDA and food feed safety,</p> <p>10 but of course that transfers to EPA we're talking</p> <p>11 about. To what degree is EPA involved and what is</p> <p>12 their engagement on this issue?</p> <p>13 DR. MCCAMMON: Oh in the OECD particularly</p> <p>14 or in general?</p> <p>15 MR. JENKINS: In general.</p> <p>16 DR. MCCAMMON: Well we have an interagency</p> <p>17 group that participates in working on a variety of</p> <p>18 aspects of LLP policies and all the regulatory</p> <p>19 agencies are involved and most of the trade agencies.</p> <p>20 So there's continual ongoing conversation and</p> <p>21 interaction on both the regulatory initiatives and the</p> <p>22 trade initiatives and their interactions. Regarding</p>	<p style="text-align: right;">52</p> <p>1 Finally, we'll hear from Rebecca</p> <p>2 Stankiewicz Gabel, our Environmental Analysis Branch</p> <p>3 Chief. Rebecca will cover what we learned in the</p> <p>4 recently completed NEPA pilot project. So with that,</p> <p>5 we'll start with Clint on the petition process.</p> <p>6 Regulatory Updates Panel Petition Process Status</p> <p>7 DR. NESBITT: Very good. Thank you, Dick.</p> <p>8 Good morning everyone. So as Dick said, just about</p> <p>9 two years ago today I was standing here in front of</p> <p>10 you at a stakeholder meeting just like this and we</p> <p>11 rolled out the big improvements to our petition</p> <p>12 process. This had been the result of a Lean Six Sigma</p> <p>13 project that Mike mentioned earlier. And so today I'm</p> <p>14 going to use the opportunity to let you know just how</p> <p>15 we've been doing over the past two years now that</p> <p>16 we've had a little experience with the new process,</p> <p>17 give you an update on completing (ph) our targets, and</p> <p>18 perhaps where we still have some room for improvement.</p> <p>19 So I won't go through the details of where</p> <p>20 we're at then, but as Mike mentioned, basically at the</p> <p>21 end 2011 we had a backlog of 22 petitions that were</p> <p>22 pending, and the average time to complete these</p>
<p style="text-align: right;">51</p> <p>1 OECD, EPA is our partner in the OECD work. So both</p> <p>2 USDA and EPA are normally at the table together.</p> <p>3 Are there any folks on the web? Okay, and</p> <p>4 I'll be glad to talk to anyone during the break or</p> <p>5 afterwards further. Thank you.</p> <p>6 MR. GEORGE: Okay, so this year three</p> <p>7 subjects that we know have been on many of your minds</p> <p>8 are petition process improvements, the way we interact</p> <p>9 with EPA in our regulatory actions, and what we learn</p> <p>10 from our NEPA pilot project. So these are the next</p> <p>11 three items on the agenda. I'll introduce all three</p> <p>12 of our presenters who will speak in turn on these</p> <p>13 subjects.</p> <p>14 First, Clint Nesbitt is Chief of our Plant</p> <p>15 Pests and Protectants Branch. Many of you will recall</p> <p>16 that two years ago at this meeting Clint announced</p> <p>17 this initiative. Today, he'll fill us in on the</p> <p>18 results so far and where we go from here.</p> <p>19 After Clint, Assistant Deputy Administrator,</p> <p>20 Sid Abel, will cover how we interact and coordinate</p> <p>21 our regulatory activities with those of the</p> <p>22 Environmental Protection Agency.</p>	<p style="text-align: right;">53</p> <p>1 petitions had reached three years or more, and highly</p> <p>2 variable in terms of the amount of time that it took.</p> <p>3 And at that time there was very little pressure to do</p> <p>4 something about it.</p> <p>5 So in November of 2011 we announced the big</p> <p>6 changes that we were implementing to the petition</p> <p>7 process. And I won't go through all the gory details</p> <p>8 of what we've done, but more or less, just in a</p> <p>9 nutshell, it was an overall streamlining of the</p> <p>10 process, reducing redundant steps, creating</p> <p>11 milestones, sort of reallocating staff a little bit</p> <p>12 differently, and to some extent changing the order of</p> <p>13 the steps that we were doing.</p> <p>14 So the next three slides I'm also not going</p> <p>15 to go into detail about because you should have seen</p> <p>16 all these two years ago and probably in subsequent</p> <p>17 presentations. But I do want you to have the more</p> <p>18 detailed version of the process because as you'll see,</p> <p>19 each one of these little boxes has a number of days --</p> <p>20 oh that's -- no, you can't see that at all, sorry.</p> <p>21 Each one of those little boxes has a number</p> <p>22 of days. That's the target for that particular step</p>

Capital Reporting Company Stakeholder's Meeting 11-20-2013

<p style="text-align: right;">54</p> <p>1 to be completed, and later in my talk I'll go through 2 the data of how we're meeting those milestones. So 3 later if you want to flip back and forth you'll be 4 able to see how the targets correspond to the various 5 steps in the process. 6 But at a very high level -- I'm sorry, back 7 up just a little bit -- in terms of process 8 improvements, some of the biggest changes to the 9 process involves fairly dramatically compressing the 10 amount of time that we take to review the petitions 11 for completeness at the beginning, how we allocate 12 staff to do that. 13 The next big improvement was to add a 14 comment period early in the process where we're taking 15 comments on the petition itself. This then enables us 16 to use those comments before we prepare our analyses, 17 particularly NEPA analyses, so that ideally we don't 18 have to respond those same set of comments again 19 later. 20 The next big improvement was that we begin 21 preparing our risk assessments, which was the basis of 22 our decision early in the process while the petition</p>	<p style="text-align: right;">56</p> <p>1 So all together that first path was supposed 2 to take about 13 months from start to finish. The 3 longer path takes just over 16 months from start to 4 finish. And that was where we were two years ago. 5 This is how the plan was laid out. 6 Again, I want to underscore that these are 7 petitions for which an EA is sufficient. This does 8 not include petitions that require an EIS. At the 9 time we implemented these changes we hadn't had any 10 petitions that went through with an EIS yet so there 11 was no data to kind of figure out what would the 12 process look like for EISs. So there aren't these 13 established milestones and steps and timelines for EIS 14 dependent petitions. These are only for the ones that 15 have EAs. 16 So just to kind of give you an idea of how 17 we implemented these changes, we announced all the 18 changes at the stakeholder meeting about two years 19 ago. We have implemented most of the changes by the 20 time that we announce them. The (inaudible) parts 21 were already ongoing. 22 By March of 2012, you'll recall there was a</p>
<p style="text-align: right;">55</p> <p>1 is out for public comment. And then the staff that's 2 preparing that risk assessment was very formally 3 separated in time and in responsibilities from the 4 staff that prepares our NEPA analysis shortly after 5 that. So two distinct staffs; two different steps for 6 our PPRAs versus our NEPA documentation. 7 And then finally there are two different 8 paths that the petition can take at the end in terms 9 of how we announce our determinations. What we're 10 calling Path 1 is a slightly shorter path. This is 11 where we publish an environmental assessment with a 12 preliminary determination. We have a 30-day review 13 period and then shortly after that, if there are any 14 comments that would cause us to change our 15 determination, we post the final information on the 16 web. 17 What we're calling Path 2 is slightly 18 longer. We actually publish a draft environmental 19 assessment for public comment, formal public comment. 20 We then use those public comments to revise our draft 21 EA final information and then post that again in the 22 Federal Register.</p>	<p style="text-align: right;">57</p> <p>1 Federal Register notice in which we announced which 2 petitions would be transitioned into the new process 3 versus continuing on the old. And then the first 4 petitions were published for the new comment period in 5 July of 2012. So that's kind of the first big steps 6 that you saw visibly. 7 So now, how are we doing? What's happened 8 so far since then? Okay, so this first slide is a 9 little bit complicated so I'm going to show it to you 10 piecemeal so you will not have to puzzle through it on 11 your handouts. But basically where we were two years 12 ago in our stakeholder meeting is that we had a 13 backlog, as others have mentioned, of 22 petitions 14 total. 15 We had about five of those that were 16 currently in review for completeness. One was waiting 17 for feedback from the petitioners. Five PPRAs in 18 preparation, seven draft EAs, two final EAs and two 19 EISs at the time. Those two EISs by the way were 20 creeping bentgrass and sugar beets. 21 So since then when we announced the 22 transition of how we would be phasing those petitions</p>

Capital Reporting Company Stakeholder's Meeting 11-20-2013

<p style="text-align: right;">58</p> <p>1 into old or new, we decided that 12 of those would be 2 transitioned into the new process, eight would 3 continue as they were on the old process because they 4 were a little further along, and then of course the 5 two EISs would continue on the EIS path. 6 So of those that were on the new process, we 7 have since received nine more petitions, and of those 8 nine plus 12, we have actually had two of them 9 withdrawn -- well this part doesn't work so I can't 10 show you my cute little -- is there a laser on this? 11 (Inaudible) times two. Two of those have been 12 withdrawn; seven have been deregulated; four of them 13 have been transitioned into the EIS determined 14 process; and then eight of those are still pending. 15 Next, of the olds ones that we transitioned 16 to the old process, six of those have been deregulated 17 and two of those have now moved on to be covered by 18 EISs. So I just want to stress that of the old ones, 19 none of them are still in process except for the two 20 that are now waiting on EISs. So no more old process 21 petitions left. And then finally, of the two that 22 were originally waiting on EISs, one EIS was finished</p>	<p style="text-align: right;">60</p> <p>1 the right, the red dots, are the ones that have 2 followed the new and improved process. 3 So what you can see here is there is a 4 dramatic improvement in the amount of time that we 5 take to review the petition for completeness in the 6 beginning. In the old days, it was taking an average 7 of 205 days, and our current average is now 28 days; 8 so a huge savings in time. Nearly -- what does that 9 work out to be? Six months or more time savings just 10 from that first step alone. The slide says that we 11 have one pending at this step, but actually since then 12 we've sent the petitions, the letter back to the 13 company so there is one pending in this particular 14 step. 15 This is the next step in the process. How 16 long does it take the company to get revisions to the 17 petition back to us? Under the new system we allow 18 the companies 30 days, and we can see that in this 19 case the companies are all doing that. So this is not 20 only a time savings, but we're getting that data back 21 quickly from the companies so that can continue our 22 review. So thank you to you companies who make the</p>
<p style="text-align: right;">59</p> <p>1 and deregulated, that was the sugar beets, and then 2 creeping bentgrass is still in the EIS base. 3 So in total where we are today, right, as 4 others have mentioned, I think Mike mentioned, we've 5 got 15 in the queue. Of those 15, actually two of 6 them are new petitions that are waiting on additional 7 data from the petitioners. We have six draft EAs that 8 are either in process or have been published for 9 public comment, and then we seven of our pendings 10 waiting on EISs. So quite a bit of throughput. And 11 as Mike mentioned earlier, this is a fairly massive 12 number of determinations in this given time period. 13 Okay, so in terms of how we're doing and in 14 terms of meeting our targets. This is the very first 15 step of the petition process. This is how long it 16 takes us to review the petition for completeness when 17 it first comes in the door. The target for this new 18 review is 35 days. 19 And what I've showed you is that the green 20 dots on the left represent the amount of time 21 petitions took for this step before we improved the 22 process, going back to about 2005. And the dots on</p>	<p style="text-align: right;">61</p> <p>1 deadlines on this. This is the part that you have 2 control over and it's doing very well so far. Again, 3 another massive time savings. 4 Okay, so this is the third step of that 5 petition review phase. This is how long it then takes 6 us to review what the companies send back to us after 7 they have corrected any deficiencies in their 8 petition. This step is also speeding up. The 9 deadline target for our new process is 21 days. 10 It's currently been taking us about 35 days, 11 but part of that is because we blew the average with 12 the first couple that went through the new process. 13 But since then you can see on the line we're actually 14 much faster than the target. So again, moving more 15 and more time savings ahead. 16 So when you add up all three of those steps, 17 how long does it take us to do a petition complete 18 from the time we receive it all the way to the end, 19 and we've gotten additional information back from the 20 company, reviewed that and deemed it complete. This 21 is the sum total of what that looks like. So again, 22 older petitions on the left in green, the newer</p>

Capital Reporting Company Stakeholder's Meeting 11-20-2013

<p style="text-align: right;">62</p> <p>1 petitions on the right in this fresh orange color. 2 So you can see very dramatic improvement on 3 the amount of time it takes to deem the petitions 4 complete. The new target is 86 days when you add up 5 all the various little steps. We have currently been 6 making an average of 65 days to deem a petition 7 complete from the time that we receive it. 8 In the past it took us almost a full year on 9 average to complete that phase of the process. So you 10 can see this is a very massive substantial time 11 savings in terms of speeding up the petition process. 12 We do have two petitions that are currently pending in 13 this phase of the process. 14 So in terms of preparation of our draft 15 planned pest risk assessment. Now the target for this 16 is a little bit squishy in the new process because the 17 idea is that people will be preparing their planned 18 pest risk assessments internally while the petition is 19 out for public comment. 20 Now ideally we want staff to finish that 21 draft PPRA by the time the public comment period 22 closes, so that then that's useful for the next step,</p>	<p style="text-align: right;">64</p> <p>1 for completing a petition. This is how long it takes 2 us to prepare and draft environmental assessment if 3 we're preparing the EA. 4 Now there are actually three different 5 datasets on this chart. The ones to the left, the 6 blue dots, I think you probably can't see the 7 difference in color (inaudible). So the six or so 8 points farthest to the left, these represent a time 9 period fairly recently where we weren't preparing 10 distinct EAs and PPRAs. This was just one single risk 11 assessment together. So those dots represent how long 12 it was taking to do that sort of combined 13 environmental assessment. 14 Not long after that we split the two apart 15 so that we were preparing draft EAs separately from 16 our PPRAs. So the second set of dots in the center, 17 the green dots, represent how long it was taking to 18 prepare the draft environmental assessment pre- 19 improvements. And then the red dots represent how 20 long it's been taking to prepare a draft EA since we 21 implemented the improvements. 22 Now, when we made the process improvements,</p>
<p style="text-align: right;">63</p> <p>1 which is the preparation of the NEPA documents. So 2 the sort of soft deadline is for people to finish by 3 the end of that public comment period. 4 We've kind of been encouraging people to get 5 that down to 60 days because that's sort of the 6 minimum that the public comment period would normally 7 be after the petition is deemed complete. So you can 8 see that on those red dots about, let's see, five of 9 the nine that have completed this so far have had 10 their draft PPRAs finished in less than 60 days. A few 11 A few have gone considerably longer, but for this 12 particular step it doesn't matter. It doesn't have 13 any impact on the overall timeline because the next 14 step isn't really waiting on that first step to be 15 completed. So an improvement. We're still saving on 16 average 51 days, but that also includes a lot of them 17 that went much longer than if they had formerly ended 18 (ph) this period (ph) with that public comment period. 19 Okay, so the next step. This is the last 20 step of the process that I'm going to highlight. No, 21 I think there's actually one more, but this is a 22 pretty substantial contributor to the overall timeline</p>	<p style="text-align: right;">65</p> <p>1 we estimated that it would take about 180 days to 2 prepare our draft environmental assessment. The 3 average before we made the improvements was 213 days. 4 And our new average, after we improved the process, is 5 267 days. So on average we're actually slowing down 6 in terms of the amount of time it takes to prepare a 7 draft EA. But this is actually to some extent by 8 design. 9 We knew that when we implemented the 10 petition process improvements, because we had that 11 huge backlog and were speeding up the amount of time 12 it takes to finish the first part of the process, it 13 actually exaggerated the wave of the backlog that goes 14 through our staff that prepares the EAs. So we knew 15 when we flipped the switch on the improvements that it 16 was going to cause this huge crash in the capacity of 17 our NEPA staff to prepare those documents. 18 So we knew for the transition period that 19 people -- that we would not be meeting those deadlines 20 at first. And you can see, we're even slightly slower 21 than we had been before we made the improvements. But 22 a couple of things I want to highlight about this is</p>

Capital Reporting Company Stakeholder's Meeting 11-20-2013

<p style="text-align: right;">66</p> <p>1 that first we're doing more in the smaller amount of 2 time, so the throughput is larger for this phase of 3 the process. And also we know that once this wave 4 passes, then these numbers will become to come back 5 down again so that we'll be meeting our 180 timelines 6 much more routinely.</p> <p>7 Another little footnote about this graph, it 8 looks a little bit odd that these are in straight 9 lines. Did you notice that? The reason that it looks 10 that way is because for that first set of petitions 11 that we moved into the new process, you remember we 12 published a batch of them all at once for public 13 comment.</p> <p>14 So basically, all of those draft EAs started 15 on the first day, all on the same day. And so as 16 they're finished, they appear on the graph as a 17 straight line. They all start at the same point and 18 they're all finishing on different days.</p> <p>19 So we have, as I mentioned before, six EAs 20 that are pending in this phase. Four of them are 21 currently in process, and two of them are out for 22 comment right now. This is one of the phases, as Mike</p>	<p style="text-align: right;">68</p> <p>1 were routinely being completed in about 180 days or 2 so. And then around 2000 -- we've showed you this 3 graph before -- things sort of went off the rails and 4 started getting longer and longer and more and more 5 variable. Such that by 2005 or so, which is the very 6 far right-hand side of the graph, things were very 7 long and highly variable.</p> <p>8 The average since 2005, in this particular 9 calculation, is about a little over three years, a 10 little under three years, 1000 days, 1001 days and 11 nights. And then this graph now shows the first few 12 petitions that have made it all the way off the end 13 under the new process.</p> <p>14 The four yellowish gold dots, that I hope 15 you can tell the difference on your graphs, these are 16 the ones that started in the old process but were 17 transitioned into the new process and have finished 18 the new process. So that's the little cluster of 19 yellowish ones.</p> <p>20 And then the red dot is the first petition 21 that's made it through from start to finish under the 22 new process. That petition, which made it all the way</p>
<p style="text-align: right;">67</p> <p>1 mentioned earlier, where we are not meeting our 2 timelines yet and we know that, but we do expect that 3 fairly soon, over the course of the next year, as more 4 of these draft EAs are cleared out and published, that 5 these timeframes will start to come down again.</p> <p>6 So finally, this is the very last step of 7 the process for those new Path 2 petitions. How long 8 does it take us to revise the draft EA and publish it 9 after a public comment period? So this only applies 10 to Path 2 in the new process.</p> <p>11 In the past the average was about three 12 months. We have one that's made it through Path 2 so 13 far in this phase, and that made it out in 26 days, 14 which was even faster than the target for this. So 15 we're doing good with a sample size of one.</p> <p>16 Okay, so now, finally this slide will give 17 you the overall picture. This graph includes a 18 dataset that's larger than the sub-graphs that I 19 showed you before. This is how long it's taken to do 20 all petitions since the beginning of time, since about 21 1992 when we first implemented the process.</p> <p>22 So you can see in the early days, petitions</p>	<p style="text-align: right;">69</p> <p>1 through start to finish, Mike highlighted earlier, 2 that one made it out in 658 days. Clearly not our 3 target of 419 days, but still substantially faster 4 than the average had been, and I think you can see on 5 the graph that not only are we starting to bring the 6 curve down, but the spread is becoming smaller also.</p> <p>7 So it's part of the goal is, if you remember, was that 8 it's not just bringing the time down, but decreasing 9 the variability of how long it takes.</p> <p>10 So that's where we are as of today. Looking 11 ahead, what should you expect? Well first, we 12 actually expect that most of the petitions that are 13 currently pending should have decisions published 14 within the next year. So you will continue to see 15 timelines go down and still a high throughput of 16 things coming out the door over the course of the next 17 year.</p> <p>18 As we clear out the backlog through our NEPA 19 staff in particular, we will see the timelines 20 continue to improve, to drop back down towards the 21 targets. And finally we do expect to be reaching our 22 new targets routinely by early 2015 once this backlog</p>

Capital Reporting Company Stakeholder's Meeting 11-20-2013

<p style="text-align: right;">70</p> <p>1 is finally cleared out. 2 That's it. Any questions? Yes? 3 MR. CORZINE: Thank you for the 4 presentation. Leon Corzine, Christian County, 5 Illinois farmer. I was involved a number of years in 6 the process, or the early years, and one of the issues 7 was between USDA and the industry, that first step 8 kept bouncing back and forth maybe three or four 9 times. Can that still happen or have we eliminated 10 that? 11 DR. NESBITT: Yes, one of the improvements 12 that we built in was that we give our staff a set 13 amount of time to send a deficiency letter to the 14 company. And then the company has 30 days to respond 15 to that deficiency. If they don't respond within 30 16 days, we basically drop the petition from our list, 17 and then the company is free to resubmit whenever they 18 want. 19 And then at the end of that 30 days, if they 20 do resubmit, we review that. We say basically yes or 21 no. And if it's a yes, we move on, if it's a no, we 22 again say sorry you didn't meet the deficiencies and</p>	<p style="text-align: right;">72</p> <p>1 process. And also the companies are great about 2 addressing deficiencies over the 30-day period, so 3 very good. 4 MR. CORZINE: How is the breakdown on the 5 process between say your higher volume crops and maybe 6 the lower volume crops? Is there much difference then 7 from what you've seen? 8 DR. NESBITT: In terms of how long it takes? 9 MR. CORZINE: Yes. 10 DR. NESBITT: Off the top of my head, I 11 would say no. I mean in terms of the early steps 12 we're reviewing for deficiencies and so forth, it's 13 pretty much the same crop by crop. 14 The distinction that affects the timeline 15 might be some of the newer crops, newer traits will 16 likely go through the Path 2 which takes longer. But 17 also some of those may need to have an EIS prepared 18 which of course would also affect the timeline. So we 19 do see some variation, but just in terms of the behind 20 scene steps there's not a lot of difference based on 21 crop or trait. 22 MR. CORZINE: Okay, well I certainly applaud</p>
<p style="text-align: right;">71</p> <p>1 drop it from our list. 2 So we did that so that it breaks that cycle 3 of looping around and around. And it also removes 4 things from our list, for which we're basically 5 waiting on the company to give us new data. What we 6 saw in our initial datasets is that for our deficiency 7 letters that we send, they tend to be either fairly 8 minor technical deficiencies that are easy to address 9 by the company, or requests that really generate a lot 10 of data. 11 So it kind of was bimodal: either easy to 12 address, we did get it done quickly, or we got to wait 13 a long time. So that process improvement was intended 14 also to kind of keep the ones going that are close to 15 going, and sort of drop the ones that aren't quite 16 ready for prime time. 17 MR. CORZINE: Okay, thank you. I would 18 assume that everybody is getting more used to the 19 system and my hope was you wouldn't see that bounce 20 back and forth so many times. 21 DR. NESBITT: Absolutely. So we haven't had 22 any bounce backs since we started, that's part of the</p>	<p style="text-align: right;">73</p> <p>1 your efforts because it's important to me as a farmer 2 to get the more predictability, get the process, get 3 it back on the rails as you -- in your terms. 4 A question that I'm not clear on, and some 5 of the acronyms I had a little trouble with. You know 6 I'm kind of in the world that's more JD or CIH or John 7 Deere and Case IH and that. I'm only on boards for 8 the industry, on the seed industry too, on who's who, 9 but I won't go into that. But how do you determine, 10 can you say, I don't want a lengthy answer, but you do 11 your EA, and that's a pretty rigorous process I think. 12 DR. NESBITT: Absolutely. 13 MR. CORZINE: It seems like where you're 14 really getting bogged down is in the EIS part of the 15 deal. And how do we determine that because I think 16 there's a lot of question on whether -- where those 17 are needed, where they're not. And we've got one 18 particular one that's pretty important now that wow, 19 we've been going four years, okay. 20 DR. NESBITT: Sure. I'll address it in 21 general and I'll let someone else who's talking about 22 NEPA give you more specifics of individual cases. But</p>

Capital Reporting Company Stakeholder's Meeting 11-20-2013

74	<p>1 you know as a general rule, the way that NEPA works is 2 that ideally you prepare an environmental assessment 3 first. And the purpose of the environmental 4 assessment is to determine whether or not there will 5 be significant impacts on the environment. 6 And if there are not, you publish what we 7 call a FONSI, which is a Finding of No Significant 8 Impact, then you monitor termination. If you're 9 unable to reach that FONSI, then the next step is to 10 prepare a larger environmental impact statement. And 11 the purpose of that analysis is then to figure out 12 what are those significant impacts going to be. 13 So it's ideally step wise, you sort of do an 14 EA first and then if you need to you do an EIS. And 15 the decision to do an EIS is based upon that question, 16 are we going to be able to defend the decision that 17 there will be no significant impacts resulting from 18 our decision. So that's kind of the logic of the 19 decision. I'll let somebody else perhaps later 20 address the question of how we make the individual 21 decisions, but that's the way NEPA is supposed to 22 work.</p>	76
75	<p>1 It's also possible -- you don't have to 2 prepare an EA first before you decide to do an EIS. To 3 some extent if get time savings, if you know upfront 4 that there's not a very high likelihood that can say 5 or defend that there are no significant impacts, 6 there's no reason why you can't decide to do an EIS 7 upfront without doing an EA first. But that's sort of 8 the basic logic of how the decision happens. 9 MR. CORZINE: Do you take a look at, on both 10 sides in an EIS, as far as, there is an economic 11 impact a lot of times, or an environmental impact, if 12 it is slowed down, if we don't have it, if what this 13 product on a positive is where as well as what the 14 concerns might be? 15 DR. NESBITT: Yeah, but the NEPA analysis 16 isn't just negative impacts, it's positive and 17 negative impacts. So that kind of thing you're 18 talking about is part of the analysis in NEPA. 19 Absolutely. 20 MR. CORZINE: Okay. Thank you. 21 DR. NESBITT: Other questions? There's one 22 way back in the back.</p>	77

1 MS. REED: Hi, I'm Genna Reed from Food and
2 Water Watch. I just wonder if you guys are somehow
3 evaluating the impact of a hastened process on the
4 rigor or actual quality of the work of the
5 environmental assessments.
6 DR. NESBITT: Absolutely. When we launched
7 this petition process improvement project one of the
8 things that we wanted to do, from the beginning, is to
9 improve the efficiency of staff resources, to improve
10 our ability to sort of use our staff resources
11 effectively and efficiently in a timely way. So we're
12 really focusing on how we use the expertise that we
13 have.
14 But we made it a goal from the very
15 beginning that we would absolutely not be cutting
16 corners on how we do the analysis. So the rigor from
17 the beginning was held to at least where it was in the
18 beginning, and that we were very explicitly saying
19 we're not going to go faster by doing sloppy work, you
20 know what I mean? So it really was the bar was held
21 at where we were before we made the process
22 improvements and the process improvements wouldn't

1 decrease the quality of the analysis.
2 Now that's just the official process
3 improvement process. This is sort of a business
4 practice type of improvement. Independently of that,
5 we are also working to improve the way we do our
6 analyses. So we have internal work that's improving
7 how we prepare plant risk assessments. There have
8 been other pilot projects that I think Rebecca will
9 talk about that are exploring some ways to improve how
10 we do our NEPA analyses. But those are sort of
11 separate projects that are ongoing at the same time.
12 MS. REED: I just have one more comment to
13 make.
14 DR. NESBITT: Sure.
15 MS. REED: When you initially started the
16 process and you let out all those dockets for a
17 comment, I think it was actually also an impediment,
18 as a member of the public and a lot of our
19 organizations like mine who try to look at all of the
20 new plants that are coming through and do a careful
21 evaluation on you know the environmental assessments
22 that USDA is comparing.

Capital Reporting Company Stakeholder's Meeting 11-20-2013

78	<p>1 DR. NESBITT: Sure.</p> <p>2 MS. REED: That was also you know</p> <p>3 problematic for us because we had now nine that we had</p> <p>4 to do within a 30-day comment period. So that's tough</p> <p>5 and I just wanted to raise a red flag there for you</p> <p>6 guys in the future.</p> <p>7 DR. NESBITT: Absolutely. I appreciate</p> <p>8 that. Anything else? Other questions? Any questions</p> <p>9 on the phone?</p> <p>10 MR. GEORGE: Again, just a reminder if</p> <p>11 you're on the phone, or the webcast, and you'd like to</p> <p>12 ask a question, hit 1 then 0 then we'll see that you</p> <p>13 want to ask a question. Or you could go to the Q&A</p> <p>14 button and go to the text box and type a question and</p> <p>15 ask it. So we'll pause here for just a second to see</p> <p>16 if there's other questions. And if not, we shall move</p> <p>17 on. That's it. Thank you. Thanks, Clint.</p> <p>18 DR. NESBITT: Very good.</p> <p>19 Coordination with Environmental Protection Agency</p> <p>20 DR. ABEL: Good morning, everyone. I'm Sid</p> <p>21 Abel, the Assistant Deputy Administrator for</p> <p>22 Biotechnology Regulatory Services, and my talk today</p>	80
79	<p>1 will be Coordination Efforts with EPA.</p> <p>2 Now I know there's been a lot of interest by</p> <p>3 a lot of the industry, also others, about how we are</p> <p>4 interacting with EPA in the process of developing our</p> <p>5 decisions on petitions. But also there's a lot of</p> <p>6 interest on what EPA is doing on the opposite side for</p> <p>7 those products that are linked to our petitions, such</p> <p>8 as herbicide tolerant crops, and what they're doing in</p> <p>9 terms of their process, so at the end of the day we</p> <p>10 come out with some kind of coordinated effort.</p> <p>11 So we've been struggling I think over the</p> <p>12 last few years to really work out a process with EPA</p> <p>13 so we can be coordinated. So earlier this year, I</p> <p>14 think it was a kicked off from last year, around</p> <p>15 December, when EPA senior officials and senior</p> <p>16 officials here from BRS got together in a room</p> <p>17 downtown in Washington and kind of talked about issues</p> <p>18 that were related to EIS that was being planned for a</p> <p>19 particular product that was going through our petition</p> <p>20 process.</p> <p>21 And during that conversation I think the</p> <p>22 senior leadership in that group recognized that we</p>	81

Capital Reporting Company Stakeholder's Meeting 11-20-2013

82	<p>1 communication process is EPA, FDA and ourselves, we 2 have monthly meetings where we, at the working level, 3 where we talk about things such as you know issues 4 that the three agencies may be confronting, the status 5 of petitions or the status of regulatory actions at 6 EPA or consultations with FDA that may be going 7 through the process at the same time.</p> <p>8 We also talk about new arrivals when we get 9 a new petition or EPA get a registration for a 10 herbicide tolerant crop, or the herbicide to use on a 11 herbicide tolerant crop and did we have that same 12 petition. And we also kind of talk about what pending 13 actions that may be occurring before the agencies, 14 such as the recent announcement of two petitions for 15 public comment here at BRS.</p> <p>16 Also in that coordinating effort we have 17 (inaudible) meetings with our sister agencies in 18 programs in Canada and in Mexico. So there's some 19 coordination going on even at the national level 20 between three countries as well as the three programs 21 here in the United States.</p> <p>22 We've also, as I've mentioned earlier, we</p>	84	<p>1 right now between US EPA and USDA.</p> <p>2 This is something I think probably most of 3 you are going to be interested in, coordinating with 4 EPA, and specifically on the deregulations and the 5 registrations, and those timelines that are associated 6 with those. As I think many of you know, we have 7 going through the process right now two EISs, one for 8 2, 4-D (inaudible) product and the other one for 9 dicamba products. And we work together, the two 10 agencies, to synchronize our decision making so we're 11 going to come out of the back end of these review 12 periods at about the same time and making our way 13 toward determinations.</p> <p>14 But to do that you've got to back up. You've 15 got to say okay, what are the steps in each of our 16 processes that need to be coordinated with sharing of 17 information, for public comments and public reviews, 18 for addressing public comments that come in, all that 19 work that must come before making that decision. So 20 we've taken our two timelines for these and we put 21 them together, we've looked at them together and we 22 coordinate those timelines where we're getting our</p>
83	<p>1 established senior liaisons with the two agencies. So 2 myself, and then I've got Gwen (ph) who's here. Gwen's 3 also my partner in coordinating activities with EPA. 4 So at the senior level within the program there's 5 someone that they can reach into and talk to about 6 having an issue down at the working level but between 7 the two agencies.</p> <p>8 And that brings me to the next topic, one 9 that's on my list here that we have the subject 10 matter of topic that are experts within the two 11 programs. So when we're working through a 12 deregulation for a herbicide tolerant crop for 13 instance, we have a team of staff here that are 14 working on that petition, but EPA also has a team of 15 staff that are working on the registration side. So 16 those two groups are working together at that working 17 level sharing information, describing issues that 18 they're confronting, coordinating their schedules 19 together.</p> <p>20 Now we also have interagency working, topic 21 specific working groups such as the herbicide 22 resistance management activities that are going on</p>	85	<p>1 information from EPA in a timely manner, we're sending 2 information into EPA in a timely manner. And at the 3 end of the day we all come out of the back end of the 4 process with pretty much synchronous decision making.</p> <p>5 Will this help (inaudible) farmers with 6 being able to get products into their hands much 7 quicker, but it also helps the two agencies to make 8 sure neither one is left vulnerable because one is so 9 far out ahead of the others. The work that one is 10 doing may impact that decision making that the other 11 agency has already made.</p> <p>12 So we've made pretty good progress on that. 13 We've got two test cases that are going through the 14 process as I mentioned right now that are linked to 15 two EISs, then we have another one that's kind of 16 linked just to an EA. And we'll know here in the next 17 you know six to eight months how good we were at doing 18 this.</p> <p>19 So far we've had some challenges. The 20 shutdown created some challenges for both agencies and 21 we reformulated those schedules so we both were 22 working through this process at about the same time.</p>

Capital Reporting Company Stakeholder's Meeting 11-20-2013

<p style="text-align: right;">86</p> <p>1 But right now, everything seems to be going okay. But 2 again we're very early in that process and we hope at 3 the end of the day we'll be coming out at about the 4 same time with our decision making. 5 We're also sharing work across each other. 6 In the past we worked with our biopesticide program 7 for instance in sharing, you know sharing the review 8 of those other work products that come into EPA. And 9 I think we're going to try and get back to doing more 10 of that in the future now that we're beginning to 11 settle down the two programs in terms of the 12 workloads. That's something we're hoping we can do 13 here in the near future. 14 And then of course there are these cross 15 agency reviews, so when we're done with our EIS for 16 example, those sections of the EIS that use EPA's 17 information, pesticide (inaudible) risk assessment, 18 the pesticide environmental risk assessment. While we 19 capture that information in our environmental 20 documents and summarize it, we return those to EPA 21 just to validate what we said is accurate and 22 consistent with their statute.</p>	<p style="text-align: right;">88</p> <p>1 And so in the future when we have a joint 2 product that we're both working on, we'll know what 3 those needs are, we'll now about when those needs are 4 because we'll establish this timeline and we'll make 5 sure each agency is delivering the products in a 6 timely manner. 7 As I mentioned earlier, we've mapped the 8 agency's processes so we know how long it takes them 9 to do their job. As Clint mentioned earlier, we know 10 how long it takes us to do our job in terms of the 11 petition, and is it just kind of odd that it worked 12 out without intentionally doing it with their 13 pesticide, their registration improvement act for a 14 new use. 15 It takes them about the same time to do 16 their regulatory decision as it does for us to 17 complete a petition. So as long as an EIS is not 18 involved and we're just using the EA process, we 19 should be coming out the back end of those 20 consistently in the future on those regulation and 21 determinations on our side and pesticide registrations 22 on their side for those products that are common to</p>
<p style="text-align: right;">87</p> <p>1 Now a couple of other areas where we're 2 beginning to do some coordination on is these new and 3 emerging topics that come up, new technologies for 4 example. We're starting to work a little bit together 5 on those as well. 6 And I think another thing I'd like to do 7 this year, and EPA's probably not aware of this yet, 8 but one of the things we'd like to do is kind of look 9 back at doing -- look back at what we did with the 10 drought tolerant corn and the joint review we did with 11 them on that, and look at the lessons learned on that 12 and try to reestablish that relationship between work 13 sharing or joint reviews in the future on those 14 products that are common to the three agencies. 15 And then on the collaboration side, we 16 understand that there's certain data that we need, 17 there's certain data that the EPA can use from us, and 18 so we've worked out a process between the two agencies 19 that identify those data needs and when that data is 20 most helpful to both of the agencies. And we've 21 developed what we call base set of information needs 22 that the two agencies will need.</p>	<p style="text-align: right;">89</p> <p>1 both agencies. 2 And then finally again we're, in the 3 emerging issues area as herbicide resistant weed 4 management, for example, is the one that there's a lot 5 of interest in a lot of folks on that data. We're 6 working on in terms of collaboration on how we deal 7 with this whole issue of resistant weeds in the 8 environment as a result of these herbicides, and 9 especially those herbicides that are used in planting 10 (inaudible) crops. 11 So finally some of the outcomes. You know 12 we've coordinated our schedules for the joint 13 regulatory actions using these mapped processes. Again 14 we're kind of in that first test phase to see how well 15 they work. We'll know here in the next six to eight 16 months how successful we are. 17 There's a timely sharing of information 18 which will facilitate the respective assessments that 19 both agencies must go through before they can take 20 that process. There's processes set up to identify 21 issues early on so we can resolve them so it doesn't 22 impact the schedule. And we've got very clear roles</p>

Capital Reporting Company Stakeholder's Meeting 11-20-2013

<p style="text-align: right;">90</p> <p>1 and responsibilities now that (inaudible) help. 2 So with that, we'll take any questions. I 3 knew it. 4 MR. JENKINS: Dan Jenkins with Monsanto. 5 Sid, could you clarify something for me? So thank you 6 for that and certainly we support the goals and your 7 plans here, but could you clarify for me the sort of 8 meaning of coordination here? 9 In other words, you know under the law of 10 meeting the standard of no unreasonable adverse 11 effects at EPA, that leads to a registration, you know 12 with PRIA. And then at USDA it's a plant hazard risk 13 determination, right? So synchronicity is a good goal 14 I guess but the processes are independent. 15 So in other words if EK (ph) is occurring at 16 a slightly different time, because really the timing 17 depends on when we submit under PRIA, right? USDA 18 would move forward independently with its process, et 19 cetera, is that correct? 20 MR. ABEL: Well in those cases where -- I'm 21 going to give you an example -- where we've already 22 deregulated a particular crop trait combination, so</p>	<p style="text-align: right;">92</p> <p>1 When you were talking about you and EPA together 2 looking back at how you interacted on the joint review 3 of drought tolerant corn, did I hear that correctly? 4 MR. ABEL: Yes, you did. 5 MR. MASSEY: Okay. 6 MR. ABEL: Yeah, we haven't done that yet, 7 or at least we haven't formally don't that yet, but 8 it's something that I think EPA was interested in 9 doing the last time I talked with folks over there. So 10 I'm kind of hoping maybe we can resurrect that and see 11 if there's opportunities in the future to do these 12 things. 13 MR. GEORGE: Any questions online? 14 UNIDENTIFIED SPEAKER: Dick, did you want to 15 check the phone? 16 MR. GEORGE: We're fine. NEPA Pilot Closeout 17 DR. STANKIEWICZ GABEL: Hello. So this is 18 our fourth and final briefing on the NEPA pilot 19 project. It was this time in 2010, at the stakeholder 20 meeting that we announced the NEPA pilot project with 21 the goal of looking at some tools to evaluate the 22 efficiency, the cost effectiveness and the quality of</p>
<p style="text-align: right;">91</p> <p>1 for example a herbicide tolerant, glyphosate tolerant 2 (inaudible) for example. And you were coming in with 3 another registration for glyphosate EPA at the same 4 time you're doing a deregulation with us, we'd 5 probably, if the schedules don't work out well, we 6 would probably move out ahead of them because we don't 7 believe in those cases there is significant 8 differences in the outcome of those assessments that 9 would keep us from being able to proceed with our 10 process in the same 13-month schedule, while theirs 11 might take 16, or you know whatever, we would move out 12 ahead of them. 13 We've talked about that and I think EPA's 14 comfortable with us doing that. But for those 15 products where it's the first time for us and the 16 first time for them, we're going to do everything we 17 can to coordinate those because we're going to be 18 dependent on their assessments at that point in time 19 because we won't have the historical assessments to 20 use. 21 MR. MASSEY: Hi, Sid. Adrian Massey, BIO. I 22 just want to verify that I heard something correctly.</p>	<p style="text-align: right;">93</p> <p>1 our NEPA documents. 2 So today what I'm going to talk about is the 3 data that we collected over the pilot project and some 4 of the things that, the outcomes of our pilot project. 5 And I promise you won't have to hear about this in 6 another stakeholder meeting. 7 So we collected data, the amount of staff 8 hours that it took to develop our NEPA documents, from 9 December of 2011 to March of 2013. And you'll notice 10 that these timeframes actually coincide with the 11 petition process improvement timeframe, so there are a 12 lot of moving parts that were happening while we were 13 collecting this data. 14 Our goal was to actually measure staff hours 15 on each of the individual products, and we were 16 looking at a couple of variables. One was staff hours 17 to prepare an EA in house versus staff hours to work 18 with a contractor preparing an EA. And we also looked 19 at EAs that we prepared with the assistance of an 20 environmental report provided by the petitioner versus 21 those that didn't have an environmental report. 22 Some of the things I want to mention about</p>

Capital Reporting Company Stakeholder's Meeting 11-20-2013

<p style="text-align: right;">94</p> <p>1 that, we had actually very few petitions without 2 environmental reports. We did have two in this 3 dataset that we used, but I kind of want to put a 4 caveat in there because one was an extension and one 5 was very similar to something else. So you know as we 6 talk about what happened, I want you to keep that in 7 mind.</p> <p>8 We were looking at staff basically as a 9 proxy for cost, so staff hours, obviously we pay our 10 staff and that's a cost. And then there's additional 11 costs for hiring a contractor and maintaining those 12 contracts. In some cases, some of the petitioners 13 entered into what's called a cooperative agreement 14 where they provided the funds for us to hire a 15 contractor, and we're not actually evaluating that 16 cost or the cost of the contractor for the rest of the 17 time. So what I'm going to talk about today is just 18 staff time, okay.</p> <p>19 And then the other thing I just want to 20 point out throughout this, we also were looking at the 21 quality of our data but those were more subjective. It 22 wasn't just counting hours. We were looking at things</p>	<p style="text-align: right;">96</p> <p>1 closer to 200 hours. Okay, and this is staff hours. 2 This is people physically working on these 3 (inaudible). So it's not days, it's actually hours.</p> <p>4 And the other thing I wanted to point out 5 was some of the ones that are a little shorter were 6 actually similar to other EAs that we had done in the 7 same timeframe. So if you'll notice the one that's 8 labeled 4 on the bottom, and the one that's labelled 9 20 on the bottom, both of those were actually 10 glyphosate resistant corn products. And the one that 11 was labeled 20 was done after the one that was 12 labelled 4, and you can see that the staff time 13 actually decreases on the second EA for a similar 14 document.</p> <p>15 And the same is also true for number 1 and 16 number 9. Those were two different canola EAs. Okay, 17 so the first one that went through took over 350 hours 18 whereas the second one took less than 250. So just to 19 give you an idea of one of the things that wasn't 20 really part of the pilot project but as we looked at 21 it, we did become more efficient on the second EA that 22 was similar to one that we had done during that same</p>
<p style="text-align: right;">95</p> <p>1 like consistency and also quality, number of 2 typographical errors, that kind of thing.</p> <p>3 I'm not going to present data on that, but 4 that was something we were evaluating or reviewing as 5 we were going through. So the idea was to maintain 6 the quality of the environmental documents throughout 7 the process while measuring these other variables.</p> <p>8 So in the NEPA pilot process, there were 9 actually 22 petitions. What I want to focus on today 10 were this group right here. And the reason I chose 11 these was that these draft EAs were actually all 12 completed during the data collection period. The 13 other petitions, parts of the petitions were finished 14 inside and outside of the data collection period, so 15 we didn't have an entire base (ph) of one, was what we 16 were calling the draft EA, dataset.</p> <p>17 And so the numbers along the bottom are just 18 the numbers of the petitions as they were signed in 19 the dataset. So looking at them, you can tell that 20 the number of staff hours is variable amongst the 21 petitions. Some of them were as long as a little over 22 450 hours, or is that 462, and some of them were</p>	<p style="text-align: right;">97</p> <p>1 time period.</p> <p>2 And the ones that are a little higher were 3 actually new uses or new products to us. So they 4 weren't extensions. They weren't, they were path -- 5 actually most of those were actually in the old 6 process, okay, so they're a little older than the ones 7 that are a little -- 9 and 20 were in the new process, 8 so in the new process.</p> <p>9 Okay, next slide. So on average it takes us 10 330 hours to do a draft EA, and the median is 371 11 hours. I think this might be a little bit of an 12 underestimate of staff time because this is people 13 actually logging the amount of time they spent working 14 on documents and so it's possible that people weren't 15 logging every second of every day that they were 16 working on it. There may be certain activities that 17 weren't logged in along the way, but on average we're 18 looking at about 330 hours to prepare a draft EA, with 19 a minimum of 203.</p> <p>20 And as I pointed out, that was -- can we 21 just go back to the previous slide -- that's actually 22 number 20 over there and that was the second of a</p>

Capital Reporting Company Stakeholder's Meeting 11-20-2013

<p style="text-align: right;">98</p> <p>1 glyphosate resistant corn product. And then our 2 maximum was at 462 hours. 3 And as you can see looking at this, if we 4 look just at staff hours, it is reasonable that we can 5 meet our timelines in the new petition process if we 6 can initiate the beginning of the EA analysis at the 7 end of the comment period. So once we've moved 8 through the backlog it should be very feasible to meet 9 that. 10 So under our findings, there were no 11 significant differences in the number of staff hours 12 between in-house and contracted draft EAs. It took 13 our staff the same amount of time whether they wrote 14 it in-house, or a contractor wrote it and they 15 reviewed it. So there's no staff time savings there. 16 And there's also no significant difference 17 between the ones that were prepared with an 18 environmental report and the ones that weren't. But 19 again, I wanted the caveat that we only had two that 20 didn't have environmental reports and they were both 21 for things that we were already relatively familiar 22 with. So I'm not sure how valid that really would be</p>	<p style="text-align: right;">100</p> <p>1 that is if we're going to continue to use ERs, 2 everyone agrees, we need to update our guidance. 3 The other thing that NEPA analysts thought 4 was that contractors were most effective for discrete 5 tasks, so not doing the entire EA, contracting out the 6 entire EA. It didn't actually save any staff time, 7 but they thought that for discrete tasks like perhaps 8 doing, developing common summaries, that contractors 9 could actually assist the staff in, aid in that type 10 of activity. And participants that responded to the 11 surveys supported the use of contractors. 12 So our next steps. One of the things we 13 need to do is engage you, the pilot project 14 participants, on your interest in continuing to submit 15 ERs. As you can tell from the data, we did not find 16 that there was a significant difference between the 17 amount of staff hours required to prepare an EA with 18 and without an ER, although the staff found them 19 useful. So that's something that we need to discuss 20 with you. And if it's your desire to continue to do 21 that, we have to work to develop new guidance. 22 The other thing that we're going to do is</p>
<p style="text-align: right;">99</p> <p>1 in the long run. Nevertheless, we, as a staff, found 2 that a well prepared ER could be very useful to us. 3 We also did a survey at the conclusion of 4 the pilot project and probably the take home message 5 from the pilot project was that NEPA analysts valued 6 ERs. So I should say the survey, there were two 7 different surveys that were done. One was for the 8 NEPA staff, and the other was for the participants, 9 you were part of that survey. 10 And so in the discussions with the NEPA 11 analysts they found that the quality of the ERs was 12 variable. Some of them were excellent and some of 13 them were not as useful for preparing an EA. And the 14 NEPA staff suggested that if ERs are going to be 15 useful that updating the guidance would be essential. 16 Participants thought that ERs didn't save 17 time but they can provide useful information, and the 18 dataset does support observation. They did not save 19 time, but the staff did find that they provided useful 20 information, and the participants also suggested that 21 we should, if we continue to use ERs, we should update 22 the guidance. So I think the take home message from</p>	<p style="text-align: right;">101</p> <p>1 continue to develop our current staff to maximize 2 their internal capacity. During the pilot project we 3 also doubled the size of our NEPA staff. It's also 4 made it a little interesting analyzing the data along 5 the way as well because so many variables were moving 6 while we were doing this it's not really surprising 7 that we weren't finding a lot of statistically 8 significant differences, because it was hard to hold 9 things as, hold (ph) concepts (ph) as we were growing 10 as a staff, changing our approaches to doing our EAs, 11 and also doing the petition process improvement on top 12 of everything, okay. So all these things were 13 happening at the same time. 14 But on that note, we have doubled our staff 15 and we're working to improve our internal capacity. We 16 are on track currently to complete all the pending 17 petitions in 2014. I say currently we're on track to 18 do that. So our goal is to start meeting the SOP 19 guidelines by FY2015. This year we should start to 20 see the first of our petitions come through that were 21 actually able to initiate the EA at the close of the 22 comment period, which we haven't been able to do yet</p>

Capital Reporting Company Stakeholder's Meeting 11-20-2013

<p style="text-align: right;">102</p> <p>1 in the petition process improvement.</p> <p>2 Okay, so any questions?</p> <p>3 UNIDENTIFIED SPEAKER: (Inaudible).</p> <p>4 Shouldn't logically the high quality ERs result in</p> <p>5 less review time, at least in the future? Maybe the</p> <p>6 data wasn't for now, but wouldn't you expect that?</p> <p>7 DR. STANKIEWICZ GABEL: One would expect</p> <p>8 that. As I said, the data didn't support it but we</p> <p>9 only had two documents that we prepared without ERs,</p> <p>10 without some sort of ER. And they were both things</p> <p>11 that we were familiar with already in-house, so it's</p> <p>12 really hard to make the judgment on something that's</p> <p>13 you know completely new.</p> <p>14 The staff really felt that they helped when</p> <p>15 they, you know when they had them, and they read them.</p> <p>16 So it helped them. I think by reading through them,</p> <p>17 it helped them get organized, find a starting place.</p> <p>18 The other thing that it really helps with is you know</p> <p>19 when you're starting out doing an EA without the ER,</p> <p>20 you're doing your search and looking. You had to have</p> <p>21 that first lit search already done. You had that</p> <p>22 first bit of information and you're searching out from</p>	<p style="text-align: right;">104</p> <p>1 time and that helps everybody's process, right.</p> <p>2 DR. STANKIEWICZ GABEL: Right, but at this</p> <p>3 time we don't have the data to support that.</p> <p>4 MR. CORZINE: Okay. Okay.</p> <p>5 DR. STANKIEWICZ GABEL: So that's why we</p> <p>6 want to talk to our pilot project participants and</p> <p>7 find out if they're still interested in continuing to</p> <p>8 do them.</p> <p>9 MR. CORZINE: Is that a big burden to the</p> <p>10 submitters to do an ER on it, do you think?</p> <p>11 DR. STANKIEWICZ GABEL: I would have to ask</p> <p>12 the submitters if it was a big burden, but I see the</p> <p>13 looks out there, so if anybody wants to comment on</p> <p>14 that, they're more than welcome to.</p> <p>15 MR. CORZINE: Okay.</p> <p>16 UNIDENTIFIED SPEAKER: It's a lot of work.</p> <p>17 MR. CORZINE: It is? Okay, well I would</p> <p>18 hope that something could be done to not duplicate,</p> <p>19 right. So anyway, thank you. Did you also, or have</p> <p>20 you taken a look at, for example, back on your scale,</p> <p>21 why, for example, 5, 7 and 13 I guess it is were</p> <p>22 worse, did take twice as many staff hours as -- I know</p>
<p style="text-align: right;">103</p> <p>1 that as opposed to starting from scratch. So I think</p> <p>2 in the long run they will, but we didn't really have</p> <p>3 good data to say that there was a statistically</p> <p>4 significant difference between them.</p> <p>5 UNIDENTIFIED SPEAKER: Yeah, if you have the</p> <p>6 time and resources to keep collecting the data I think</p> <p>7 that would be useful to learn more next year.</p> <p>8 DR. STANKIEWICZ GABEL: Okay. Thank you.</p> <p>9 MR. CORZINE: Leon Corzine again. A couple</p> <p>10 questions on the -- are you moving forward with</p> <p>11 guidance so those ERs will be more helpful and I would</p> <p>12 assume that that would cut down on some of the staff</p> <p>13 time then for you? I mean are you -- going to get it</p> <p>14 moving forward? Is that part of your process?</p> <p>15 DR. STANKIEWICZ GABEL: Well that's</p> <p>16 something that we want to discuss with the</p> <p>17 participants in the pilot project, do they desire to</p> <p>18 continue moving forward with ERs. And if they do,</p> <p>19 then yes, that will be one of the projects that we</p> <p>20 undertake in improving our guidance.</p> <p>21 MR. CORZINE: Well I would assume that they</p> <p>22 would be receptive because that cuts down on staff</p>	<p style="text-align: right;">105</p> <p>1 some of them -- you explained why some were shorter</p> <p>2 but is there a particular reason why number 13 was so</p> <p>3 lengthy more so than the others?</p> <p>4 DR. STANKIEWICZ GABEL: You know I actually</p> <p>5 can't say why number 13 was more staff hours just</p> <p>6 looking at it. That actually was in the old process.</p> <p>7 So I'm not -- it was during that transition time. So</p> <p>8 some of the efficiencies that we're seeing within our</p> <p>9 own staff may be reflected in some of these numbers as</p> <p>10 well.</p> <p>11 MR. GEORGE: Other questions? Again those</p> <p>12 of you that are online, hit the 1 and 0 and we'll know</p> <p>13 you want to ask a question. There are none and we'll</p> <p>14 thank, Rebecca. So thank you.</p> <p>15 DR. STANKIEWICZ GABEL: Well thank you.</p> <p>16 MR. GEORGE: So we're running a little</p> <p>17 behind time so we're going to actually change our</p> <p>18 schedule just a little bit, take a break now. I will</p> <p>19 remind folks that we're going to have this listening</p> <p>20 session after the break, after a couple presentations.</p> <p>21 If you would like to comment, and have not signed up</p> <p>22 to do so, you can still do that. Just let me know or</p>

Capital Reporting Company Stakeholder's Meeting 11-20-2013

<p style="text-align: right;">106</p> <p>1 go to the registration desk outside. So we will 2 reconvene at about, I've got 20 of, so about five of 3 11 we'll reconvene. Thank you very much. 4 BREAK 5 MR. GEORGE: We're going to get started 6 again please. Thank you. Yes, if we could get 7 started again please. Please take your seats. Okay. 8 Thank you very much. Thanks everybody. 9 Those of you actively engaged in developing 10 genetically engineered organisms, know that the 11 permitting and notification process is where the 12 rubber meets the road here in BRS in terms of the 13 field testing and movement of regulated GE organisms. 14 Here to update us on design protocols, 15 separation distances and the number of test sites for 16 petitions is John Turner, Director of the BRS 17 Environmental Risk Analysis Program. John? 18 Permit Information & Guidance 19 DR. TURNER: Okay. Good morning everyone. 20 It's really great to be here today and see you all. I 21 got to tell you, I'm really very impressed with the 22 very informed and thoughtful questions we've had so</p>	<p style="text-align: right;">108</p> <p>1 So I wanted to mention a few things. Our 2 objectives of course are to ensure that they're 3 adequate to maintain confinement and identity of 4 regulated articles. Another objective is to provide a 5 timely review, and this is one of the reasons I'm 6 putting this up here. Last year the reviews weren't 7 that timely and we certainly don't want field tests to 8 be delayed, so we're committed to being more timely 9 this year. 10 We're also coordinating with our compliance, 11 with our Office of Compliance Assistants, OCA in reg 12 operations to make sure there's no duplication of 13 effort and you're receiving consistent communications 14 of our actions. And of course we want to assure 15 consistency across applicants, that people are all 16 meeting or exceeding minimum standards. 17 One of the things which should facilitate 18 our review of these design protocols is clear 19 communication, the sum of our minimal standards to 20 you. So this past August we put on the website a 21 separation distance table for nine common crops. And 22 there are handouts of this on the back table. And</p>
<p style="text-align: right;">107</p> <p>1 far, and I look forward to hearing more about your 2 thoughts later in the morning. 3 So I'm really going to talk about some nuts 4 and bolts of what we do in my program, reviewing 5 permits and notifications and petitions. I hope it 6 will be of interest to everyone here, but there are 7 certainly things we get questions about. We thought 8 this would be a great forum to roll some of this out. 9 So while we're talking about great technological 10 achievements, I'm told the slide advancer now works. 11 So that was successful. 12 Well first off, this is the season, not only 13 of the holidays but for us to review design protocols. 14 So what are these? These are standard protocols which 15 are used by the developers of biotechnology for their 16 field testing. 17 When they field test under notification, 18 you're required to meet the performance standards, and 19 we require them to have a protocol on how they're 20 going to do that, and we review these annually. So 21 we're doing that right now for field tests that will 22 take place in the spring and summer.</p>	<p style="text-align: right;">109</p> <p>1 these nine crops comprise the vast majority of all our 2 permits and notifications. 3 So about the table, this table is very 4 general and again it's minimal standards. In some 5 cases greater or lesser distances are appropriate. 6 Regulated trials must be separated by a minimum of 10 7 feet from any commercial crop, regardless of sexual 8 compatibility, to prevent mechanical mixing. 9 So in this case we're not so worried about 10 gene flow to a sexually compatible plant but just to 11 ensure that the regulated crop is not inadvertently 12 harvested in something it's adjacent to. Greater 13 distances are of course required if you have equipment 14 which requires a greater distance. 15 Also we've been asked several times whether 16 this has to be a fallow zone or can a cover crop be 17 planted in this 10 foot zone. And the answer is a 18 cover crop is allowable but if it's plowed under and 19 not harvested and not used for food or feed. 20 And finally this table that we published is 21 a living document. It's designed such that we can add 22 crops over time and we can make adjustments as needed</p>

Capital Reporting Company Stakeholder's Meeting 11-20-2013

<p style="text-align: right;">110</p> <p>1 to reflect the latest information and of course the 2 best possible science. 3 In the table one particular thing that I 4 wanted to highlight is our confinement standards for 5 cotton. Traditionally, over the years, we've always 6 required 660 feet from sexually compatible cotton, or 7 40 feet of border rows comprised of a similar cotton 8 which is synchronously flowering. 9 When the table was published in August, we 10 strengthened those confinement standards for 11 situations where the cotton is near any sexually 12 compatible wild, ruderal or feral cotton, or from seed 13 production cotton. And in these cases we decided that 14 we should require 1320 feet, or if you wanted to use 15 border rows, 165 feet of separation, which includes 60 16 feet of non-transgenic border rows. 17 And very recently we've made a small 18 adjustment to this, so since the table went up in 19 August I want to make sure you're aware of. Again for 20 those situations where it's near production cotton or 21 wild or feral cotton, 1320 feet, that's the same, and 22 165 feet of separation which includes 60 feet of non-</p>	<p style="text-align: right;">112</p> <p>1 is for the purposes of petition and gathering of 2 agronomic data, eight sites would be the minimum 3 requirement. 4 And I would add at this point that this 5 recommendation is probably applicable to most 6 agronomic crops with familiar traits. And if you had 7 questions the thing to do would be of course to talk 8 to us in a pre-consultation meeting before you 9 submitted your petition. 10 There are some caveats that go with this 11 recommendation of eight sites. The following language 12 is on the website for corn and I think it's applicable 13 to all of these. 14 "Data should be collected on enough sites to 15 adequately represent the major growing regions 16 targeted by the product. The sites should be selected 17 in a way to ensure exposure to a reasonably wide range 18 of environmental conditions. For corn with common 19 agronomic crops or previously deregulated traits, 20 APHIS recommends a minimum of eight sites be selected 21 to represent the major growing regions of the U.S. 22 Data from the eight sites may be collected in one or</p>
<p style="text-align: right;">111</p> <p>1 transgenic border rows, or that 60 feet can be reduced 2 to 40 feet if effective measures are taken to reduce 3 cross pollination by insects. 4 Effective measures must be validated as 5 effective, and their implementation documented for 6 inspection purposes. And pesticides used must be in 7 accordance with the labels. So this reflects the 8 science of course that if there are not insect 9 pollinators, cotton is mostly nearly entirely self- 10 pollinating. 11 So I wanted to make you all aware of that 12 since it changed last year and has changed again very 13 recently these two final standards for cotton, which 14 are reflected again in the table on our website and on 15 the table in the back. 16 I want to also talk about, a little bit 17 about the number of field sites for petitions. Last 18 year we amended our guidance for corn to recommend a 19 minimum of eight sites. Prior to this it was about 20 16. And we've recently decided to expand this 21 guidance to cover our most commonly petitioned crops 22 of corn, soybean, cotton and canola. So again, this</p>	<p style="text-align: right;">113</p> <p>1 more years. When field testing corn with less 2 familiar traits or for traits where there is a reason 3 to expect that there might be plant pest effects, more 4 sites should be considered." 5 I think the last part is especially 6 important, to realize that just because something is 7 genetically engineered, the process itself wouldn't 8 lead to an expectation that there would be greater 9 plant test effects, so you should really think about 10 the trait and the biology of what you end up with. And 11 if there were questions there then more sites or 12 additional research might be needed to address those. 13 And I think that's all I have. Maybe my 14 short presentation will get us back on track a bit. 15 MR. GEORGE: Questions for John? Any online 16 questions? One then zero. The instructions get 17 shorter as we go along. One then zero on your 18 telephone keypad. Okay. Thanks John. 19 DR. TURNER: Okay. Compliance & Inspections 20 MR. GEORGE: As we all know, where there are 21 rules and regulations you need to make sure they're 22 followed. That's pretty important. It's even better</p>

Capital Reporting Company Stakeholder's Meeting 11-20-2013

114	<p>1 if the people doing that are also working to help 2 people learn and understand the processes so 3 compliance issues are prevented. In BRS those tasks 4 are handled by the regulatory operations program. Ed 5 Jhee is the director of that program. Ed? 6 DR. JHEE: Good morning everybody. Thanks 7 for coming to his meeting and thank you for everybody 8 that's actually looking and listening to all of those 9 presentations via online. 10 I wanted to take a moment, a brief moment to 11 bring you guys up to speed in terms of some of the 12 highlights that we had in 2013 as well as what we 13 anticipate in terms of some of the report activities 14 for 2014. I was also reminded earlier that as a 15 director in terms of overseeing the compliance branch 16 is that you know we are a little off track in terms of 17 today's agenda so to make sure that we do get back on 18 track. That's going to be my responsibility. 19 All right, so to get started with what 20 happened in 2013, this was another active year for 21 BRS, especially our compliance branches. We issued 22 over 735 inspections last year. And we actually,</p>	116	<p>1 of our division moving forward is to leverage internal 2 processes in terms of continual improvement. Over 3 this past year the compliance and evaluation 4 enforcement branch took some time to evaluate its core 5 internal processes and see where they could gain some 6 efficiencies in how they operate their business. 7 One of the business process improvement 8 projects that was conducted was to explore ways to 9 produce paperwork as well as increase quality 10 consistency of the reviews, and the timeliness of 11 their compliance responses to the regulated community. 12 The branch began this fiscal year, back in 13 October after we all came back, through implementing a 14 paperless route. So we're along the lines of being 15 green, as well as reducing costs to the agency and 16 becoming more efficient. This paperless route, in 17 terms of processing compliance cases, has a goal of 18 reducing paperwork overall, focusing on the improved 19 quality and consistency, especially in terms of our 20 reviews. And then in addition to improving the 21 consistency and quality of those reviews, reducing the 22 amount of time it takes to provide a timely response.</p>
115	<p>1 based on the number of those inspections completed 2 through this process, we had a compliance rate of over 3 98 percent. I want to take a moment to thank the 4 regulated community for doing your best efforts to 5 comply with our regulations and this number also 6 reflects efforts on our part to provide oversight, and 7 your efforts to comply with our regulations. 8 A common question we receive is what are 9 your plans for 2014 in terms of inspections? Well 10 it's not an easy question to answer. It's largely 11 dependent upon the activities of the regulated 12 community. Inspections are typically based on the 13 number of sites planted or the number of authorized 14 plantings. 15 In addition, it is also relative to the 16 number of authorization, meaning the number of 17 notifications and permits issued. As we're all aware, 18 these numbers can fluctuate on an annual basis, and so 19 it's not prudent for us to say we're going to shoot 20 for a bean count target of 800 or 900 inspections a 21 year. Again, this is largely dependent upon you guys. 22 As Mike had mentioned earlier, a key focus</p>	117	<p>1 Mike had also mentioned earlier about the 2 efforts of the compliance assistance, the Office of 3 Compliance Assistance, and this again remains a key 4 focus of operations, the operation of the division. 5 The BQMS program, as Mike had mentioned, continues to 6 grow. We had 21 new, or 21 participants that have 7 been recognized as voluntarily adopting this program. 8 This reflects the efforts of the regulated community 9 to be good stewards of the research and development 10 products that they're developing, as well as focusing 11 on compliance with the regulations. 12 I don't want to get back into the numbers 13 but I think Mike had mentioned upwards to 97 percent 14 of all the field released acreage is linked to those 15 entities that participate in this program. So again, 16 that demonstrates a strong commitment towards 17 compliance with the regulations. 18 Another key effort that was conducted by the 19 Office of Compliance Assistance -- or let me 20 backtrack, it was coordinated by the Office of 21 Compliance Assistance, was conducting nationwide 22 compliance outreach and education workshops. Now</p>

Capital Reporting Company Stakeholder's Meeting 11-20-2013

<p style="text-align: right;">118</p> <p>1 although this was coordinated through the Office of 2 Compliance Assistance, this was a true collaborative 3 effort within all of BRS, including Dick and his team 4 with the communications branch, John and his team in 5 terms of risk assessment branch, and the support from 6 our Deputy Administrator's office.</p> <p>7 In fiscal year '13, we held four workshops 8 across the United States. These included Louisiana 9 State University, University of Tennessee-Knoxville, 10 Virginia Tech University, as well as the University of 11 Alabama-Huntsville. In addition we were also invited 12 by NIH to partner with them in a presentation at an 13 Institutional Biosafety Convention conference. That 14 was held in Seattle, Washington.</p> <p>15 The objectives of these workshops are to 16 increase the participant's knowledge about the risk 17 assessment application process and the compliance 18 inspection and enforcement obligations that they have. 19 Another objective is to communicate to them the 20 differences between the permitting system and the 21 notification system and how to navigate e-permits. 22 Based on some feedback received, and some of</p>	<p style="text-align: right;">120</p> <p>1 for helping to expedite non-regulated articles that 2 may be similar to a regulated article, typically 3 through the importation process. Courtesy permits are 4 still issued by BRS, especially in terms of the -- 99 5 percent of courtesy permits issued to drosophila 6 melanogaster fruit flies, but what we intended on 7 doing was providing documentation to the importer that 8 would actually expedite the importation of the non- 9 regulated articles and get them to the intended 10 destination quicker.</p> <p>11 In addition, we took a look at just the 12 sheer number of these courtesy permits issued and the 13 overall cost to the agency. When we started crunching 14 some numbers we realized we could actually, from a 15 federal perspective, save the government over \$200,000 16 by implementing a bypass of the plant inspection 17 stations during the import process, only for these 18 courtesy permits.</p> <p>19 So the bottom line is we're expediting 20 drosophila coming into the United States to its 21 intended destination. There is no plant pest risk and 22 we're saving not only the government money, but we're</p>
<p style="text-align: right;">119</p> <p>1 the similar types of questions we obtained back in 2 2012, a lot of the questions were still around how to 3 navigate e-permits. How do I comply with regulations? 4 When an inspector comes to my site, what do I expect? 5 So a lot of the 108 some odd participants that 6 attended these workshops walked away with a better 7 knowledge of what to expect if and when they do apply 8 for an authorization.</p> <p>9 We are going to continue with these 10 workshops in fiscal year '14. Our first one is 11 scheduled for a little more than two-and-a-half weeks 12 away at UC-Davis. We are open to conducting 13 additional workshops based on demand.</p> <p>14 Again, continuing our focus on business 15 process improvement. Our Permits and Programs 16 Services branch led an effort coordinated with Plant 17 Protection Quarantine and the Customs and Border 18 Protection and Department of Homeland Security to 19 explore ways, another approach to expediting business 20 processes.</p> <p>21 This business process improvement deals 22 directly with courtesy permits. Courtesy permits are</p>	<p style="text-align: right;">121</p> <p>1 also saving the importer money as well, making sure 2 that these articles, these non-regulated articles get 3 from point A to point B in a timely manner.</p> <p>4 What are our plans for 2014? So the next 5 couple of slides I just wanted to touch base on some 6 key activities that I'll be working with my team on. 7 We are in the process of putting together a business 8 or a strategic/operational plan for our division. We 9 want to focus on lessons learned. We want to focus on 10 this past year, which was a very challenging year in 11 terms of exploring how we operate, what are our core 12 processes, and what do we want to do moving forward 13 into 2014 and beyond.</p> <p>14 We want to take opportunities to benchmark. 15 What are the successes of other programs in APHIS? 16 What are the successes of other agencies in terms of 17 compliance oversight, and how can we integrate all 18 this into the overall approach we want to take here in 19 BRS?</p> <p>20 So what we did is I met with my management 21 team to discuss really what's our vision, what do we 22 want to do and what's our mission in terms of</p>

Capital Reporting Company Stakeholder's Meeting 11-20-2013

122	<p>1 supporting APHIS or BRS, APHIS as well as the 2 department's efforts? It's our vision to increase 3 public value for the compliance related activities. We 4 feel that all the goals associated with our mission, 5 as well as what we do operational around here 6 (inaudible) is intended to increase public value as 7 well as comments.</p> <p>8 Our mission is pretty straightforward; it's 9 to protect American agriculture and the environment by 10 ensuring compliance to the regulations for the 11 introduction of GE organisms through compliance 12 assurance, enforcement and assistance. Those are the 13 three key branches that you often hear about.</p> <p>14 Now lastly I'll share with you guys some 15 draft goals that were submitted to me by my team. 16 These are to ensure compliance to the regulations by 17 responding promptly to non-compliance incidents and 18 providing consistent and objective enforcement. In 19 addition, providing compliance assistance to 20 facilitate compliance to the regulations, also 21 ensuring high quality of the inspections, and then 22 finally exploring ways to continually improve our</p>	124	<p>1 UNIDENTIFIED SPEAKER: -- approach and how 2 that --</p> <p>3 DR. JHEE: Yeah, this may help you actually. 4 So in terms of the approach that we take with 5 selecting inspections, there is a risk-based paradigm 6 or an approach that we take, especially for permits 7 and there are two key categories of permits that we 8 issue, the pharma industrial type of permits as well 9 as your standard permits.</p> <p>10 And then from an overall BRS perspective, we 11 also issue authorizations in terms of permits and 12 notifications. If you are somewhat familiar with the 13 regulations, the notification process is intended to 14 be an expedited process for those regulated articles 15 that are similar in terms of -- and familiarity, okay, 16 in what BRS reviewed and the past.</p> <p>17 And so we consider, from a compliance 18 standpoint, to those be of lower risk category in 19 terms of those that are permitted or those that have 20 elevated to the industrial and pharmaceutical type of 21 trial.</p> <p>22 In terms of the pharmaceutical trials and</p>
123	<p>1 business processes and collaborate internally with 2 other programs within BRS.</p> <p>3 For the last slide, I do want to take a 4 moment to thank my team. I think with the efforts of 5 them as we move forward in 2014 we will realize the 6 impact of this business plan that we're putting 7 together and we'll continue to have success moving 8 forward. Thank you. Willing to take any questions.</p> <p>9 MS. REED: Hi, Genna Reed from Food and 10 Water Watch again. I was just wondering on your slide 11 how many compliance inspections there were, how many 12 were applications, how many were permits and then out 13 how many of (inaudible)?</p> <p>14 DR. JHEE: Good question. I don't have that 15 data presently in front of me, but what I can do is 16 get that information to you if you're interested.</p> <p>17 MS. REED: Okay.</p> <p>18 DR. JHEE: If that helps.</p> <p>19 MS. REED: Thanks.</p> <p>20 UNIDENTIFIED SPEAKER: Ed, why don't you 21 explain kind of the risk factor, risk based -- 22 DR. JHEE: Approach?</p>	125	<p>1 the industrial trials, we will inspect those five plus 2 two. What we mean by five plus two is that on an 3 annual basis they'll be inspected at least five times, 4 including from pre-planting, their site selection, all 5 the way through planting activities, and then 6 termination of the trial. The plus two indicates 7 volunteer monitoring to make sure that the regulated 8 article does not persist (ph) in the environment.</p> <p>9 When it comes down to standard permits, our 10 compliance and assurance branches work together to 11 receive -- with the industry -- to receive plant 12 import information. This was a slide where Mike had 13 requested to the industry when you receive an 14 authorization, it would help BRS greatly if you guys 15 could do the best you can to plan accordingly where 16 you're going to be planting.</p> <p>17 The planting information is what we base our 18 inspections on, so when a site is planted we know that 19 we evaluate that area for whether or not it's a permit 20 or notification, how many sites are planted, what's 21 the acreage, what is the phenotype of the organism out 22 there, what are the constructs. And then take all</p>

Capital Reporting Company Stakeholder's Meeting 11-20-2013

<p style="text-align: right;">126</p> <p>1 those factors into a risk-based calculation and select 2 that site for inspection. 3 Notifications currently, because they are 4 under a more lower tier, I guess, for lack of better 5 words, we will randomly select across the United 6 States sites to be selected. So it's not necessarily 7 a surprise visit but we do make sure we stay on top of 8 any notification trials out there as well. Does that 9 help? 10 MR. COKER: We have an online question. 11 DR. JHEE: Sure. 12 MR. COKER: The gentleman's name is Mike 13 Cooper and his question is concerning the drosophila. 14 What Q&A is in place to ensure what is coming in is 15 actually what is on the permit? 16 DR. JHEE: So the question you're asking is 17 what kind of Q&As are available or guidance is 18 available? 19 UNIDENTIFIED SPEAKER: Quality assurance. 20 UNIDENTIFIED SPEAKER: QA. 21 UNIDENTIFIED SPEAKER: Quality control. 22 DR. JHEE: Quality control. Okay. The</p>	<p style="text-align: right;">128</p> <p>1 diligence upfront when we review the applications, 2 because sometimes something may come through where 3 somebody may think it is a courtesy and in fact they 4 then have to go through a regulated traditional permit 5 process and vice versa. 6 There's things that people put in thinking 7 that are regulated and in fact qualify under courtesy, 8 or if they're not regulated and then we will provide 9 them with the documents that we would for courtesy. So 10 maybe that will help clear it up a little bit. 11 DR. JHEE: Thanks Steve. Any additional 12 questions? 13 MR. GEORGE: That was actually Steve Bennett 14 commenting from (inaudible). Other questions? One 15 then zero on your telephone keypad. No? Okay. In 16 that case, so thanks very much. 17 DR. JHEE: I got you back on track. 18 MR. GEORGE: Okay, well I'd say I think the 19 meeting has gone very well so far, but you know what, 20 this is really a quiet group. (Inaudible) quiet, so I 21 think we really need to make some noise and I think we 22 have a really good reason to make some noise because</p>
<p style="text-align: right;">127</p> <p>1 quality control in my understanding is done during the 2 application process and review by our risk assessment 3 staff. So when an application occurs, the permit is 4 received by BRS, is there a risk assessment staff that 5 is going to be evaluating whether or not this organism 6 does pose a plant pest risk. 7 Upon that determination, the courtesy permit 8 is either issued because it is not a regulated 9 article, but if it is determined to be a regulated 10 article, it is brought in under 340. Steve? 11 DR. BENNETT: I think I can also add some 12 information to the import process. Although it may be 13 not being directed to a plant inspection station, 14 there are still stringent reviews and clearance 15 process that take place through CDP (ph), CDP add 16 (ph), and they will occasionally take things off the 17 list that may not be listed as regulated and still go 18 to a plant inspection station. So there's a lot of 19 checks and balances in place. We've just kind of 20 streamlined not having to go through that process 21 every time. 22 And also as I mentioned, we do our due</p>	<p style="text-align: right;">129</p> <p>1 Ed Jhee almost got us back on schedule. So we need a 2 thunderous round of applause. 3 DR. JHEE: Okay, thanks very much. Listening 4 Session 5 MR. GEORGE: So the next and the last item 6 on our agenda is our listening session. As mentioned 7 earlier, this not a question and answer session but 8 rather an opportunity for stakeholders to give us 9 comments, feedback, thoughts, basically anything on 10 your mind you think we should know about the growing 11 (ph) biotechnology. 12 And we have three commenters signed up to 13 make comments so they'll speak first and then if there 14 are others who would like to comment, that's fine too. 15 And first is Kevin Cook. Kevin, are you here? 16 Terrific. If you could just come up to our stand. 17 MR. COOK: Hi there. Thanks for the 18 opportunity to comment today. I'm the Co-Director of 19 the Bloomington Drosophila Stock Center, the national 20 depository for genetically characterized strains of 21 drosophila melanogaster. As most of you know, 22 drosophila is widely used as a model organism for</p>

Capital Reporting Company Stakeholder's Meeting 11-20-2013

<p style="text-align: right;">130</p> <p>1 biomedical research.</p> <p>2 My facility is sponsored by the National</p> <p>3 Science Foundation and the National Institutes of</p> <p>4 Health. Within the National Institutes of Health</p> <p>5 we're sponsored by the Office of Research</p> <p>6 Infrastructure Programs within the Office of the</p> <p>7 Director, the National Institute of General Medical</p> <p>8 Sciences, and the National Institute of Child Health</p> <p>9 and Human Development.</p> <p>10 There are about 2,700 laboratories in 63</p> <p>11 countries using drosophila as their primary</p> <p>12 experimental subject and every year they continue to</p> <p>13 make significant biological discoveries and then</p> <p>14 publish heavily (ph).</p> <p>15 Their work is well-funded by governmental</p> <p>16 agencies and research foundations. Just this year the</p> <p>17 National Institute of Health alone has spent more than</p> <p>18 \$292 million on grants focused on drosophila. And</p> <p>19 this is plus other foundations funding research,</p> <p>20 including the National Science Foundation, American</p> <p>21 Cancer Society and the American Heart Association, as</p> <p>22 well as foundations in other countries such as the</p>	<p style="text-align: right;">132</p> <p>1 for drosophila movement are standardized and easy for</p> <p>2 BRS to process.</p> <p>3 Third, as Ed Jhee talked about, at the end</p> <p>4 of September BRS simplified import procedures. Rather</p> <p>5 than sending all drosophila shipments coming into the</p> <p>6 country under courtesy permits to an agent's</p> <p>7 inspection station, BRS is now issuing courtesy</p> <p>8 permits with so called letters of no jurisdiction that</p> <p>9 tell customs agents that shipments can be forwarded</p> <p>10 directly to permit holders rather than going to</p> <p>11 inspection stations. This has sped up delivery times</p> <p>12 and it's substantially reduced the workload of</p> <p>13 inspection stations. And this reform has been quite</p> <p>14 popular within the drosophila research community.</p> <p>15 From my perspective, drosophila import</p> <p>16 permits are going quite smoothly now. Nevertheless, I</p> <p>17 see one potential danger that could lead to major</p> <p>18 problems for both drosophila scientists and BRS. I am</p> <p>19 concerned that drosophila melanogaster might be</p> <p>20 classified as a plant pest in the future. There's</p> <p>21 apparently this agreement within agents regarding the</p> <p>22 pest status of drosophila melanogaster.</p>
<p style="text-align: right;">131</p> <p>1 Welland (ph) Trust in the European Union and</p> <p>2 charities.</p> <p>3 The success of this entire research</p> <p>4 enterprise depends on researchers being able to</p> <p>5 collaborate and to ship live fly cultures to each</p> <p>6 other. Most drosophila strains are not -- are</p> <p>7 transgenic, and the volume of drosophila imports is</p> <p>8 high enough, a substantial fraction of import permits</p> <p>9 BRS issues every year for drosophila shipments.</p> <p>10 Nevertheless, these shipments are pretty</p> <p>11 easy for agents to handle. First, BRS does not</p> <p>12 consider drosophila melanogaster a plant pest with</p> <p>13 regard to (inaudible) permits and most transgenic</p> <p>14 strains do not carry DNA sequences from plant pests.</p> <p>15 That means that most permits for imported flies are</p> <p>16 courtesy permits and interstate movement permits are</p> <p>17 rarely issued.</p> <p>18 Second, I've worked with BRS staff over the</p> <p>19 last few years to provide guidance to drosophila</p> <p>20 scientists using the e-permit system. We have</p> <p>21 (inaudible) pages on our website providing templates</p> <p>22 for completing applications, so now most applications</p>	<p style="text-align: right;">133</p> <p>1 I know of no formal public document</p> <p>2 classifying drosophila as a plant pest, but many PBQ</p> <p>3 practices indicate that it is treated as one in some</p> <p>4 situations, and I have heard different opinions from</p> <p>5 the APHIS staff.</p> <p>6 This inconsistency suggests to me that the</p> <p>7 BRS practices may be subject to change. This would</p> <p>8 substantially complicate the exchange of research</p> <p>9 samples and would increase BRS expenses considerably.</p> <p>10 For example, BRS would have issued more than 12,000</p> <p>11 interstate movement permits in 2012 to me. This is in</p> <p>12 addition -- besides that there are all the scientists</p> <p>13 and all the labs exchanging specimens.</p> <p>14 So I urge you to resist vigorously any</p> <p>15 effort to classify drosophila melanogaster as a plant</p> <p>16 pest. Ideally, I would like to see a formal public</p> <p>17 document declaring drosophila melanogaster as a non-</p> <p>18 pest species to clear up this issue once and for all.</p> <p>19 I'd also like to suggest a change that would</p> <p>20 simplify the movement of many transgenic strains of</p> <p>21 most model organisms used for laboratory research. I'd</p> <p>22 like BRS to give special status to piggyback</p>

Capital Reporting Company Stakeholder's Meeting 11-20-2013

<p style="text-align: right;">134</p> <p>1 transformation vectors. This family of transformation 2 vectors is now used in many different laboratory 3 organisms and is becoming increasingly popular. The 4 problem is that the piggyback system was derived from 5 transposon for bonafide plant pests, the cabbage 6 looper moth, so piggyback constructs are considered 7 regulated items. 8 In practical terms, these vectors are no 9 different than any other transformation vector, and 10 they're now considered generic molecular biology tools 11 by most scientists. It seems rational for BRS policy 12 to recognize the special status of these elements and 13 to provide some sort of exception for laboratory 14 strains. 15 Piggyback sequences are the most common 16 plant pest sequence in many transgenic lab animals so 17 giving them special consideration would save everyone 18 time and money and not require standard import permits 19 or interstate movement permits. Thank you. 20 MR. GEORGE: Thank you, Kevin. Our second 21 commenter that is signed up is Christopher Marrero 22 (ph). Christopher, are you here? Are you online</p>	<p style="text-align: right;">136</p> <p>1 there's a new acronym for you. You can maybe learn 2 some of mine; I'm trying to learn yours. 3 And I somehow got involved through the 4 biotech area in the National Corn Growers Association, 5 so I'm a past president of the National Corn Growers 6 and also a member of AC21 where we've talked a lot 7 about co-existence issues. As you know we had a 8 specific charge from the Secretary. I appreciate 9 being involved there. 10 It's a good thing for me as being a Central 11 Illinois farmer because I have two organic neighbors 12 and we do a lot of things that coexist that I can go 13 into later. You've addressed some of them, these 14 distances, you know the whole thing about different 15 planting dates and all of those kind of things, we 16 work through. 17 And by the way, a good way to communicate, 18 our wives are good friends, as we are, and the two of 19 them they have coffee twice a week so if we're doing 20 something not quite right, we find out about it pretty 21 quickly. 22 You know I really recognize and I've been</p>
<p style="text-align: right;">135</p> <p>1 perhaps listening in? If you are, then hit 1 then 0 2 and we'll know that you'd like to speak. Christopher 3 Marrero from BakerHostetler LLP. No? Okay. 4 Then the last person who has signed up is 5 Leon Corzine. So Leon, it's all yours. If others 6 would like to comment, we'll allow that (inaudible). 7 MR. CORZINE: Thank you. Thank you very 8 much for the opportunity. I really applaud the 9 efforts in this meeting. I understand you may have 10 had it a couple years. It got on my radar screen 11 because as a farmer I thought well there's a 12 stakeholder meeting and these issues I think being on 13 the farm I may be one of the largest or the largest, 14 the biggest stakeholder in the whole realm of the 15 issue. And so I thought it was important to be here. 16 A little bit of difficulty in Central 17 Illinois, we're just finishing up harvest and some of 18 those kind of things and I've got to get flowers for 19 my wife going home because she didn't know until 20 yesterday morning that I was going to be here today. 21 Also acronyms, I am a CIFCF, which means a 22 Central Illinois Family Coexistence Farmer. So</p>	<p style="text-align: right;">137</p> <p>1 proud that the United States has had, we, collectively 2 have had the best regulatory system going. It works. 3 It has worked. But you know that doesn't mean that we 4 can sit still, and I applaud your efforts. 5 It's important for me to see that, for us to 6 see that, because on the farm we don't quite frankly 7 often. And because the others are catching up or 8 there are concerns where some other countries things 9 get deregulated faster. But also it is a balance and 10 I recognize that because everything that I use, and I 11 talk about it a lot, that everything, our biotech 12 products, that technology is more -- more steps are 13 taken to prove that it is safe than anything else I 14 use. 15 And since it is still relatively new, the 16 consumer groups I talk to, there should be some real 17 assurance there, and I want them to have that 18 assurance. I want us to have that assurance on our 19 family farm as well because we want to continue. Our 20 mantra is to make the farm better than we found it. 21 And I am a fifth generation farmer. My son is on the 22 farm, six generations, so between my son, my wife and</p>

Capital Reporting Company Stakeholder's Meeting 11-20-2013

<p style="text-align: right;">138</p> <p>1 I, you know we truly are a family farm and it keeps us 2 looking to the future. 3 You know as we look at this system we've 4 really got to have something that is predictable, you 5 know it's practical, and defensible. And I 6 appreciated talking to Mike Firko about defensibility 7 because this EIS issue, and that's why I asked the 8 question, I'm still a little fuzzy on that, but I 9 understand the defensibility part of it. But out on 10 the farm quite frankly it's looked like a delay tactic 11 by some groups. And some of the lawsuit issues and 12 some of those things, but that's kind of the world 13 that we're operating in. 14 And it does, I want you to understand that 15 there is frustration on our part, because these delays 16 cost me on the farm environmentally, as well as 17 economically. We're trying; we've changed our system 18 with the new technologies. One thing that is very 19 important to me is my son runs the corn plant now. I 20 don't -- all the new technology also from John Deere, 21 it's a little tough for me to keep up with so, so he 22 does, and that works out great.</p>	<p style="text-align: right;">140</p> <p>1 competitiveness with other countries. We have other 2 countries who have gotten ahead of us. I guess we can 3 question whether their system does as much proof in 4 the way of safety, but it looks like it does and so 5 anyway we can continue to adjust to be safe, to prove 6 safety, but still also we've got to be able to keep 7 these things on, fast track's not the right word, but 8 we've got to be timely and predictable because it also 9 removes competitiveness because there are only so many 10 biotech providers that can afford the delays and the 11 unpredictability. So we lose that research and a lot 12 of that competitiveness as we go along. 13 The trade issues that we have, and we've got 14 this one with China that I mentioned earlier, and the 15 whole low level presence issue, as we move forward I 16 think I'm really glad that we're working with the 17 other countries and around the world, but we've got 18 include those BRIC countries and we've got to take a 19 look at the low level presence policy in our country 20 since there are some things being approved in Brazil, 21 or deregulated, that are not here yet. 22 So I see that as an issue because we've got</p>
<p style="text-align: right;">139</p> <p>1 But with that, the (inaudible) for example, 2 we have eliminated a whole class of chemicals that I 3 used to have to handle, and my son had to handle. And 4 that's important because we do all the safety things 5 with gloves, with long-sleeved stuff and goggles, but 6 you know it's always going to be windy sometimes, and 7 even checking for seed depth, and some of those 8 practical things that some people don't think about. 9 You don't -- my son doesn't even have to have that 10 exposure anymore. And that's why these products are 11 so important to me. 12 And that being said, we don't use absolutely 13 every product on our farm that's going to be 14 deregulated. We're going to take a look at them, but 15 it's kind of what works. And I know that's tough for 16 EPA as well as APHIS to take a look. Just because 17 it's deregulated doesn't mean that it's going to go on 18 every acre of corn that's planted. You know there's 19 some practicality to that as well and I don't know how 20 that helps you insert that, but if you can I think you 21 should. 22 Those delays are also costly as far as</p>	<p style="text-align: right;">141</p> <p>1 to have access for my products in the world market, 2 because we produce a lot more than we can use here in 3 this country, and we want to provide, whether it's on 4 an economic basis or even in providing food aid to 5 some of the other countries. We've got to get this 6 low level presence thing done. 7 And like I said, I'm really here just 8 because I'm a family farmer and I'm concerned about 9 our future and what these products can and will do for 10 us. But also, as your system evolves, I want you all 11 to know how important you are to us out on the farm, 12 and that's what I hope to bring, that as you think 13 about that, maybe even as you're driving home or as 14 you do your work, you know think about the effect that 15 you're having on us because you have in some ways I've 16 mentioned, and I could talk the rest afternoon about 17 other ways that it has. 18 Because we are doing things, we have changed 19 tillage practices because of biotechnology. We have 20 changed what we do in erosion control, all of those 21 things. Our soils are better than they were 10 years 22 ago on some of our farms because we've been able to</p>

Capital Reporting Company Stakeholder's Meeting 11-20-2013

142	<p>1 build up organic matter because we've been able to 2 change what we do in tillage practices. 3 We have less carbon emissions because we 4 don't have to till the ground as much, so there's less 5 fuel use. All of these things I hope you can keep in 6 mind, and that's why it's very, very important to us. 7 And once again, I thank you all for the 8 opportunity and the chance to speak with you and 9 hopefully I'll try to stay in touch. Thank you. 10 MR. GEORGE: Thank you. And I had the 11 pleasure of observing, kind of participating a little 12 bit, in the AC21 meetings that Leon was a part of and 13 that he brought a very high perspective to those 14 meetings and farm meetings also. So thank you very 15 much. 16 We have no one else that has signed up and 17 asked to comment. We have one on the phone. Okay. 18 MR. COOPER: Guys, Mike Cooper with the 19 National Plant Board. And some of this is going back 20 to the drosophila question and some of our members 21 over those years have expressed a concern that if 22 there's this trade (inaudible) of drosophila</p>	144	<p>1 is Kevin Cook with the Drosophila Stock Center. One 2 of the primary quality control means for drosophila 3 melanogaster is its culture conditions. Drosophila 4 melanogaster was adopted for use in laboratories 5 because it's easy to culture. It's a garbage species. 6 It can grow on just about any culture medium. 7 That's not true for other drosophilae. It's 8 very difficult to culture other drosophilae, such as 9 drosophila suzukii and any other members of the family 10 drosophilidae. The other pest species of concern to 11 USDA is now (inaudible) genus drosophila zaprionus. 12 It's within the same family. But drosophila 13 melanogaster is so much easier to culture than any 14 other drosophilid or any tephritid that it's 15 essentially impossible to confuse the two. 16 In terms of the scientists working with 17 drosophila, we score very subtle phenotypes of 18 drosophila on a daily basis. I can tell you how many 19 hairs are on the haltere of a fruit fly. And I can 20 tell you that no drosophila geneticist would ever 21 confuse drosophila suzukii or zaprion syndicus (ph) 22 with drosophila melanogaster. It's simply impossible</p>
143	<p>1 melanogaster around the country, either permitted or 2 expedited, what quality control is in place to ensure 3 that it is actually drosophila melanogaster in those 4 shipments? 5 Because I'm sure in a lot of the labs, 6 there's 2,600 labs around the world, those labs have 7 other species of drosophila and other species of fruit 8 flies they're working with. And is there assurance 9 that the permitted species is the one that's actually 10 being moved? Is anybody looking at the shipments? 11 We have a problem now in the U.S. with 12 drosophila suzukii, which came in through a permitted 13 -- (inaudible) system into California a number of 14 years ago and escaped and is now becoming a 15 significant agriculture pest. And we're concerned 16 that nobody is actually monitoring the shipments to 17 see if the shipments are (inaudible) the species as 18 permit. Thank you. 19 MR. GEORGE: All right. Is there anyone 20 else in the room who would like to comment before we 21 close? 22 MR. COOK: Can I respond? All right, this</p>	145	<p>1 to do on a phenotypic basis. 2 So all drosophila melanogaster strains are 3 exchanged between biosafety level one facilities, or 4 their equivalent in other countries. And so the 5 quality control comes from the scientific expertise of 6 the drosophila geneticists who are handling the 7 strains. 8 Typically in drosophila labs it's solely 9 drosophila melanogaster that's cultured because it's 10 been developed for the last 100 years as a genetic 11 model organism. Other drosophila species do not have 12 the kind of genetic tools available to them. It's a 13 species specific research enterprise. Only drosophila 14 melanogaster is considered a genetic model organism. 15 Thank you. 16 MR. GEORGE: Thanks again, Kevin. I would 17 like to mention that all of you who have registered 18 for this meeting will receive an email survey sometime 19 in the next couple of days. Please take a minute or 20 two to fill that out. In particular we're interested 21 in how well the webcast was working. So those of you 22 that are online, we're interested in your opinions,</p>

Capital Reporting Company
Stakeholder's Meeting 11-20-2013

Page 1

<u> </u> \$	31:21 59:5	2014 37:21,22	4 96:8,12
\$200,000 120:15	16 22:8,13 56:3	101:17 114:14	40 3:10 110:7
\$292 130:18	91:11 111:20	115:9 121:4,13	111:2
<u> </u>	165 110:15,22	123:5	419 69:3
<u> </u> 0	17 3:7	2015 69:22	450 95:22
0 8:19 9:3 10:6	18 13:14	203 97:19	462 95:22 98:2
39:21 49:21	180 65:1 66:5 68:1	205 60:7	4700 1:14
78:12 105:12	18th 46:10	20737 1:15	4-D 84:8
135:1	19 149:10	21 61:9 117:6	4-D-tolerant 31:2
<u> </u>	1948 41:15	213 65:3	<u> </u>
<u> </u> 1	1961 41:15	21st 29:15	<u> </u> 5
1 8:18 9:3 10:6	1992 67:21	22 26:1,5 52:21	5 3:2 104:21
39:21 49:20	<u> </u>	57:13 95:9	50 28:7,14
55:10 78:12	<u> </u> 2	23 26:2 28:4	51 63:16
96:15 105:12	2 31:1 55:17	25 32:11	52 3:13,14
135:1	67:7,10,12 72:16	250 96:18	<u> </u>
10 15:13 109:6,17	84:8	259 27:6	<u> </u> 6
141:21	2,600 143:6	26 67:13	60 63:5,10
10,000 32:9	2,700 130:10	267 65:5	110:15,22 111:1
100 145:10	20 1:10 36:21	28 60:7	63 130:10
1000 68:10	96:9,11 97:7,22	<u> </u>	65 62:6
1001 68:10	106:2	<u> </u> 3	658 27:16 69:2
106 4:2,3	200 96:1	30 32:11 60:18	660 110:6
108 119:5	2000 68:2	70:14,15,19	<u> </u>
11 3:4 21:2 106:3	2005 59:22 68:5,8	30-day 55:12 72:2	<u> </u> 7
11:49 147:13	2007 41:3	78:4	7 20:17,21 21:8
114 4:6	2009 41:3	330 97:10,18	38:7 104:21
12 41:16 58:1,8	2010 92:19	34 41:19 46:13	735 114:22
12,000 133:10	2011 25:19 52:21	340 38:8 127:10	78 3:17
13 3:7 15:13 28:7	53:5 93:9	35 59:18 61:10	<u> </u>
56:2 104:21	2012 21:4 56:22	350 96:17	<u> </u> 8
105:2,5 118:7	57:5 119:2	364 27:17	8 20:17 21:9
1320 110:14,21	133:11	371 97:10	800 115:20
13-month 91:10	2013 1:10 5:8 18:4	3rd 30:14	86 62:4
14 3:8 119:10	34:17 36:10 93:9	<u> </u>	<u> </u>
146 4:7	114:12,20	<u> </u> 4	<u> </u> 9
15 17:10 28:4	149:10	<u> </u>	9 96:16 97:7

(866) 448 - DEPO

Capital Reporting Company
Stakeholder's Meeting 11-20-2013

<p>900 115:20 9001:2008 34:8 92 3:19 97 33:21 117:13 98 34:1 115:3 99 120:4</p> <hr/> <p style="text-align: center;">A</p> <hr/> <p>a.m 147:13 Abel 2:2 3:18 4:10 51:20 78:20,21 90:20 92:4,6 ability 14:1,9 24:11 76:10 81:8 able 7:6,9 8:2 11:16 49:1 54:4 74:16 85:6 91:9 101:21,22 131:4 140:6 141:22 142:1 146:1 absolutely 31:10 71:21 73:12 75:19 76:6,15 78:7 139:12 AC21 29:14 30:6 136:6 142:12 access 6:8 25:5 30:13 141:1 accident 42:12 accompany 10:14 accomplished 12:4 37:16 accordance 111:7 accordingly 125:15 account 33:21 accountable 30:11 34:10</p>	<p>accurate 86:21 achievements 107:10 acknowledge 30:11 40:18 acre 139:18 acreage 117:14 125:21 acronym 24:4 136:1 acronyms 73:5 135:21 across 20:4 40:20 48:4 86:5 108:15 118:8 126:5 act 88:13 acting 2:4 3:9 4:9 11:1,17 18:14,18,21 29:11 action 148:10,15 actions 10:15 51:9 82:5,13 89:13 108:14 active 23:15 35:17 49:3 114:20 actively 38:11 45:2 46:16,18 48:17,21 106:9 activities 22:22 30:6 31:22 51:21 80:7 83:3,22 97:16 114:13 115:11 121:6 122:3 125:5 activity 35:18 38:9 100:10 actual 76:4 actually 6:22</p>	<p>15:16,22 18:10 22:12 32:6,12,17 55:18 58:8 59:5 60:11 61:13 63:21 64:4 65:5,7,13 69:12 77:17 81:1 93:10,14 94:1,15 95:9,11 96:3,6,9,13 97:3,5,13,21 100:6,9 101:21 105:4,6,17 114:8,22 120:8,14 124:3 126:15 128:13 143:3,9,16 add 54:13 61:16 62:4 109:21 112:4 127:11,15 addition 7:3 115:15 116:20 118:11 120:11 122:19 133:12 additional 16:2 59:6 61:19 94:10 113:12 119:13 128:11 address 49:1 71:8,12 73:20 74:20 113:12 146:19 addressed 25:7 136:13 addressing 26:22 72:2 84:18 adequate 108:3 adequately 112:15 adjacent 109:12 adjust 140:5 adjustment</p>	<p>110:18 adjustments 109:22 administration 19:18 36:5 47:17 administrative 41:14 administrator 2:2,4,14 3:5,9,18 4:9,10 11:1,6 12:2 13:18 18:14,15,22 19:2 51:19 78:21 administrators 18:19 administrator's 18:19 118:6 admit 39:10 admitting 25:9 adopted 144:4 adopting 117:7 Adrian 91:21 advance 9:21 advancer 107:10 advantage 18:5 38:4 adverse 90:10 advisor 2:10 3:11 11:18 17:16 37:15 Advisory 29:14 affect 72:18 affected 22:21 24:11 affects 72:14 afford 140:10 afternoon 141:16</p>
--	---	---	--

Capital Reporting Company
Stakeholder's Meeting 11-20-2013

Page 3

<p>afterwards 51:5</p> <p>agencies 16:17 24:11 36:17 50:19 80:12,17 81:1,5,9 82:4,13,17 83:1,7 84:10 85:7,20 87:14,18,20,22 89:1,19 121:16 130:16</p> <p>agency 3:17 36:5 51:22 78:19 81:4 85:11 86:15 88:5 116:15 120:13</p> <p>agency's 88:8</p> <p>agenda 3:1,12 4:1 10:10 51:11 114:17 129:6</p> <p>agents 131:11 132:9,21</p> <p>agent's 132:6</p> <p>ago 21:17 51:16 52:9 53:16 56:4,19 57:12 141:22 143:14</p> <p>agreed 36:14</p> <p>agreement 36:18 42:15 94:13 132:21</p> <p>agriculture 1:13 12:14 13:7 14:15 19:6,8,9 22:17 29:15,22 30:1 36:8 122:9 143:15</p> <p>Agriculture's 2:15 3:6</p> <p>agronomic 112:2,6,19</p> <p>ahead 5:10 22:9</p>	<p>37:21 47:9 61:15 69:11 85:9 91:6,12 140:2</p> <p>aid 100:9 141:4</p> <p>Alabama- Huntsville 118:11</p> <p>alert 8:19</p> <p>Alimentarius 46:2</p> <p>allocate 54:11</p> <p>allot 10:11</p> <p>allow 60:17 135:6</p> <p>allowable 109:18</p> <p>allowed 7:20 9:17</p> <p>alone 60:10 130:17</p> <p>aloud 8:17 10:6</p> <p>already 6:15 13:15 26:18 28:18 34:12 37:21 43:9 56:21 85:11 90:21 98:21 102:11,21</p> <p>am 132:18 135:21 137:21 148:9,12 149:4</p> <p>amended 111:18</p> <p>America 13:7 19:5,7</p> <p>American 12:14 14:2 35:13 122:9 130:20,21</p> <p>Americas 46:15</p> <p>among 80:11</p> <p>amongst 95:20</p> <p>amount 53:2 54:10 59:20 60:4 62:3 65:6,11 66:1 70:13 93:7 97:13</p>	<p>98:13 100:17 116:22</p> <p>analyses 54:16,17 77:6,10</p> <p>analysis 2:6 3:21 4:4 52:2 55:4 74:11 75:15,18 76:16 77:1 98:6 106:17</p> <p>analysts 99:5,11 100:3</p> <p>analyzing 101:4</p> <p>and-a-half 25:22</p> <p>animal 1:6,14 2:15 3:6 20:14,16 42:9</p> <p>animals 134:16</p> <p>annex 46:4</p> <p>announce 55:9 56:20</p> <p>announced 51:16 53:5 56:17 57:1,21 92:20</p> <p>announcement 82:14</p> <p>annoyance 36:11</p> <p>annual 5:9 115:18 125:3</p> <p>annually 107:20</p> <p>answer 5:11 8:17 9:10 34:20,22 73:10 109:17 115:10 129:7</p> <p>answered 34:21</p> <p>anticipate 114:13</p> <p>ANTI- INFECTIVE 1:5</p> <p>anybody 6:17</p>	<p>104:13 143:10</p> <p>anymore 139:10</p> <p>anyone 6:7 39:18,20 49:20 51:4 143:19</p> <p>anything 13:7 14:12 41:4 47:13 49:5 78:8 129:9 137:13</p> <p>anyway 104:19 140:5</p> <p>apart 64:14</p> <p>APHIS 1:7 2:15 3:6 11:6 12:2 13:18 14:18 15:14,22 17:3 18:15,17 19:17 20:4,10,14 21:11 22:19 23:19 24:13 33:11 34:4 36:4 81:7 112:20 121:15 122:1 133:5 139:16</p> <p>APHIS,+ 19:12</p> <p>APHIS's 18:20 20:8</p> <p>APHIS-wide 15:10</p> <p>apparently 40:13 132:21</p> <p>appear 66:16</p> <p>appeared 35:7</p> <p>appears 148:4</p> <p>applaud 72:22 135:8 137:4</p> <p>applause 129:2</p> <p>applicable 112:5,12</p> <p>applicants 108:15</p>
--	---	---	--

(866) 448 - DEPO

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Capital Reporting Company
Stakeholder's Meeting 11-20-2013

Page 4

<p>application 44:16 118:17 127:2,3</p> <p>applications 123:12 128:1 131:22</p> <p>applied 24:10</p> <p>applies 67:9</p> <p>apply 119:7</p> <p>appreciate 16:3 30:7 78:7 136:8</p> <p>appreciated 138:6</p> <p>approach 119:19 121:18 123:22 124:1,4,6</p> <p>approached 44:6</p> <p>approaches 21:18 36:18 101:10</p> <p>appropriate 32:20 109:5</p> <p>appropriated 22:19,20</p> <p>appropriation 15:15</p> <p>appropriations 15:12</p> <p>appropriators 15:18</p> <p>approvals 45:17 80:13</p> <p>approve 32:2 38:1</p> <p>approved 32:4,12 39:2 140:20</p> <p>approving 32:16</p> <p>AQI 22:17</p> <p>arduous 42:16</p> <p>area 42:8,9 89:3 125:19 136:4</p>	<p>areas 36:19 87:1</p> <p>aren't 48:5 56:12 71:15</p> <p>army 33:11</p> <p>arrivals 82:8</p> <p>article 21:16 33:5 120:2 125:8 127:9,10</p> <p>articles 108:4 120:1,9 121:2 124:14</p> <p>Asia 46:15</p> <p>aspect 46:8 47:18</p> <p>aspects 47:12,22 50:18 81:4</p> <p>assessment 41:11 42:6 44:9,20 45:5 46:5,8 47:22 55:2,11,19 62:15 64:2,11,13,18 65:2 74:2,4 86:17,18 118:5,17 127:2,4</p> <p>assessments 27:10 54:21 62:18 76:5 77:7,21 89:18 91:8,18,19</p> <p>assessor 45:1</p> <p>assessors 44:8</p> <p>assist 100:9</p> <p>assistance 93:19 117:2,3,19,21 118:2 122:12,19</p> <p>Assistant 2:2 3:18 4:10 51:19 78:21</p> <p>Assistants 108:11</p> <p>associate 18:18,22</p> <p>associated 84:5</p>	<p>122:4</p> <p>Association 130:21 136:4</p> <p>assume 71:18 103:12,21</p> <p>assurance 122:12 125:10 126:19 137:17,18 143:8</p> <p>assure 108:14</p> <p>asynchronous 45:18</p> <p>attained 27:15</p> <p>attend 7:2,9</p> <p>attendance 7:5</p> <p>attended 119:6</p> <p>attending 9:19</p> <p>attenuated 35:8</p> <p>attorney 148:13</p> <p>August 108:20 110:9,19</p> <p>auspices 41:1</p> <p>Australia 45:19</p> <p>authenticated 6:8</p> <p>authorization 42:19 43:1,3 44:18 45:7 115:16 119:8 125:14</p> <p>authorizations 124:11</p> <p>authorize 44:10</p> <p>authorized 115:13</p> <p>Availability 41:11</p> <p>available 6:11,19 7:8 38:14,18 126:17,18 145:12</p>	<p>Avalos 17:17</p> <p>average 25:21 27:18 52:22 60:6,7 61:11 62:6,9 63:16 65:3,4,5 67:11 68:8 69:4 97:9,17</p> <p>aware 12:18 33:14 34:17 42:1 87:7 110:19 111:11 115:17</p> <p>away 26:4 119:6,12</p> <hr/> <p style="text-align: center;">B</p> <hr/> <p>backlog 26:1,3,4,7 52:21 57:13 65:11,13 69:18,22 98:8</p> <p>backs 71:22</p> <p>backtrack 117:20</p> <p>backup 50:6</p> <p>bad 15:14</p> <p>BakerHostetler 135:3</p> <p>balance 137:9</p> <p>balances 127:19</p> <p>bar 76:20</p> <p>base 59:2 87:21 95:15 121:5 125:17</p> <p>based 72:20 74:15 115:1,12 118:22 119:13 123:21</p> <p>basic 75:8</p> <p>basically 52:20 57:11 66:14 70:16,20 71:4</p>
--	---	---	---

(866) 448 - DEPO

Capital Reporting Company
Stakeholder's Meeting 11-20-2013

Page 5

<p>94:8 129:9</p> <p>basis 54:21 115:18 125:3 141:4 144:18 145:1</p> <p>batch 66:12</p> <p>bean 115:20</p> <p>bear 14:2</p> <p>became 12:1 21:3 34:17 35:8</p> <p>become 6:22 35:9 47:8 66:4 96:21</p> <p>becoming 48:6 69:6 116:16 134:3 143:14</p> <p>Beethoven's 5:19</p> <p>beets 57:20 59:1</p> <p>begin 54:20</p> <p>beginning 34:18 54:11 60:6 67:20 76:8,15,17,18 86:10 87:2 98:6</p> <p>behalf 80:9</p> <p>behind 72:19 105:17</p> <p>beliefs 19:3</p> <p>believe 91:7</p> <p>belt 24:14 26:13</p> <p>benchmark 121:14</p> <p>benefits 31:8</p> <p>Bennett 6:7 31:15 127:11 128:13</p> <p>bentgrass 57:20 59:2</p> <p>besides 133:12</p> <p>best 16:10,22 34:10 110:2</p>	<p>115:4 125:15 137:2</p> <p>better 10:21 11:14 12:10 16:1 80:1 113:22 119:6 126:4 137:20 141:21 147:7</p> <p>beverage 6:3</p> <p>beyond 121:13</p> <p>biggest 54:8 135:14</p> <p>billion 15:10,12</p> <p>bimodal 71:11</p> <p>BIO 91:21</p> <p>biological 130:13</p> <p>Biologics 21:7</p> <p>biology 45:8 113:10 134:10</p> <p>biomedical 130:1</p> <p>biopesticide 86:6</p> <p>biosafety 118:13 145:3</p> <p>biotech 1:4 15:6,15,16 17:2 21:14 29:17 35:22 46:11 136:4 137:11 140:10</p> <p>biotechnology 3:4 5:6,11 9:9,11 11:8 14:1 15:22 16:17 17:18 18:1,4 19:22 22:2 25:1 29:14 33:18 36:6 37:2 42:5 78:22 107:15 129:11 141:19</p> <p>BioTrack 46:11</p>	<p>bit 37:17 41:5 42:14,16 53:11 54:7 57:9 59:10 62:16 66:8 81:20 87:4 97:11 102:22 105:18 111:16 113:14 128:10 135:16 142:12</p> <p>blew 61:11</p> <p>Bloomington 129:19</p> <p>blue 64:6</p> <p>board 49:17 142:19 146:16,17,19</p> <p>boards 73:7</p> <p>body 41:14,16 42:10,16 46:6</p> <p>bogged 73:14</p> <p>bolts 107:4</p> <p>bonafide 134:5</p> <p>border 110:7,15,16 111:1 119:17</p> <p>bottom 95:17 96:8,9 120:19</p> <p>bounce 71:19,22</p> <p>bouncing 70:8</p> <p>box 8:15 9:3 10:2,5 78:14</p> <p>boxes 53:19,21</p> <p>BQMS 20:1 33:18 34:3,9 117:5</p> <p>branch 2:5,6,7,12,13 3:3,15,16,20,21 5:6 6:6 51:15 52:2 114:15</p>	<p>116:4,12 118:4,5 119:16</p> <p>branches 114:21 122:13 125:10</p> <p>brand 26:6,9</p> <p>Brazil 45:16 46:16 47:9 140:20</p> <p>break 4:2 6:4,5 51:4 105:18,20 106:4</p> <p>breakdown 72:4</p> <p>breaking 146:11</p> <p>breaks 71:2</p> <p>BRIC 46:16 48:14 140:18</p> <p>brief 114:10</p> <p>briefing 81:18 92:18</p> <p>bring 8:15 10:5 14:1,17,19 44:13 45:10 69:5 114:11 141:12</p> <p>bringing 69:8</p> <p>brings 83:8</p> <p>brought 29:16 127:10 142:13</p> <p>BRS 2:11 3:11 4:8 5:8 8:8 11:1 18:2,3 19:1 20:5,18 21:1,8,11 22:8,20 23:1,19 24:5 35:18 37:9,15 39:5 40:19 79:16 81:7,12,13 82:15 106:12,16 114:3,21 118:3 120:4 121:19 122:1 123:2</p>
--	---	--	--

(866) 448 - DEPO

Capital Reporting Company
Stakeholder's Meeting 11-20-2013

<p>124:10,16 125:14 127:4 131:9,11,18 132:2,4,7,18 133:7,9,10,22 134:11 146:4,14</p> <p>BRS's 22:1</p> <p>Bryan 1:19 7:11 148:2,19</p> <p>budget 15:1,21</p> <p>build 25:1 80:3 142:1</p> <p>built 16:7 70:12</p> <p>bullet 28:17</p> <p>bunch 14:19</p> <p>burden 104:9,12</p> <p>burst 5:19</p> <p>business 12:20 21:1,5,7 22:8 25:12,14 26:11 31:19 77:3 116:6,7 119:14,19,21 121:7 123:1,6</p> <p>businesses 31:16</p> <p>busy 5:12</p> <p>button 8:14,16 9:1 10:5 78:14</p> <p>bypass 120:16</p> <hr/> <p style="text-align: center;">C</p> <hr/> <p>cabbage 134:5</p> <p>cafeteria 6:3</p> <p>calculation 68:9 126:1</p> <p>California 21:22 143:13</p> <p>Canada 35:21 41:18 48:20</p>	<p>82:18</p> <p>Cancer 130:21</p> <p>canola 96:16 111:22</p> <p>capacity 65:16 101:2,15</p> <p>Capital 1:19</p> <p>capture 44:4 86:19</p> <p>carbon 142:3</p> <p>careful 22:3 77:20</p> <p>carefully 48:22</p> <p>CARPOL 24:4,12,15,17,20 25:3,6</p> <p>carry 12:6,17 16:19 131:14</p> <p>case 60:19 73:7 109:9 128:16</p> <p>cases 73:22 85:13 90:20 91:7 94:12 109:5 110:13 116:17</p> <p>catching 137:7</p> <p>categories 124:7</p> <p>category 124:18</p> <p>cause 43:9 55:14 65:16</p> <p>cautious 146:22</p> <p>caveat 94:4 98:19</p> <p>caveats 112:10</p> <p>CBI 81:3</p> <p>CDP 127:15</p> <p>ceiling 23:8</p> <p>cell 5:17</p> <p>center 21:6 64:16 129:19 144:1</p>	<p>Central 47:4 135:16,22 136:10</p> <p>Century 29:15</p> <p>certain 43:21 80:18 87:16,17 97:16</p> <p>certainly 11:14 16:12 17:1 23:2 32:12 37:7 48:4 72:22 90:6 107:7 108:7</p> <p>CERTIFICATE 147:22 149:1</p> <p>certify 148:3 149:4</p> <p>cetera 90:19</p> <p>chair 42:3</p> <p>chairs 42:12</p> <p>challenge 7:2</p> <p>challenges 18:5,9 22:7 26:17 32:10,13 85:19,20</p> <p>challenging 23:13,14 121:10</p> <p>chance 9:11,16 142:8</p> <p>change 55:14 105:17 133:7,19 142:2</p> <p>changed 38:15 111:12 138:17 141:18,20</p> <p>changes 38:10 53:6 54:8 56:9,17,18,19</p> <p>changing 53:12 101:10</p> <p>characterized 20:9</p>	<p>129:20</p> <p>charge 136:8</p> <p>charities 131:2</p> <p>chart 64:5</p> <p>check 7:16 92:15 146:15</p> <p>checking 139:7</p> <p>checks 127:19</p> <p>chemicals 139:2</p> <p>Chief 2:5,7,12 3:3,15,20 5:6 6:7 51:14 52:3</p> <p>Child 130:8</p> <p>China 36:16 39:1 46:17 48:12 140:14</p> <p>Chinese 36:9,12,15</p> <p>choose 9:8</p> <p>chose 95:10</p> <p>Christian 70:4</p> <p>Christopher 134:21,22 135:2</p> <p>CIFCF 135:21</p> <p>CIH 73:6</p> <p>CINDY 149:4,15</p> <p>circumstances 28:10</p> <p>citrus 21:13,14,19,21 22:5</p> <p>clarify 90:5,7</p> <p>clarity 32:19</p> <p>class 139:2</p> <p>classified 132:20</p> <p>classify 133:15</p>
---	--	---	--

Capital Reporting Company
Stakeholder's Meeting 11-20-2013

Page 7

<p>classifying 133:2</p> <p>clear 21:3 69:18 73:4 89:22 108:18 128:10 133:18</p> <p>clearance 127:14</p> <p>cleared 28:6 67:4 70:1</p> <p>clearing 27:22</p> <p>clearly 36:7,15 69:2</p> <p>click 8:13,15 9:1</p> <p>clicker 17:22</p> <p>Clint 2:12 3:15 26:12 51:14,16,19 52:5 78:17 88:9</p> <p>close 71:14 101:21 143:21 146:7</p> <p>closely 11:22 19:13 36:4,7</p> <p>Closeout 3:19 92:16</p> <p>closer 96:1</p> <p>closes 62:22</p> <p>cluster 68:18</p> <p>CNN 23:7</p> <p>Code 38:7</p> <p>Codex 46:2</p> <p>Co-Director 129:18</p> <p>coexist 29:20,22 30:2 136:12</p> <p>coexistence 29:21</p> <p>co-existence 136:7</p> <p>Coexistence 135:22</p>	<p>coffee 5:22 136:19</p> <p>coincide 93:10</p> <p>COKER 126:10,12</p> <p>collaborate 80:11 123:1 131:5</p> <p>collaboration 87:15 89:6</p> <p>collaborative 118:2</p> <p>collected 93:3,7 112:14,22</p> <p>collecting 93:13 103:6</p> <p>collection 95:12,14</p> <p>collectively 19:10 137:1</p> <p>color 62:1 64:7</p> <p>combination 90:22</p> <p>combined 64:12</p> <p>comes 47:13 49:5 59:17 119:4 125:9 145:5</p> <p>comfortable 11:3 91:14</p> <p>coming 23:8 28:1 47:10,15 69:16 77:20 86:3 88:19 91:2 114:7 120:20 126:14 132:5</p> <p>comment 9:8,11,19,20 10:1,2,4,6,14 16:8,12 30:3,6,14 54:14 55:1,19 57:4 59:9 62:19,21 63:3,6,18</p>	<p>66:13,22 67:9 77:12,17 78:4 82:15 98:7 101:22 104:13 105:21 129:14,18 135:6 142:17 143:20 146:10</p> <p>commenter 134:21</p> <p>commenters 10:8 129:12</p> <p>commenting 128:14</p> <p>comments 4:8 9:13 11:7 16:13 17:5 30:8,12 54:15,16,18 55:14,20 84:17,18 122:7 129:9,13 146:14 147:3</p> <p>commercial 42:20 109:7</p> <p>commitment 117:16</p> <p>commitments 39:14</p> <p>committed 31:10,20 108:8</p> <p>Committee 29:14</p> <p>Commodities 41:10</p> <p>common 87:14 88:22 100:8 108:21 112:18 115:8 134:15</p> <p>commonly 111:21</p> <p>communicate 80:11 118:19</p>	<p>136:17</p> <p>communication 82:1 108:19</p> <p>communications 2:7 3:3 5:6 9:14 34:4 108:13 118:4</p> <p>community 34:5 115:4,12 116:11 117:8 132:14</p> <p>companies 60:18,19,21,22 61:6 72:1</p> <p>company 1:19 60:13,16 61:20 70:14,17 71:5,9</p> <p>comparing 77:22</p> <p>compatibility 109:8</p> <p>compatible 32:22 109:10 110:6,12</p> <p>competitiveness 140:1,9,12</p> <p>complement 46:7</p> <p>complete 7:13 52:22 61:17,20 62:4,7,9 63:7 88:17 101:16 149:9</p> <p>completed 7:19 27:10 28:7,16 52:4 54:1 63:9,15 68:1 95:12 115:1</p> <p>completely 102:13</p> <p>completeness 27:4 54:11 57:16 59:16 60:5</p> <p>completing 52:17 64:1 131:22</p>
--	--	--	--

(866) 448 - DEPO

Capital Reporting Company
Stakeholder's Meeting 11-20-2013

Page 8

<p>compliance 4:5 23:1,3 31:17 34:6 38:2 43:16 44:14 45:11 108:10,11 113:19 114:3,15,21 115:2 116:3,11,17 117:2,3,11,17,19 ,21,22 118:2,17 121:17 122:3,10,11,16,1 9,20 123:11 124:17 125:10</p> <p>complicate 133:8</p> <p>complicated 57:9</p> <p>comply 47:14 49:6 115:5,7 119:3</p> <p>compressing 54:9</p> <p>comprise 109:1</p> <p>comprised 110:7</p> <p>concept 37:12</p> <p>concepts 101:9</p> <p>concern 38:21 142:21 144:10</p> <p>concerned 132:19 141:8 143:15</p> <p>concerning 126:13</p> <p>concerns 75:14 137:8</p> <p>concluded 147:13</p> <p>conclusion 99:3</p> <p>conditions 112:18 144:3</p> <p>conducted 30:18 116:8 117:18</p> <p>conducting 27:9 117:21 119:12</p>	<p>conference 118:13</p> <p>confident 23:14</p> <p>confinement 108:3 110:4,10</p> <p>confronted 81:5</p> <p>confronting 82:4 83:18</p> <p>confuse 144:15,21</p> <p>Congress 15:17</p> <p>consider 27:6 32:8 124:17 131:12</p> <p>considerably 63:11 133:9</p> <p>consideration 134:17</p> <p>considered 36:12 113:4 134:6,10 145:14</p> <p>consistency 95:1 108:15 116:10,19,21</p> <p>consistent 19:7 86:22 108:13 122:18</p> <p>consistently 88:20</p> <p>consolidated 41:15</p> <p>constantly 31:16</p> <p>construct 43:5</p> <p>constructs 125:22 134:6</p> <p>consultations 82:6</p> <p>consulting 24:22</p> <p>consumer 137:16</p> <p>contained 46:3</p> <p>contains 42:17</p> <p>contingent 7:4</p>	<p>continual 31:10 50:20 116:2</p> <p>continually 122:22</p> <p>continue 14:4,6 19:15 23:10,11 33:16 37:22 38:20 39:4,6,13 58:3,5 60:21 69:14,20 99:21 100:1,20 101:1 103:18 119:9 123:7 130:12 137:19 140:5</p> <p>continues 117:5</p> <p>continuing 23:5 57:3 100:14 104:7 119:14</p> <p>contracted 43:19 98:12</p> <p>contracting 100:5</p> <p>contractor 93:18 94:11,15,16 98:14</p> <p>contractors 100:4,8,11</p> <p>contracts 94:12</p> <p>contributed 40:19</p> <p>contributor 63:22</p> <p>control 61:2 126:21,22 127:1 141:20 143:2 144:2 145:5</p> <p>convenient 31:8</p> <p>Convention 118:13</p> <p>conversation 50:20 79:21</p> <p>conversations 17:21</p>	<p>convoluted 42:14</p> <p>Cook 129:15,17 143:22 144:1 146:12</p> <p>Cooper 126:13 142:18 146:13,16</p> <p>cooperating 33:12</p> <p>Cooperation 37:19 41:2,13</p> <p>cooperative 94:13</p> <p>coordinate 41:20 51:20 80:5,7,11 84:22 91:17</p> <p>coordinated 36:3 79:10,13 81:9,18 84:16 89:12 117:20 118:1 119:16</p> <p>coordinating 80:1 82:16 83:3,18 84:3 108:10</p> <p>coordination 3:17 78:19 79:1 80:18 82:19 87:2 90:8</p> <p>coordinations 81:12</p> <p>copy 20:19 30:5</p> <p>core 19:3 116:4 121:11</p> <p>corn 39:1 87:10 92:3 96:10 98:1 111:18,22 112:12,18 113:1 136:4,5 138:19 139:18</p> <p>corner 7:12</p> <p>corners 16:6 76:16</p> <p>correct 11:10</p>
---	--	--	--

(866) 448 - DEPO

Capital Reporting Company
Stakeholder's Meeting 11-20-2013

Page 9

<p>90:19 149:9 corrected 61:7 correctly 91:22 92:3 correspond 54:4 Corzine 47:1,3 48:2 49:7 70:3,4 71:17 72:4,9,22 73:13 75:9,20 103:9,21 104:4,9,15,17 135:5,7 146:13 cost 43:15 92:22 94:9,10,16 120:13 138:16 costly 139:22 costs 94:11 116:15 cotton 110:5,6,7,11,12, 13,20,21 111:9,13,22 counsel 148:9,12 count 115:20 counterparts 36:15 counting 94:22 countries 35:19,21 36:21 37:5,11 41:17,20 42:20 43:13 44:5 45:13,16,18 46:13,14,16,17 48:14 82:20 130:11,22 137:8 140:1,2,17,18 141:5 145:4 country 23:4 39:3 42:21 43:2,15 45:14 47:8,14 48:7 49:5 132:6</p>	<p>140:19 141:3 143:1 County 70:4 couple 7:14 10:20 25:9 61:12 65:22 87:1 93:16 103:9 105:20 121:5 135:10 145:19 courage 13:19 course 11:17 15:5 22:9 24:6 47:13 50:10 58:4 67:3 69:16 72:18 86:14 108:2,14 109:13 110:1 111:8 112:7 court 7:11 148:19 149:5,7 courtesy 119:22 120:3,5,12,18 127:7 128:3,7,9 131:16 132:6,7 courting 46:16 courts 12:15 cover 43:3 51:20 52:3 109:16,18 111:21 covered 30:21 31:1 45:12 58:17 146:2 covering 146:3 Crackberrys 22:12 crash 65:16 created 10:9 85:20 creates 48:13 creating 53:10 creeping 57:20 59:2</p>	<p>crop 31:2 44:2 72:13,21 82:10,11 83:12 90:22 109:7,11,16,18 crops 31:2 32:21 36:20 72:5,6,15 79:8 89:10 108:21 109:1,22 111:21 112:6,19 cross 86:14 111:3 crunching 120:13 Cs 81:21 culpa 25:9 cultivation 42:20 culture 144:3,5,6,8,13 cultured 145:9 cultures 131:5 current 19:17 60:7 101:1 currently 23:5 30:3 41:19 57:16 61:10 62:5,12 66:21 69:13 101:16,17 126:3 curve 69:6 customs 119:17 132:9 cut 16:6 27:5 103:12 cute 58:10 cuts 15:1,21 103:22 cutting 76:15 cycle 71:2 <hr/><p style="text-align: center;">D</p><hr/></p>	<p>daily 144:18 damage 21:20 Dan 50:2,4,8 90:4 danger 132:17 data 54:2 56:11 59:7 60:20 71:5,10 87:16,17,19 89:5 93:3,7,13 94:21 95:3,12,14 100:15 101:4 102:6,8 103:3,6 104:3 112:2,14,22 123:15 databases 44:19 dataset 67:18 94:3 95:16,19 99:18 datasets 64:5 71:6 Date 149:15 dates 136:15 day 6:20 11:14 13:22 17:5 21:5 25:5 37:9 41:6 66:15 79:9 80:8 85:3 86:3 97:15 days 22:8,9,13 27:6,16,18 53:19,22 59:18 60:6,7,18 61:9,10 62:4,6 63:5,10,16 65:1,3,5 66:18 67:13,22 68:1,10 69:2,3 70:14,16,19 96:3 145:19 DC 36:22 deadline 61:9 63:2 deadlines 61:1</p>
--	---	--	---

(866) 448 - DEPO

Capital Reporting Company
Stakeholder's Meeting 11-20-2013

Page 10

<p>65:19 deal 20:16 73:15 89:6 dealing 28:1 43:6 deals 29:12 119:21 dealt 45:13 debate 147:1 debt 23:8 December 79:15 93:9 decide 75:2,6 decided 15:3 58:1 110:13 111:20 decision 54:22 74:15,16,18,19 75:8 84:10,19 85:4,10 86:4 88:16 decisions 69:13 74:21 79:5 80:9 declaring 133:17 decrease 77:1 decreases 96:13 decreasing 29:4,5 69:8 deem 62:3,6 deemed 61:20 63:7 Deere 73:7 138:20 defend 74:16 75:5 defensibility 138:6,9 defensible 138:5 deficiencies 61:7 70:22 71:8 72:2,12 deficiency 70:13,15 71:6</p>	<p>definitely 147:2 definition 42:13 degree 50:11 delay 24:18 138:10 delayed 108:8 delays 138:15 139:22 140:10 deliverable 146:15 delivering 9:15 88:5 delivery 23:22 132:11 demand 119:13 demonstrates 117:16 Department 1:13 2:14 3:5 119:18 department's 122:2 dependent 56:14 91:18 115:11,21 depends 90:17 131:4 deposition 148:3,5,8,11 depository 129:20 depth 139:7 Deputy 2:2,4 3:9,18 4:9,10 11:1,17 19:1 29:11 51:19 78:21 118:6 deregulated 58:12,16 59:1 90:22 112:19 137:9 139:14,17 140:21 deregulation</p>	<p>12:22 16:5 83:12 91:4 deregulations 84:4 derived 134:4 describing 18:7 83:17 design 65:8 106:14 107:13 108:18 designed 109:21 desire 100:20 103:17 desk 9:22 106:1 destination 120:10,21 detail 14:5 20:19 53:15 detailed 53:18 details 27:7 37:20 52:19 53:7 detection 35:4 determination 27:14 55:12,15 90:13 127:7 determinations 55:9 59:12 84:13 88:21 determine 73:9,15 74:4 determined 58:13 127:9 develop 42:5 43:12 93:8 100:21 101:1 developed 24:21 28:22 45:15 87:21 145:10 developers 22:3 29:18 107:15</p>	<p>developing 15:19 24:4,20 79:4 100:8 106:9 117:10 development 24:19 37:7,16,19 41:2,13 117:9 130:9 devices 5:17 dicamba 84:9 dicamba-tolerant 31:2 Dick 2:7 3:3 5:5 11:2 18:20 30:16 52:7,8 92:14 118:3 146:9 147:4 difference 22:16 64:7 68:15 72:6,20 98:16 100:16 103:4 differences 91:8 98:11 101:8 118:20 different 6:3 20:22 32:6 33:4,10 36:16,19 37:13 44:5 55:5,7 64:4 66:18 90:16 96:16 99:7 133:4 134:2,9 136:14 differently 53:12 difficult 35:7 144:8 difficulty 135:16 Digital 148:19 diligence 128:1 directed 127:13 direction 148:7 directly 119:22</p>
---	--	---	---

(866) 448 - DEPO

Capital Reporting Company
Stakeholder's Meeting 11-20-2013

<p>132:10 director 2:9 4:4,6 31:18 106:16 114:5,15 130:7 Directorate 42:2 discoveries 130:13 discrete 100:4,7 discuss 100:19 103:16 121:21 discussion 49:3 discussions 99:10 disease 22:6 diseases 12:13 distance 108:21 109:14 distances 32:20 33:2,5,7 106:15 109:5,13 136:14 distinct 55:5 64:10 distinction 72:14 diverse 29:17 division 116:1 117:4 121:8 DNA 131:14 dockets 77:16 document 37:19 40:19 41:8 43:6 44:4,7 45:3 46:6,9,21 47:20 96:14 109:21 133:1,17 documentation 55:6 120:7 documented 33:9 111:5 documents 42:6 45:22 63:1 65:17 86:20 93:1,8</p>	<p>95:6 97:14 102:9 128:9 dollars 15:11,12 22:20 43:10 done 8:8 13:15 28:8,15 32:17 33:22 34:2 41:1 42:8 44:20 53:8 71:12 86:15 92:6 96:6,11,22 99:7 102:21 104:18 127:1 141:6 door 6:1 59:17 69:16 dot 68:20 dots 59:20,22 60:1 63:8 64:6,11,16,17,19 68:14 double 7:16 doubled 101:3,14 downtown 36:22 79:17 Dr 2:3,5,8,10,12 3:8,10,15,20 4:3,6,9 18:20 40:4,16 47:12 48:16 49:18 50:7,13,16 52:7 70:11 71:21 72:8,10 73:12,20 75:15,21 76:6 77:14 78:1,7,18,20 92:17 102:7 103:8,15 104:2,5,11 105:4,15 106:19 113:19 114:6 123:14,18,22 124:3 126:11,16,22</p>	<p>127:11 128:11,17 129:3 draft 55:18,20 57:18 59:7 62:14,21 63:10 64:2,15,18,20 65:2,7 66:14 67:4,8 95:11,16 97:10,18 98:12 122:15 dramatic 60:4 62:2 dramatically 54:9 driving 141:13 drop 69:20 70:16 71:1,15 drosophila 120:5,20 126:13 129:19,21,22 130:11,18 131:6,7,9,12,19 132:1,5,14,15,18 ,19,22 133:2,15,17 142:20,22 143:3,7,12 144:1,2,3,9,11,1 2,17,18,20,21,22 145:2,6,8,9,11,1 3 drosophilae 144:7,8 drosophilid 144:14 drosophilidae 144:10 drought 87:10 92:3 Drug 36:5 47:16 DRUGS 1:5</p>	<p>due 127:22 duly 148:5 duplicate 104:18 duplication 108:12 during 5:20 6:4,5 10:4 29:2 34:17 36:10 47:18 51:4 79:21 95:12 96:22 101:2 105:7 120:17 127:1</p> <hr/> <p style="text-align: center;">E</p> <hr/> <p>EA 55:21 56:7 64:3,20 65:7 67:8 73:11 74:14 75:2,7 85:16 88:18 93:17,18 95:16 96:13,21 97:10,18 98:6 99:13 100:5,6,17 101:21 102:19 earlier 16:4 48:17 52:13 59:11 67:1 69:1 79:13 80:2 82:22 88:7,9 114:14 115:22 117:1 129:7 140:14 early 54:14,22 67:22 69:22 70:6 72:11 86:2 89:21 EAs 56:15 57:18 59:7 64:10,15 65:14 66:14,19 67:4 93:19 95:11 96:6,16 98:12 101:10 easier 144:13 easy 71:8,11 80:4 115:10 131:11</p>
---	--	---	---

Capital Reporting Company
Stakeholder's Meeting 11-20-2013

Page 12

<p>132:1 144:5 eat 6:4 echo 147:4 economic 37:18 41:2,12 43:14 75:10 141:4 economically 138:17 Ed 2:8 4:6 31:18 114:4,5 123:20 129:1 132:3 education 117:22 educational 33:17 Edward 17:17 effect 141:14 effective 12:8 17:2 100:4 111:2,4,5 effectively 16:20 76:11 effectiveness 92:22 effects 90:11 113:3,9 efficiencies 105:8 116:6 efficiency 76:9 92:22 efficient 12:7 14:7 17:3 96:21 116:16 efficiently 13:3 16:9,20 76:11 effort 21:8 29:7 31:12 37:13 43:10 79:10 82:16 108:13 117:18 118:3 119:16 133:15 efforts 24:17 73:1</p>	<p>79:1 80:2,10 115:4,6,7 117:2,8 122:2 123:4 135:9 137:4 eight 58:2,14 85:17 89:15 111:19 112:2,11,20,22 EIS 31:2 56:8,10,13 58:5,13,22 59:2 72:17 73:14 74:14,15 75:2,6,10 79:18 86:15,16 88:17 138:7 EISs 56:12 57:19 58:5,18,20,22 59:10 84:7 85:15 either 8:12 28:8 59:8 71:7,11 127:8 143:1 EK 90:15 elements 134:12 elevated 124:20 eliminated 70:9 139:2 else 14:13 73:21 74:19 78:8 94:5 137:13 142:16 143:20 elsewhere 43:22 email 10:19 145:18 emerging 87:3 89:3 emissions 142:3 emphasize 16:15 employed</p>	<p>148:10,13 employee 148:12 enables 54:15 encourage 30:13 31:4 49:15 encouraging 63:4 enforcement 116:4 118:18 122:12,18 engage 100:13 engaged 48:21 106:9 engagement 35:18 50:12 engineered 12:7 106:10 113:7 enjoys 17:1 ensure 108:2 109:11 112:17 122:16 126:14 143:2 ensuring 122:10,21 entered 94:13 enterprise 131:4 145:13 entire 11:21 20:13 95:15 100:5,6 131:3 entirely 111:9 entities 117:15 environment 12:13,14 42:2 45:8 48:1 74:5 89:8 122:9 125:8 environmental 2:6 3:17,21 4:4 30:19,21 36:4 41:10 42:6,19</p>	<p>46:7 47:22 51:22 52:2 55:11,18 64:2,13,18 65:2 74:2,3,10 75:11 76:5 77:21 78:19 86:18,19 93:20,21 94:2 95:6 98:18,20 106:17 112:18 environmentally 138:16 EPA 50:10,11 51:1,2,9 79:1,4,6,12,15 80:3,5 81:10,13,16,22 82:1,6,9 83:3,14 84:1,4 85:1,2 86:8,20 87:17 90:11 91:3 92:1,8 139:16 EPA's 86:16 87:7 91:13 e-permit 6:9 24:21 131:20 e-permits 118:21 119:3 equipment 109:13 equivalent 145:4 ER 99:2 100:18 102:10,19 104:10 erosion 141:20 errors 95:2 ERs 99:6,11,14,16,21 100:1,15 102:4,9 103:11,18 escaped 143:14 especially 81:13 89:9 113:5</p>
---	--	--	--

(866) 448 - DEPO

Capital Reporting Company
Stakeholder's Meeting 11-20-2013

<p>114:21 116:19 120:4 124:6 essential 99:15 essentially 144:15 establish 88:4 established 56:13 83:1 estimated 65:1 et 90:18 eucalyptus 30:21 European 41:17 46:14 131:1 evaluate 92:21 116:4 125:19 evaluating 76:3 94:15 95:4 127:5 evaluation 47:16 77:21 116:3 event 43:5 events 5:13 33:11 everybody 8:2 17:4 31:4 49:13,16 71:18 106:8 114:6,7 everybody's 104:1 everyday 32:9 everyone 5:3,5 10:11 11:11 23:6 33:14 52:8 78:20 100:2 106:19 107:6 134:17 everything 29:18 86:1 91:16 101:12 137:10,11 evolve 49:1 evolves 141:10</p>	<p>exaggerated 65:13 example 20:2 22:14 34:11 36:19 86:16 87:4 89:4 90:21 91:1,2 104:20,21 133:10 139:1 examples 45:13 exceeding 108:16 excellent 99:12 except 49:5 58:19 exception 134:13 exchange 133:8 exchanged 145:3 exchanging 133:13 exercises 30:10 exhaustive 12:20 expand 111:20 expect 13:11 30:4 45:15 67:2 69:11,12,21 102:6,7 113:3 119:4,7 expectation 113:8 expedite 120:1,8 expedited 124:14 143:2 expediting 119:19 120:19 expenses 133:9 experience 31:19 44:4 52:16 experimental 130:12 expertise 76:12 145:5</p>	<p>experts 83:10 explain 123:21 explained 105:1 explicitly 76:18 explore 116:8 119:19 exploring 77:9 121:11 122:22 export 14:1 exporting 39:2 exposure 112:17 139:10 express 16:22 expressed 142:21 expressing 11:12 extension 94:4 extensions 97:4 extent 53:12 65:7 75:3 extra 16:7 48:7 extremely 30:9</p> <hr/> <p style="text-align: center;">F</p> <hr/> <p>facilitate 22:4 89:18 108:17 122:20 facilities 145:3 facility 130:2 fact 14:20 15:17 16:7 26:2 35:13 128:3,7 factor 123:21 factors 126:1 fair 36:10 fairly 54:9 59:11 64:9 67:3 71:7</p>	<p>fallow 109:16 falls 47:19 familiar 14:18 19:21 24:7 26:14 29:3 34:12 36:2 98:21 102:11 112:6 113:2 124:12 familiarity 124:15 family 134:1 135:22 137:19 138:1 141:8 144:9,12 farm 35:5 47:4 135:13 137:6,19,20,22 138:1,10,16 139:13 141:11 142:14 farmer 70:5 73:1 135:11,22 136:11 137:21 141:8 farmers 14:2 29:18 80:9 85:5 farms 141:22 farthest 64:8 FAS 36:8 fashion 39:15 fast 140:7 faster 16:5 61:14 67:14 69:3 76:19 137:9 favorite 5:20 FDA 42:12 50:9 81:10 82:1,6 feasible 98:8 February 23:9,12 24:2</p>
--	---	---	---

Capital Reporting Company
Stakeholder's Meeting 11-20-2013

Page 14

<p>federal 24:11 27:14 38:9 40:20 55:22 57:1 120:15</p> <p>feed 42:11 44:20 50:9 109:19</p> <p>feedback 4:8 10:16 15:8 57:17 118:22 129:9</p> <p>feel 11:14 20:11 31:5 122:4</p> <p>feeling 11:15</p> <p>fees 22:17,18</p> <p>feet 109:7 110:6,7,14,15,16 ,21,22 111:1,2</p> <p>felt 102:14</p> <p>feral 110:12,21</p> <p>field 32:4,7,11,14,16 33:22 34:1 35:5 43:4 44:2 106:13 107:16,17,21 108:7 111:17 113:1 117:14</p> <p>fields 44:2</p> <p>fifth 5:19 137:21</p> <p>figure 29:19 39:4 43:22 56:11 74:11</p> <p>fill 10:20 51:17 145:20</p> <p>final 55:15,21 57:18 92:18 111:13</p> <p>finally 46:9,15 52:1 55:7 58:21 67:6,16 69:21 70:1 89:2,11 109:20 122:22</p>	<p>financially 148:14</p> <p>finding 74:7 101:7</p> <p>findings 98:10</p> <p>fine 10:1 92:16 129:14</p> <p>finish 27:11 28:17 31:13 39:14 44:17 56:2,4 62:20 63:2 65:12 68:21 69:1</p> <p>finished 28:20 58:22 63:10 66:16 68:17 95:13</p> <p>finishing 66:18 135:17</p> <p>Firko 2:3 3:8 4:9 11:1,2 17:8 19:5 40:3 138:6 146:7,9</p> <p>first 5:16 6:2 8:13 9:6 12:2 18:11 25:6 27:1 30:17 39:10 41:2 47:10 51:14 56:1 57:3,5,8 59:14,17 60:10 61:12 63:14 65:12,20 66:1,10,15 67:21 68:11,20 69:11 70:7 74:3,14 75:2,7 80:2,3 89:14 91:15,16 96:17 101:20 102:21,22 107:12 119:10 129:13,15 131:11 146:9,13</p> <p>firsts 30:15,18</p> <p>fiscal 15:13 23:16 24:16 37:22</p>	<p>116:12 118:7 119:10</p> <p>fit 45:21</p> <p>five 13:14 43:13 57:15,17 63:8 106:2 125:1,2,3</p> <p>flag 78:5</p> <p>flies 120:6 131:15 143:8</p> <p>flip 54:3</p> <p>flipped 65:15</p> <p>Florida 21:18,19,21</p> <p>flow 109:10</p> <p>flowering 110:8</p> <p>flowers 135:18</p> <p>fluctuate 115:18</p> <p>fly 131:5 144:19</p> <p>focus 48:9 95:9 115:22 117:4 119:14 121:9</p> <p>focused 130:18</p> <p>focusing 47:5 76:12 116:18 117:10</p> <p>folks 19:20 31:6,9 34:2 40:18 51:3 89:5 92:9 105:19</p> <p>FONSI 74:7,9</p> <p>food 36:5 42:11 43:19 46:4 47:16,17 50:9 76:1 109:19 123:9 141:4</p> <p>foot 109:17</p> <p>footnote 66:7</p> <p>Force 42:10</p>	<p>forces 36:16</p> <p>foregoing 148:2,4</p> <p>foregoing/ attached 149:8</p> <p>foreign 36:7 41:17</p> <p>form 8:12</p> <p>formal 55:19 133:1,16</p> <p>formalized 81:15</p> <p>formally 21:2 55:2 92:7</p> <p>formerly 63:17</p> <p>forms 29:21,22</p> <p>forth 27:3 54:3 70:8 71:20 72:12</p> <p>forthcoming 35:12</p> <p>forum 107:8</p> <p>forward 3:7 17:7 24:19 81:11 90:18 103:10,14,18 107:1 116:1 121:12 123:5,8 140:15</p> <p>forwarded 132:9</p> <p>fosters 37:7</p> <p>Foundation 130:3,20</p> <p>foundations 130:16,19,22</p> <p>fourth 92:18</p> <p>fraction 131:8</p> <p>framework 36:3</p> <p>frankly 137:6 138:10</p> <p>free 9:8 32:15 70:17</p>
--	---	--	--

(866) 448 - DEPO

Capital Reporting Company
Stakeholder's Meeting 11-20-2013

Page 15

<p>fresh 62:1</p> <p>friends 136:18</p> <p>front 32:14 52:9 123:15</p> <p>fronts 37:14</p> <p>fruit 120:6 143:7 144:19</p> <p>frustration 138:15</p> <p>fuel 142:5</p> <p>full 20:19 45:7 62:8</p> <p>fully 12:18</p> <p>function 24:7 25:6</p> <p>fund 24:12</p> <p>funded 22:17,19,20</p> <p>funding 16:2 130:19</p> <p>funds 94:14</p> <p>furlough 24:17</p> <p>future 10:21 31:5 38:12 78:6 86:10,13 87:13 88:1,20 92:11 102:5 132:20 138:2 141:9</p> <p>fuzzy 138:8</p> <p>FY 3:7,8</p> <p>FY13 17:7</p> <p>FY14 17:7</p> <p>FY2015 101:19</p> <hr/> <p style="text-align: center;">G</p> <hr/> <p>Gabel 2:5 3:20 52:2 92:17 102:7 103:8,15 104:2,5,11</p>	<p>105:4,15</p> <p>Gail 6:18</p> <p>gain 116:5</p> <p>garbage 144:5</p> <p>gathering 112:1</p> <p>GE 28:11 34:16 35:5 106:13 122:11</p> <p>gene 109:10</p> <p>general 26:16 30:2 50:14,15 73:21 74:1 109:4 130:7</p> <p>generate 71:9</p> <p>generation 137:21</p> <p>generations 137:22</p> <p>generic 134:10</p> <p>genetic 145:10,12,14</p> <p>genetically 12:7 106:10 113:7 129:20</p> <p>geneticist 144:20</p> <p>geneticists 145:6</p> <p>Genna 76:1 123:9</p> <p>gentleman's 126:12</p> <p>genus 144:11</p> <p>George 2:7 3:3 5:3,5 39:20 40:9 46:22 47:2 49:19 50:3 51:6 78:10 92:13,16 105:11,16 106:5 113:15,20 128:13,18 129:5 134:20 142:10 143:19 145:16</p>	<p>gets 8:3 49:11</p> <p>getting 47:9 60:20 68:4 71:18 73:14 84:22</p> <p>given 43:4 59:12 148:8</p> <p>gives 31:6 37:4 46:12</p> <p>giving 134:17</p> <p>glad 5:8 7:7 41:6 48:14 51:4 140:16</p> <p>global 48:18</p> <p>gloves 139:5</p> <p>glyphosate 91:1,3 96:10 98:1</p> <p>goal 29:19 44:10 69:7 76:14 81:12 90:13 92:21 93:14 101:18 116:17</p> <p>goals 12:3 13:18,20,21,22 90:6 122:4,15</p> <p>goggles 139:5</p> <p>gold 68:14</p> <p>gone 15:16 18:17 63:11 128:19</p> <p>gory 53:7</p> <p>gotten 25:10 61:19 140:2</p> <p>government 35:10 36:9 40:20 80:8 120:15,22</p> <p>governmental 130:15</p> <p>governments 33:13 43:17</p>	<p>government's 19:9</p> <p>grain 41:10 47:19 48:10</p> <p>grains 47:7,15 48:8,19</p> <p>grants 130:18</p> <p>graph 66:7,16 67:17 68:3,6,11 69:5</p> <p>graphs 68:15</p> <p>grateful 147:5,6</p> <p>great 11:5 13:9,13,16,19 15:21 24:13 35:11 40:7 72:1 106:20 107:8,9 138:22</p> <p>greater 20:19 32:19 33:6 109:5,12,14 113:8</p> <p>greatly 30:6,7 125:14</p> <p>green 26:13 59:19 61:22 64:17 116:15</p> <p>greening 21:19 22:5</p> <p>Gregoire 18:22</p> <p>ground 142:4 146:11</p> <p>Groundhog 41:6</p> <p>group 3:10 29:13,17,19 35:20 40:15 42:3,4 46:18 50:17 79:22 95:10 128:20</p> <p>groups 30:8 83:16,21 137:16</p>
--	--	---	---

(866) 448 - DEPO

Capital Reporting Company
Stakeholder's Meeting 11-20-2013

Page 16

<p>138:11 grow 117:6 144:6 Growers 136:4,5 growing 49:14 101:9 112:15,21 129:10 guess 24:1 46:19 90:14 104:21 126:4 140:2 guidance 4:3 32:20 44:7 99:15,22 100:2,21 103:11,20 106:18 111:18,21 126:17 131:19 guideline 46:4 guidelines 101:19 guy 6:10 guys 14:22 15:1 76:2 78:6 114:11 115:21 122:14 125:14 142:18 Gwen 83:2 Gwen's 83:2</p> <hr/> <p style="text-align: center;">H</p> <hr/> <p>hairs 144:19 half 21:8 hall 6:1 haltere 144:19 handle 131:11 139:3 handled 114:4 handling 145:6 handoffs 25:16 29:5</p>	<p>handout 6:15 handouts 6:12,14 57:11 108:22 hands 85:6 hang 8:8 hanging 146:4 happen 13:8 24:2 70:9 happened 35:14 57:7 94:6 114:20 happens 41:4 75:8 happy 34:15 hard 12:9,20 19:18 36:11 39:13 45:16 101:8 102:12 harmonization 35:22 42:4 48:3 harmonize 41:20 harvest 135:17 harvested 109:12,19 hastened 76:3 haven't 6:14 71:21 92:6,7 101:22 having 14:14 83:6 127:20 141:15 146:11 hazard 90:12 head 72:10 health 1:6,14 2:15 3:6 20:15,16 130:4,8,17 healthy 13:6 19:5,6 hear 7:15 8:2 14:5 31:6,7 34:15 36:14 37:5 39:12</p>	<p>52:1 92:3 93:5 122:13 146:1 heard 23:7 29:20 91:22 133:4 hearing 20:1 21:4 26:12 37:14 107:1 Heart 130:21 heavily 20:21 130:14 held 76:17,20 118:7,14 he'll 7:12 51:17 hello 8:10 92:17 help 6:7,8,10 10:20 13:8 25:1 30:1 32:17 85:5 90:1 114:1 124:3 125:14 126:9 128:10 helped 102:14,16,17 helpful 34:4 87:20 103:11 146:18 helping 120:1 147:6 helps 85:7 102:18 104:1 123:18 139:20 herbicide 79:8 82:10,11 83:12,21 89:3 91:1 herbicides 89:8,9 hereby 148:3 149:4 Here's 33:19 hereto 148:13 he's 17:10 25:13</p>	<p>31:15 Hi 76:1 91:21 123:9 129:17 high 12:5 26:2 54:6 69:15 75:4 102:4 122:21 131:8 142:13 higher 72:5 97:2 highest 81:15 highlight 63:20 65:22 110:4 highlighted 20:7,17 69:1 highlights 114:12 highly 53:1 68:7 hire 94:14 hiring 94:11 historical 91:19 hit 8:18 9:3 10:6 39:21 40:12 49:20 78:12 105:12 135:1 hold 7:18 33:16 34:10 101:8,9 holders 132:10 holding 13:4 holidays 107:13 Holtzman's 11:12 home 40:11 99:4,22 135:19 141:13 Homeland 119:18 hope 5:14 14:6 30:9 34:22 38:11 47:6 48:2,8 68:14 71:19 86:2 104:18 107:5 141:12 142:5</p>
--	--	--	--

(866) 448 - DEPO

Capital Reporting Company
Stakeholder's Meeting 11-20-2013

Page 17

<p>hopeful 23:10</p> <p>hopefully 142:9</p> <p>hoping 11:14 86:12 92:10</p> <p>hotline 23:1</p> <p>hours 9:15 93:8,14,16,17 94:9,22 95:20,22 96:1,3,17 97:10,11,18 98:2,4,11 100:17 104:22 105:5</p> <p>house 28:4 93:17</p> <p>housekeeping 5:16</p> <p>huge 60:8 65:11,16</p> <p>Human 130:9</p> <hr/> <p style="text-align: center;">I</p> <hr/> <p>I'd 12:3 17:11 87:6 128:18 133:19,21 147:4</p> <p>idea 56:16 62:17 95:5 96:19</p> <p>ideally 54:17 62:20 74:2,13 133:16</p> <p>identify 8:7 43:5 87:19 89:20</p> <p>identity 108:3</p> <p>IH 73:7</p> <p>ill 11:13</p> <p>I'll 17:6 18:2,7 51:4,11 54:1 73:20,21 74:19 121:6 122:14 142:9</p> <p>Illinois 47:4 70:5 135:17,22</p>	<p>136:11</p> <p>I'm 5:5,8 7:22 11:4 18:11 23:6 33:22 40:9 41:6 47:3 48:13 52:13 53:14 54:6 57:9 63:20 73:4,6,7 76:1 78:20 81:20 90:20 92:10 93:2 94:17 95:3 98:22 105:7 106:21 107:3,10 108:5 129:18 136:2,5 138:8 140:16 141:7,8 143:5</p> <p>impact 30:19,21 34:6 63:13 74:8,10 75:11 76:3 85:10 89:22 123:6</p> <p>impacts 74:5,12,17 75:5,16,17</p> <p>impediment 77:17</p> <p>impeding 14:8</p> <p>implementation 34:9 111:5</p> <p>implemented 21:1,2 27:12 28:19 33:9 56:9,17,19 64:21 65:9 67:21</p> <p>implementing 28:13 53:6 116:13 120:16</p> <p>import 42:21 120:17 125:12 127:12 131:8 132:4,15 134:18</p> <p>importance 15:18,19</p>	<p>important 14:21,22 20:9,11 21:12 37:3 43:8 73:1,18 80:6,22 81:4 113:6,22 135:15 137:5 138:19 139:4,11 141:11 142:6</p> <p>importation 120:3,8</p> <p>imported 131:15</p> <p>importer 120:7 121:1</p> <p>importing 39:3 43:2</p> <p>imports 131:7</p> <p>impossible 144:15,22</p> <p>impressed 106:21</p> <p>improve 18:6 31:12 38:4,12 69:20 76:9 77:5,9 81:12 101:15 122:22</p> <p>improved 59:21 60:2 65:4 116:18</p> <p>improvement 12:21 21:1,5,8 25:13,14 26:11 27:7 31:11,16,19 52:18 54:13,20 60:4 62:2 63:15 71:13 76:7 77:3,4 88:13 93:11 101:11 102:1 116:2,7 119:15,21</p> <p>improvements 13:10 23:22 25:8 38:16 39:9 51:8 52:11 54:8</p>	<p>64:19,21,22 65:3,10,15,21 70:11 76:22</p> <p>improving 77:6 103:20 116:20</p> <p>inadvertently 109:11</p> <p>inaudible 23:4 40:21 43:10 46:22 56:20 58:11 64:7 82:17 84:8 85:5 86:17 89:10 90:1 91:2 96:3 102:3 122:6 123:13 128:14,20 131:13,21 135:6 139:1 142:22 143:13,17 144:11</p> <p>incident 28:12 34:16 35:13</p> <p>incidents 122:17</p> <p>include 47:7 48:9 56:8 140:18</p> <p>included 118:8</p> <p>includes 63:16 67:17 110:15,22</p> <p>including 5:13 48:15 118:3 125:4 130:20</p> <p>incoming 9:17</p> <p>inconsistency 133:6</p> <p>increase 13:22 43:12 116:9 118:16 122:2,6 133:9</p> <p>increased 23:20 43:15</p>
---	--	--	--

(866) 448 - DEPO

Capital Reporting Company
Stakeholder's Meeting 11-20-2013

Page 18

<p>increases 16:1</p> <p>increasing 46:14</p> <p>increasingly 134:3</p> <p>independent 90:14</p> <p>independently 77:4 90:18</p> <p>India 46:17</p> <p>indicate 133:3</p> <p>indicated 12:1 14:10 23:17 43:9 48:16</p> <p>indicates 28:17 125:6</p> <p>individual 19:10 73:22 74:20 93:15 146:5</p> <p>individually 8:9</p> <p>industrial 36:19 124:8,20 125:1</p> <p>industry 21:13,14,21 33:17 35:11 43:11,16 45:19 70:7 73:8 79:3 125:11,13</p> <p>information 4:3 9:16 19:11 27:2 37:1 38:14,17,18 41:12 44:11,13,16,18 45:2,9 55:15,21 61:19 80:17 81:3,21 83:17 84:17 85:1,2 86:17,19 87:21 89:17 99:17,20 102:22 106:18 110:1 123:16 125:12,17 127:12</p>	<p>informed 106:22</p> <p>Infrastructure 130:6</p> <p>in-house 98:12,14 102:11</p> <p>initial 71:6</p> <p>initially 77:15</p> <p>initiate 98:6 101:21</p> <p>initiating 42:9</p> <p>initiative 48:18,20 51:17</p> <p>initiatives 22:2 24:12 48:18 50:21,22</p> <p>innovation 41:22</p> <p>innovations 37:6</p> <p>input 10:16 25:2 30:7 34:13</p> <p>insect 111:8</p> <p>insects 111:3</p> <p>insert 139:20</p> <p>inside 95:14</p> <p>inspect 125:1</p> <p>inspected 125:3</p> <p>inspection 1:6,14 2:15 3:6 22:18 111:6 118:18 120:16 126:2 127:13,18 132:7,11,13</p> <p>inspections 4:5 113:19 114:22 115:1,9,12,20 122:21 123:11 124:5 125:18</p> <p>inspector 119:4</p>	<p>inspectors 33:11</p> <p>instance 47:21 80:9 83:13 86:7</p> <p>Institute 130:7,8,17</p> <p>Institutes 130:3,4</p> <p>Institutional 118:13</p> <p>instructions 9:5 10:11 113:16</p> <p>integrate 121:17</p> <p>intellectual 41:22</p> <p>intend 12:17 16:20</p> <p>intended 9:9 71:13 120:6,9,21 122:6 124:13</p> <p>intention 12:22</p> <p>intentionally 88:12</p> <p>interact 51:8,20</p> <p>interacted 92:2</p> <p>interacting 79:4</p> <p>interaction 50:21</p> <p>interactions 50:22</p> <p>interagency 50:16 83:20</p> <p>interest 16:18 19:17 21:20 31:3 79:2,6 89:5 100:14 107:6 147:5,6</p> <p>interested 11:21 29:13,21 84:3 92:8 104:7 123:16 145:20,22 146:3 148:14</p> <p>interesting 17:20</p>	<p>22:13 28:10 29:10 33:19 38:2 101:4</p> <p>interests 16:16</p> <p>interference 40:13</p> <p>internal 25:3 28:21 34:8 77:6 101:2,15 116:1,5</p> <p>internally 62:18 123:1</p> <p>international 35:17 40:22 41:16 42:16 45:22</p> <p>internationally 38:20 41:4</p> <p>interrupt 40:9</p> <p>interruption 23:11</p> <p>interstate 131:16 133:11 134:19</p> <p>intertwined 15:5</p> <p>introduce 10:22 11:6 17:9 51:11</p> <p>introduced 18:12</p> <p>introducing 40:4</p> <p>introduction 40:17 122:11</p> <p>investigating 35:4</p> <p>investigation 34:19 35:1</p> <p>invite 8:20</p> <p>invited 118:11</p> <p>involve 32:6 43:13</p> <p>involved 20:18,22 24:6 31:20 50:11,19 70:5 88:18 136:3,9</p>
--	---	--	---

(866) 448 - DEPO

Capital Reporting Company
Stakeholder's Meeting 11-20-2013

<p>involves 54:9 iPhone 22:12 isn't 63:14 75:16 ISO 31:20 34:8 issue 39:12 44:12,15 47:8 48:6,11,13 49:11,14,15 50:12 83:6 89:7 124:8,11 133:18 135:15 138:7 140:15,22 issued 114:21 115:17 120:4,5,12 127:8 131:17 133:10 issues 18:9 23:3 35:22 36:15 38:21 41:21 48:7 49:2 70:6 79:17 80:18 82:3 83:17 89:3,21 114:3 131:9 135:12 136:7 138:11 140:13 issuing 132:7 item 3:1,12 4:1 129:5 items 5:16 20:15 51:11 134:7 it's 5:12 9:4,21 10:7,17 11:5 13:20 18:10 20:14 27:17 28:4 29:4,5 33:5 36:10 37:17 41:8 42:14 46:3 50:7 61:2,10 64:20 67:19 69:7,8 70:21 72:12 73:1 74:13 75:1,16 80:4,6 81:7</p>	<p>90:12 91:15 92:8 96:3 97:14 100:20 101:3,6 102:11 104:16 106:20 109:4,12,18,21 110:20 112:12 113:22 115:10,19 122:2,8 125:19 126:6 132:12 135:5 136:10 137:5 138:5,10,21 139:6,15,17 141:3 142:6 144:5,7,12,14,22 145:8,9,12 I've 11:2 20:7,16 25:13 31:20 39:16 59:19 82:22 83:2 106:2 131:18 135:18 136:22 141:15 <hr/> J January 23:6,12 24:2 30:14 JD 73:6 Jenkins 50:2,5,8,15 90:4 jeopardize 43:18 jeopardizing 43:14 Jere 18:20 Jhee 2:8 4:6 31:18 114:5,6 123:14,18,22 124:3 126:11,16,22 128:11,17 129:1,3 132:3</p>	<p>job 14:8 24:13 35:11 36:13 80:1 88:9,10 John 4:3 73:6 106:16,17 113:15,18 118:4 138:20 join 7:9 11:16 joint 87:10,13 88:1 89:12 92:2 Jones 42:12 judgment 102:12 July 57:5 June 12:2 jurisdiction 132:8 <hr/> K Kathleen 42:12 Kevin 2:14 3:5 11:6 17:8,9,10 18:12,13,16 19:3 23:17 25:13 27:19 30:15 39:18 129:15 134:20 144:1 145:16 146:12,18 Kevin's 24:13 key 115:22 117:3,18 121:6 122:13 124:7 keypad 8:18 9:4 39:22 49:21 113:18 128:15 kicked 79:14 kinds 43:7 146:2 knew 65:9,14,18 90:3 knowledge 118:16</p>	<p>119:7 known 25:13 <hr/> L lab 134:16 labeled 96:8,11 labelled 96:8,12 labels 111:7 laboratories 130:10 144:4 laboratory 133:21 134:2,13 labs 133:13 143:5,6 145:8 lack 126:4 laid 21:17 56:5 language 112:11 largely 115:10,21 larger 66:2 67:18 74:10 largest 135:13 laser 58:10 last 10:18 14:13 15:4 18:14 19:1 23:20 24:3,8,16 25:9 26:3 30:16 63:19 67:6 79:12,14 80:15 92:9 108:6 111:12,17 113:5 114:22 123:3 129:5 131:19 135:4 145:10 146:10 lastly 122:14 late 9:21 later 7:16 20:20 26:13 54:1,3,19 74:19 107:2</p>
---	---	--	--

Capital Reporting Company
Stakeholder's Meeting 11-20-2013

Page 20

<p>136:13 latest 110:1 launched 76:6 law 12:16 90:9 laws 47:14 lawsuit 138:11 lead 113:8 132:17 leadership 24:13 79:22 leads 35:2 90:11 Lean 25:12 26:11,12,14 29:2,3,7 31:11 52:12 learn 51:9 103:7 114:2 136:1,2 learned 38:3 52:3 87:11 121:9 least 5:13 9:18 76:17 92:7 102:5 125:3 led 23:22 119:16 legal 13:19 lengthy 73:10 105:3 Leon 47:3 70:4 103:9 135:5 142:12 146:13 less 13:1,2,14 27:18 53:8 63:10 96:18 102:5 113:1 142:3,4 lesser 109:5 lessons 38:5 87:11 121:9 let's 5:15 50:3 63:8 letter 60:12 70:13</p>	<p>letters 71:7 132:8 level 3:10 36:17 38:21,22 40:15 41:9 42:13,17 47:7 48:6 54:6 81:16 82:2,19 83:4,6,17 140:15,19 141:6 145:3 levels 42:18 leverage 116:1 liaisons 81:15 83:1 likelihood 75:4 likely 72:16 limits 10:9 line 11:4,20 61:13 66:17 120:19 lines 66:9 116:14 linked 79:7 85:14,16 117:14 list 12:5 20:13,19 70:16 71:1,4 83:9 127:17 listed 127:17 listening 4:7 9:7 10:4,13 40:11 105:19 114:8 129:3,6 135:1 146:11,21 lit 102:21 little 9:16 23:13 26:13,20 32:3,14 37:17 40:13 42:14,16 52:16 53:3,11,19,21 54:7 57:9 58:4,10 62:5,16 66:7,8 68:9,10,18 73:5 81:20 87:4 95:21</p>	<p>96:5 97:2,6,7,11 101:4 105:16,18 111:16 114:16 119:11 128:10 135:16 138:8,21 142:11 146:21,22 live 8:13 131:5 living 109:21 LLP 37:12,19 38:21 39:3 43:1,14 44:9,15,22 45:6,14,20 46:3 48:18 50:18 135:3 local 43:19 Location 1:13 logged 97:17 logging 97:13,15 logic 74:18 75:8 logically 102:4 long 8:4 12:19 18:2 23:12 25:10,13,18,22 49:10 59:15 60:16 61:5,17 64:1,11,14,17,20 67:7,19 68:7 69:9 71:13 72:8 88:8,10,17 95:21 99:1 103:2 longer 27:17 55:18 56:3 63:11,17 68:4 72:16 long-sleeved 139:5 long-term 23:13 looper 134:6 looping 71:3</p>	<p>lose 140:11 lost 15:10,11 lot 5:14 14:5 19:11 20:15 28:6,12 31:3,8,18 32:16 38:3 39:17 40:18,21 63:16 71:9 72:20 73:16 75:11 77:18 79:2,3,5 89:4,5 93:12 101:7 104:16 119:2,5 127:18 136:6,12 137:11 140:11 141:2 143:5 lots 16:16 Louisiana 118:8 low 3:10 17:15 38:21,22 40:15 41:9 42:13,17 47:7 48:6 140:15,19 141:6 lower 72:6 124:18 126:4 low-level 37:12 luck 42:11 <hr/> M <hr/> macro 35:20 maintain 95:5 108:3 maintained 34:8 maintaining 94:11 major 43:18 45:4,12 112:15,21 132:17 majority 109:1 managed 35:15 management 20:1</p>
--	--	---	---

(866) 448 - DEPO

Capital Reporting Company
Stakeholder's Meeting 11-20-2013

Page 21

<p>31:21 33:19 45:20 81:18 83:22 89:4 121:20</p> <p>manager 25:4</p> <p>managing 35:11</p> <p>manner 85:1,2 88:6 121:3</p> <p>mantra 137:20</p> <p>mapped 88:7 89:13</p> <p>March 21:4 56:22 93:9</p> <p>market 13:5 16:10 30:1 141:1</p> <p>marketing 17:17 29:12</p> <p>markets 15:19</p> <p>Marrero 134:21 135:3</p> <p>Marshall 41:14</p> <p>Massey 91:21 92:5</p> <p>massive 59:11 61:3 62:10</p> <p>material 43:3</p> <p>matter 11:21 63:12 83:10 142:1</p> <p>Max 11:12,13,14,17,1 9 29:9,11</p> <p>maximize 101:1</p> <p>maximum 98:2</p> <p>Max's 16:22</p> <p>may 6:7 21:13 22:15,22 29:20 33:7 34:18 37:6 38:13,22</p>	<p>44:15,20,21 72:17 81:5 82:4,6,13 85:10 97:16 105:9 112:22 120:2 124:3 127:12,17 128:2,3 133:7 135:9,13</p> <p>maybe 31:7 70:8 72:5 92:10 102:5 113:13 128:10 136:1 141:13</p> <p>MCALLISTER 149:4,15</p> <p>McCammon 2:10 3:10 37:14 40:4,16 47:12 48:16 49:18 50:7,13,16</p> <p>MD 1:15</p> <p>Mea 25:8</p> <p>mean 72:11 76:20 103:13 125:2 137:3 139:17</p> <p>meaning 90:8 115:16</p> <p>means 19:8,12 22:9 26:15 27:11 131:15 135:21 144:2</p> <p>measure 93:14</p> <p>measures 111:2,4</p> <p>measuring 95:7</p> <p>mechanical 109:8</p> <p>median 97:10</p> <p>Medical 130:7</p> <p>medium 144:6</p> <p>meet 35:18 70:22 98:5,8 107:18</p>	<p>meeting 5:9,21 6:6,21 7:7,13 8:9,13 9:19 10:18 11:7 18:13 19:1 27:19 28:2 30:17,20 31:1 51:16 52:10 54:2 56:18 57:12 59:14 65:19 66:5 67:1 90:10 92:20 93:6 101:18 108:16 112:8 114:7 128:19 135:9,12 145:18 146:7,14,20 147:13</p> <p>meetings 9:14 10:21 14:14,16 30:19 33:16 36:9 82:2,17 142:12,14 147:3</p> <p>meets 106:12</p> <p>melanogaster 120:6 129:21 131:12 132:19,22 133:15,17 143:1,3 144:3,4,13,22 145:2,9,14</p> <p>Melinda 17:14,15,21 29:12</p> <p>member 41:19 46:13 77:18 136:6</p> <p>members 32:22 142:20 144:9</p> <p>Memorandums 80:16</p> <p>mention 93:22 108:1 145:17</p>	<p>mentioned 13:17 16:4,14 21:9 26:10 29:10 30:15,16 33:18 50:9 52:13,20 57:13 59:4,11 66:19 67:1 82:22 85:14 88:7,9 115:22 117:1,5,13 127:22 129:6 140:14 141:16</p> <p>mentor 17:11</p> <p>message 99:4,22</p> <p>met 11:19 15:4,6 35:19 36:21 121:20</p> <p>method 12:21 28:22</p> <p>methods 33:8</p> <p>Mexico 35:21 82:18</p> <p>mic 8:3 11:3</p> <p>Michael 18:22</p> <p>microbe 42:8</p> <p>microphone 8:1 50:3</p> <p>Mike 2:3 3:8 4:9 11:1 12:1 14:10 17:6 40:17,21 43:8 48:16 52:13,20 59:4,11 66:22 69:1 115:22 117:1,5,13 125:12 126:12 138:6 142:18 146:7,8,13,16</p> <p>milestones 53:11 54:2 56:13</p>
---	--	---	---

(866) 448 - DEPO

Capital Reporting Company
Stakeholder's Meeting 11-20-2013

Page 22

<p>million 130:18 millions 43:9 mind 94:7 129:10 142:6 mindful 7:3 minds 51:7 mine 24:1 77:19 136:2 mingle 147:8 minimal 108:19 109:4 minimum 33:7 63:6 97:19 108:16 109:6 111:19 112:2,20 minor 71:8 minute 145:19 minutes 10:20 mission 121:22 122:4,8 mitigate 33:4 mitigation 33:8 mitigations 32:8 mixing 109:8 mobile 5:17 model 18:17 129:22 133:21 145:11,14 moderator 8:19 modest 33:21 molecular 134:10 moment 49:21,22 114:10 115:3 123:4 money 24:15 120:22 121:1 134:18</p>	<p>monitor 74:8 monitoring 125:7 143:16 Monsanto 50:8 90:4 monthly 82:2 months 13:15 14:14 21:17 35:3 38:19 56:2,3 60:9 67:12 85:17 89:16 morning 5:3,5 11:6,10,15 52:8 78:20 106:19 107:2 114:6 135:20 mostly 111:9 moth 134:6 MOUs 80:16 81:2 move 8:5 12:21 16:10 39:7 70:21 78:16 90:18 91:6,11 123:5 140:15 moved 28:19 58:17 66:11 98:7 143:10 movement 106:13 131:16 132:1 133:11,20 134:19 moving 24:8,19 61:14 81:19 93:12 101:5 103:10,14,18 116:1 121:12 123:7 multi-billion 43:11 mute 40:12</p>	<p>myself 39:17 83:2 <hr/> N <hr/> narrow 16:19 national 17:19 82:19 129:19 130:2,3,4,7,8,17, 20 136:4,5 142:19 146:16,17,19 nationwide 117:21 navigate 118:21 119:3 nearly 60:8 111:9 necessarily 20:7,9 126:6 necessary 33:8 negative 75:16,17 neighbors 136:11 neither 85:8 148:9 NEPA 3:19 51:10 52:4 54:17 55:4,6 63:1 65:17 69:18 73:22 74:1,21 75:15,18 77:10 92:16,18,20 93:1,8 95:8 99:5,8,10,14 100:3 101:3 Nesbitt 2:12 3:15 26:12 51:14 52:7 70:11 71:21 72:8,10 73:12,20 75:15,21 76:6 77:14 78:1,7,18 Nevertheless 99:1 131:10 132:16 newer 61:22 72:15 news 15:14 35:3</p>	<p>39:1 nice 36:14 40:17 nights 68:11 NIH 118:12 nine 28:7 58:7,8 63:9 78:3 108:21 109:1 nobody 143:16 noise 128:21,22 non 20:2 27:15 110:22 120:8 133:17 non-compliance 122:17 none 40:1 58:19 105:13 non-regulated 25:20 26:22 120:1 121:2 non-regulatory 19:19,21 34:11,14 nonstop 9:16 non-transgenic 110:16 nor 148:10,13 normally 51:2 63:6 NOTARY 147:22 note 8:22 101:14 noted 44:8 notes 6:13 7:17 149:7 notice 20:7 57:1 66:9 93:9 96:7 noticed 22:15 38:13</p>
--	--	---	--

(866) 448 - DEPO

Capital Reporting Company
Stakeholder's Meeting 11-20-2013

Page 23

<p>notification 32:5 106:11 107:17 118:21 124:13 125:20 126:8</p> <p>notifications 32:2 33:15 107:5 109:2 115:17 124:12 126:3</p> <p>Novel 42:11</p> <p>November 1:10 21:2 53:5 149:10</p> <p>nuts 107:3</p> <p>nutshell 53:9</p> <hr/> <p style="text-align: center;">O</p> <hr/> <p>objective 108:4 118:19 122:18</p> <p>objectives 108:2 118:15</p> <p>obligations 118:18</p> <p>observation 99:18</p> <p>obtained 26:17 119:1</p> <p>obvious 19:21 31:8</p> <p>obviously 20:21 23:12 94:9</p> <p>OCA 108:11</p> <p>occasionally 127:16</p> <p>occur 45:20</p> <p>occurred 45:9</p> <p>occurring 82:13 90:15</p> <p>occurs 127:3</p> <p>October 116:13</p> <p>odd 66:8 80:14 88:11 119:5</p> <p>OECD 41:22</p>	<p>46:5,11,13 50:13 51:1</p> <p>OECD's 42:3</p> <p>office 2:11 3:11 13:22 17:16 18:19 40:11 108:11 117:2,19,20 118:1,6 130:5,6</p> <p>officer 148:2</p> <p>offices 22:11</p> <p>official 10:13 77:2</p> <p>officials 79:15,16</p> <p>oh 50:13 53:20</p> <p>okay 17:22 19:5 39:17 40:3,14 47:3,12 48:16 50:7 51:3,6 57:8 59:13 61:4 63:19 67:16 71:17 72:22 73:19 75:20 84:15 86:1 92:5 94:18 96:1,16 97:6,9 101:12 102:2 103:8 104:4,15,17 106:7,19 113:18,19 123:17 124:15 126:22 128:15,18 129:3 135:3 142:17</p> <p>old 27:22 57:3 58:1,3,16,18,20 60:6 68:16 97:5 105:6</p> <p>older 61:22 97:6</p> <p>olds 58:15</p> <p>one-on-one 147:10</p> <p>ones 56:14</p>	<p>58:15,18 60:1 64:5 68:16,19 71:14,15 96:5 97:2,6 98:17,18</p> <p>ongoing 34:19 39:12 50:20 56:21 77:11</p> <p>online 7:5 8:2,11 9:1 10:4 39:20 49:20 92:13 105:12 113:15 114:9 126:10 134:22 145:22</p> <p>open 11:7,11 23:1 30:4,14 38:6 119:12</p> <p>operate 116:6 121:11</p> <p>operating 138:13</p> <p>operation 32:7 117:4</p> <p>operational 122:5</p> <p>operationalized 80:20 81:2</p> <p>operations 2:9 4:6 31:17 108:12 114:4 117:4</p> <p>operative 42:22</p> <p>operator 18:10</p> <p>opinions 133:4 145:22</p> <p>opportunities 18:5,6 20:4 22:7 26:18 31:5,6,17 34:15 92:11 121:14</p> <p>opportunity 4:8 5:9 10:12 14:11 15:7 16:8,12 37:4 38:1 40:1</p>	<p>52:14 129:8,18 135:8 142:8 147:9</p> <p>opposed 103:1</p> <p>opposite 79:6</p> <p>optimistic 23:9</p> <p>option 6:22</p> <p>orange 62:1</p> <p>order 6:8 33:7 53:12</p> <p>organic 17:19 29:18 136:11 142:1</p> <p>organism 125:21 127:5 129:22 145:11,14</p> <p>organisms 12:7 42:7 106:10,13 122:11 133:21 134:3</p> <p>organization 8:7 20:15 37:18 41:1,12,19 46:2</p> <p>organizations 33:20 77:19 81:16</p> <p>organized 102:17</p> <p>originally 58:22</p> <p>others 13:16 15:6 46:17 57:13 59:4 79:3 85:9 105:3 129:14 135:5 137:7</p> <p>otherwise 31:7 148:14</p> <p>ourselves 19:14 34:10 82:1</p> <p>outcome 91:8 146:20 148:14</p>
--	---	---	---

(866) 448 - DEPO

Capital Reporting Company
Stakeholder's Meeting 11-20-2013

Page 24

<p>outcomes 89:11 93:4</p> <p>outgoing 9:16</p> <p>outreach 33:16 117:22</p> <p>outside 95:14 106:1</p> <p>overall 15:14 34:6 53:9 63:13,22 67:17 116:18 120:13 121:18 124:10</p> <p>overnight 11:13</p> <p>overseeing 114:15</p> <p>oversees 17:18</p> <p>oversight 42:4 115:6 121:17</p> <p>owns 21:8</p> <hr/> <p style="text-align: center;">P</p> <hr/> <p>page 3:1,12 4:1 49:13,17</p> <p>pages 131:21</p> <p>Panel 3:13 52:6</p> <p>paperless 116:14,16</p> <p>paperwork 116:9,18</p> <p>paradigm 124:5</p> <p>Paris 40:5,7</p> <p>participants 99:8,20 100:10,14 103:17 104:6 117:6 119:5</p> <p>participant's 118:16</p> <p>Participants 99:16</p>	<p>participate 31:4,9 117:15</p> <p>participated 36:9</p> <p>participates 50:17</p> <p>participating 33:20 46:18 48:17 142:11</p> <p>participation 34:7</p> <p>particular 27:4,15 41:7 43:12 44:1,2 46:21 47:21 48:22 49:4 53:22 60:13 63:12 68:8 69:19 73:18 79:19 90:22 105:2 110:3 145:20</p> <p>particularly 42:7 43:4 47:21 50:13 54:17</p> <p>parties 148:10,13</p> <p>partner 51:1 83:3 118:12</p> <p>partners 33:17 35:10</p> <p>passes 66:4</p> <p>past 5:10 9:14 11:5 17:10 18:18 26:20 38:19 52:15 62:8 67:11 81:11 86:6 108:20 116:3 121:10 124:16 136:5</p> <p>path 55:10,17 56:1,3 58:5 67:7,10,12 72:16 97:4</p> <p>paths 55:8</p> <p>patience 41:5</p>	<p>pause 49:21 78:15</p> <p>pay 94:9</p> <p>PBQ 22:15,16 133:2</p> <p>pending 52:22 58:14 60:11,13 62:12 66:20 69:13 82:12 101:16</p> <p>pendings 59:9</p> <p>people 7:1 9:18 40:13 45:15 62:17 63:2,4 65:19 96:2 97:12,14 108:15 114:1,2 128:6 139:8 146:3</p> <p>percent 28:8,14 32:11 33:21 34:1 115:3 117:13 120:5</p> <p>performance 107:18</p> <p>perhaps 52:18 74:19 100:7 135:1</p> <p>period 9:10 10:14 30:3,14 54:14 55:13 57:4 59:12 62:21 63:3,6,18 64:9 65:18 67:9 72:2 78:4 95:12,14 97:1 98:7 101:22</p> <p>periods 84:12</p> <p>permanent 18:15</p> <p>permit 4:3 31:17 32:5 106:18 125:19 126:15 127:3,7 128:4 132:10 143:18</p>	<p>permits 6:6 25:3 32:1 33:15 107:5 109:2 115:17 119:15,22 120:3,5,12,18 123:12 124:6,7,8,9,11 125:9 131:8,13,15,16 132:6,8,16 133:11 134:18,19</p> <p>permitted 124:19 143:1,9,12</p> <p>permitting 22:15,16 24:6,7 25:5 38:1 106:11 118:20</p> <p>persist 125:8</p> <p>person 7:2,4,9 135:4</p> <p>personal 13:18 17:11</p> <p>perspective 120:15 124:10 132:15 142:13</p> <p>pest 12:12 27:10 62:15,18 113:3 120:21 127:6 131:12 132:20,22 133:2,16,18 134:16 143:15 144:10</p> <p>pesticide 42:1 86:17,18 88:13,21</p> <p>pesticides 111:6</p> <p>pests 2:13 3:16 16:15 51:15 131:14 134:5</p>
---	---	--	--

(866) 448 - DEPO

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Capital Reporting Company
Stakeholder's Meeting 11-20-2013

Page 25

<p>petition 3:14 25:8 26:22 27:1,2,11 28:16 31:12 39:9 51:8 52:5,6,11 53:6 54:15,22 55:8 59:15,16 60:5,17 61:5,8,17 62:6,11,18 63:7 64:1 65:10 68:20,22 70:16 76:7 79:19 82:9,12 83:14 88:11,17 93:11 98:5 101:11 102:1 112:1,9</p> <p>petitioned 111:21</p> <p>petitioner 27:3 93:20</p> <p>petitioners 57:17 59:7 94:12</p> <p>petitions 13:15 25:20 26:2,6,19 27:22 28:1,3,5,7,18 29:1 39:15 52:21 53:1 54:10 56:7,8,10,14 57:2,4,13,22 58:7,21 59:6,21 60:12 61:22 62:1,3,12 66:10 67:7,20,22 68:12 69:12 79:5,7 82:5,14 94:1 95:9,13,18,21 101:17,20 106:16 107:5 111:17</p> <p>ph 52:17 63:18 81:3 83:2 90:15 95:15 101:9 125:8 127:15,16</p>	<p>129:11 130:14 131:1 134:22 144:21</p> <p>pharma 124:8</p> <p>pharmaceutical 36:19 124:20,22</p> <p>phase 61:5 62:9,13 66:2,20 67:13 89:14</p> <p>phases 66:22</p> <p>phasing 57:22</p> <p>phenotype 125:21</p> <p>phenotypes 144:17</p> <p>phenotypic 145:1</p> <p>phone 40:12 49:19 78:9,11 92:15 142:17</p> <p>phones 5:17</p> <p>physically 96:2</p> <p>pick 6:14 8:16 20:20 39:22</p> <p>picture 46:12 67:17</p> <p>piecemeal 57:10</p> <p>piggyback 133:22 134:4,6,15</p> <p>pilot 3:19 51:10 52:4 77:8 92:16,18,20 93:3,4 95:8 96:20 99:4,5 100:13 101:2 103:17 104:6</p> <p>places 44:19</p> <p>plan 41:14 47:7 56:5 81:8 121:8 123:6 125:15</p> <p>planned 62:15,17</p>	<p>79:18</p> <p>planning 23:13</p> <p>plans 45:20 90:7 115:9 121:4</p> <p>plant 1:6,14 2:13,15 3:6,16 12:12 16:15 20:14,16 21:10 27:9 33:12 45:8 46:4 51:14 77:7 90:12 109:10 113:3,9 119:16 120:16,21 125:11 127:6,13,18 131:12,14 132:20 133:2,15 134:5,16 138:19 142:19 146:16,17,19</p> <p>planted 32:12 43:20 44:1 109:17 115:13 125:18,20 139:18</p> <p>planting 32:13 44:10 89:9 125:5,16,17 136:15</p> <p>plantings 115:14</p> <p>plants 22:2 41:9 42:7 46:5 77:20</p> <p>please 5:4,16 7:18 8:1,6,22 10:19 30:5 40:12 50:4 106:6,7 145:19 147:7,9</p> <p>pleased 17:8 18:16 33:22</p> <p>pleasure 11:5,10 40:3 142:11</p>	<p>pledge 14:4</p> <p>plowed 109:18</p> <p>plus 58:8 125:1,2,6 130:19</p> <p>podium 146:8</p> <p>point 27:13 28:4 36:11 42:14 45:12 66:17 91:18 94:20 96:4 112:4 121:3</p> <p>pointed 97:20</p> <p>points 45:4 64:8</p> <p>policies 45:15 49:4 50:18</p> <p>policy 134:11 140:19</p> <p>political 36:16</p> <p>pollinating 111:10</p> <p>pollination 111:3</p> <p>pollinators 111:9</p> <p>poor 40:5</p> <p>popular 6:22 132:14 134:3</p> <p>pose 127:6</p> <p>positive 34:6 75:13,16</p> <p>possible 45:17 75:1 97:14 110:2</p> <p>post 55:15,21</p> <p>posted 7:14</p> <p>potential 132:17 146:20</p> <p>powerful 30:9</p> <p>PowerPoint 6:19</p> <p>PPRA 62:21</p> <p>PPRAs 55:6 57:17</p>
---	---	--	--

(866) 448 - DEPO

Capital Reporting Company
Stakeholder's Meeting 11-20-2013

Page 26

<p>63:10 64:10,16 practical 134:8 138:5 139:8 practicality 139:19 practice 77:4 practices 133:3,7 141:19 142:2 pre 64:18 precision 32:14 pre-consultation 112:8 predictability 49:12 73:2 predictable 29:8 138:4 140:8 predicting 32:13 prefer 8:10,17 10:1 preliminary 55:12 preparation 57:18 62:14 63:1 prepare 54:16 64:2,18,20 65:2,6,17 74:2,10 75:2 77:7 93:17 97:18 100:17 prepared 22:10 72:17 93:19 98:17 99:2 102:9 prepares 55:4 65:14 preparing 54:21 55:2 62:17 64:3,9,15 93:18 99:13 pre-planting 125:4</p>	<p>presence 3:10 37:12 38:21,22 40:15 41:9 42:14,17 47:8 48:6 140:15,19 141:6 present 95:3 presentation 7:20,21 20:20 30:5 70:4 113:14 118:12 presentations 6:11,19 7:6 14:11 53:17 105:20 114:9 presenters 7:6 51:12 presently 123:15 president 136:5 pressure 49:16 53:3 pretty 14:19 16:19 17:14 31:13 36:11 63:22 72:13 73:11,18 85:4,12 113:22 122:8 131:10 136:20 prevent 109:8 prevented 114:3 previous 28:9,15 97:21 previously 112:19 PRIA 90:12,17 primarily 21:10 24:5 primary 35:6 38:21 130:11 144:2</p>	<p>prime 71:16 principles 45:6 printed 6:12 Prior 111:19 probably 11:19 12:8 18:3 25:11 36:2 39:16 53:16 64:6 84:2 87:7 91:5,6 99:4 112:5 problem 18:10 35:9 43:17,18 44:3,12 134:4 143:11 problematic 8:4 78:3 problems 132:18 procedures 132:4 proceed 40:2 91:9 proceeding 149:5,7,10 process 3:14 12:20 14:7 21:1,5,7 25:8,10,12,14 26:11 27:3,5,12,16 28:13,19,20 29:2,8 31:12,16,19 39:9 44:18 51:8 52:5,6,12,16 53:7,10,18 54:5,7,9,14,22 56:12 57:2 58:2,3,6,14,16,1 9,20 59:8,15,22 60:2,15 61:9,12 62:9,11,13,16 63:20 64:22 65:4,10,12 66:3,11,21</p>	<p>67:7,10,21 68:13,16,17,18,2 2 70:6 71:13 72:1,5 73:2,11 76:3,7,21,22 77:2,3,16 79:4,9,12,20 82:1,7 84:7 85:4,14,22 86:2 87:18 88:18 89:20 90:18 91:10 93:11 95:7,8 97:6,7,8 98:5 101:11 102:1 103:14 104:1 105:6 106:11 113:7 115:2 116:7 118:17 119:15,21 120:3,17 121:7 124:13,14 127:2,12,15,20 128:5 132:2 processes 16:5 80:13 84:16 88:8 89:13,20 90:14 114:2 116:2,5 119:20 121:12 123:1 processing 116:17 produce 7:12 116:9 141:2 product 27:15 75:13 79:19 81:19 84:8 88:2 98:1 112:16 139:13 production 110:13,20 products 14:1 36:6 37:2 39:7 47:9 79:7 80:12 84:9</p>
--	---	--	---

(866) 448 - DEPO

Capital Reporting Company
Stakeholder's Meeting 11-20-2013

Page 27

<p>85:6 86:8 87:14 88:5,22 91:15 93:15 96:10 97:3 117:10 137:12 139:10 141:1,9</p> <p>profitable 13:6 19:6</p> <p>program 2:9 4:4,6 6:6 17:19,20 18:4,7,21 20:5 21:10,11 22:18 23:10,14 34:3,7 37:4 83:4 86:6 106:17 107:4 114:4,5 117:5,7,15 147:5</p> <p>programs 17:18 22:19 23:19 29:12 37:1 38:2 82:18,20 83:11 86:11 119:15 121:15 123:2 130:6 147:7</p> <p>progress 13:10,13,16 20:12 27:21 28:14,22 39:11 85:12</p> <p>project 40:22 41:7 51:10 52:4,13 76:7 92:19,20 93:3,4 96:20 99:4,5 100:13 101:2 103:17 104:6</p> <p>projecting 37:17</p> <p>projects 77:8,11 103:19 116:8</p> <p>promise 93:5</p> <p>promptly 122:17</p> <p>proof 140:3</p>	<p>property 41:22</p> <p>proponent 17:2 25:12,14</p> <p>proposals 48:21,22</p> <p>proposed 41:3</p> <p>protect 12:13 122:9</p> <p>Protectants 2:13 3:16 51:15</p> <p>protection 21:11 33:12 36:5 51:22 78:19 119:17,18</p> <p>protections 3:17 13:2</p> <p>protocol 107:19</p> <p>protocols 42:2 106:14 107:13,14 108:18</p> <p>proud 37:3 137:1</p> <p>prove 137:13 140:5</p> <p>provide 4:8 10:16 34:13 44:13 99:17 108:4 115:6 116:22 128:8 131:19 134:13 141:3 147:7</p> <p>provided 33:10 93:20 94:14 99:19</p> <p>providers 140:10</p> <p>providing 32:19 38:16 120:7 122:18,19 131:21 141:4</p> <p>proxy 94:9</p>	<p>prudent 115:19</p> <p>public 10:13 16:8,11,18 19:13,15,16 30:3,8,10,19 35:13 38:9 41:9 55:1,19,20 59:9 62:19,21 63:3,6,18 66:12 67:9 77:18 80:8 82:15 84:17,18 122:3,6 133:1,16 147:22</p> <p>publish 55:11,18 67:8 74:6 130:14</p> <p>published 57:4 59:8 66:12 67:4 69:13 109:20 110:9</p> <p>publishing 27:14</p> <p>pulled 44:3</p> <p>purpose 74:3,11</p> <p>purposes 45:10 111:6 112:1</p> <p>pushed 36:10</p> <p>putting 108:6 121:7 123:6</p> <p>puzzle 57:10</p> <hr/> <p style="text-align: center;">Q</p> <hr/> <p>Q&A 8:14 9:1 10:5 78:13 126:14</p> <p>Q&As 126:17</p> <p>QA 126:20</p> <p>qualify 128:7</p> <p>quality 19:22 31:21 33:18 76:4 77:1 92:22 94:21 95:1,6 99:11</p>	<p>102:4 116:9,19,21 122:21 126:19,21,22 127:1 143:2 144:2 145:5</p> <p>quarantine 21:11 22:18 33:12 119:17</p> <p>quarter 15:10,11</p> <p>question 8:12,15,16,18,21 9:1,2,10 19:14 39:21 40:1 47:4,11,13 48:15 49:20,22 50:9 73:4,16 74:15,20 78:12,13,14 105:13 115:8,10 123:14 126:10,13,16 129:7 138:8 140:3 142:20</p> <p>questions 5:11 7:7,19,20,22 8:6,9 34:19,20,21 39:16,17,18 46:19,20 70:2 75:21 78:8,16 90:2 92:13 102:2 103:10 105:11 106:22 107:7 112:7 113:11,15,16 119:1,2 123:8 128:12,14 146:5</p> <p>queue 59:5</p> <p>quick 40:10</p> <p>quicker 85:7 120:10</p> <p>quickly 16:11 35:8</p>
--	---	--	---

(866) 448 - DEPO

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Capital Reporting Company
Stakeholder's Meeting 11-20-2013

Page 28

<p>45:17 49:8 60:21 71:12 136:21 quiet 128:20 quite 43:6 59:10 71:15 132:13,16 136:20 137:6 138:10</p> <hr/> <p style="text-align: center;">R</p> <hr/> <p>radar 135:10 rails 68:3 73:3 raise 78:5 ranchers 14:3 randomly 126:5 range 112:17 rarely 131:17 rate 115:2 rather 9:10 129:8 132:4,10 rational 134:11 reach 39:14 74:9 83:5 reached 26:1 53:1 reaching 69:21 reading 102:16 ready 71:16 real 44:3 137:16 realize 113:6 123:5 realized 120:14 reallocating 53:11 really 15:2 26:7 49:10 63:14 71:9 73:14 76:12,20 79:12 90:16 96:20 98:22 101:6</p>	<p>102:12,14,18 103:2 106:20,21 107:3 113:9 121:21 128:20,21,22 135:8 136:22 138:4 140:16 141:7 realm 135:14 reason 66:9 75:6 95:10 105:2 113:2 128:22 reasonable 98:4 reasonably 112:17 reasons 35:7 108:5 Rebecca 2:5 3:20 52:1,3 77:8 105:14 recall 51:15 56:22 receive 10:19 16:2 27:1 30:9 61:18 62:7 115:8 125:11,13 145:18 received 26:7 42:19 43:1,20 58:7 118:22 127:4 receiving 108:13 147:2 recent 82:14 recently 18:20 25:19 52:4 64:9 110:17 111:13,20 receptive 103:22 recognize 13:6 134:12 136:22 137:10 recognized 21:12</p>	<p>79:22 117:7 recommend 111:18 recommendation 112:5,11 recommends 112:20 reconvene 106:2,3 record 148:8 recorded 148:6 recordings 149:8 recovered 22:10 red 60:1 63:8 64:19 68:20 78:5 reduce 111:2 reduced 26:18 27:9 111:1 132:12 148:6 reducing 29:6 53:10 116:15,18,21 redundant 53:10 Reed 76:1 77:12,15 78:2 123:9,17,19 reestablish 87:12 referred 36:3 38:14 referring 19:19 reflect 110:1 reflected 105:9 111:14 Reflections 3:7 17:7 reflects 15:17 111:7 115:6 117:8</p>	<p>reform 132:13 reformulated 85:21 reg 108:11 regard 131:13 regarding 32:20 38:10 46:20 50:22 132:21 regardless 109:7 regions 112:15,21 register 27:14 38:9 55:22 57:1 registered 7:1 145:17 registration 9:22 34:9 82:9 83:15 88:13 90:11 91:3 106:1 registrations 84:5 88:21 regrets 11:12 regularly 33:14 regulate 16:15 regulated 27:16 33:4 106:13 108:4 109:6,11 115:4,11 116:11 117:8 120:2,9 124:14 125:7 127:8,9,17 128:4,7,8 134:7 regulating 34:5 regulation 36:1,6 88:20 regulations 38:7,8,10,12 47:15 49:6 113:21 115:5,7 117:11,17 119:3</p>
--	--	---	--

(866) 448 - DEPO

Capital Reporting Company
Stakeholder's Meeting 11-20-2013

Page 29

<p>122:10,16,20 124:13 regulator 45:1 regulators 44:7 regulatory 1:4 2:9 3:13 4:6 5:7 10:15 12:6 13:1 17:2,17,19 18:1,4 20:3 28:12 29:12 36:17 37:1,3 42:4 48:4 50:18,21 51:9,21 52:6 78:22 80:13 81:19 82:5 88:16 89:13 114:4 137:2 reinitiated 24:17 rejected 39:1 43:21 related 9:9,12 79:18 122:3 148:9 relationship 87:12 relative 115:15 148:12 relatively 98:21 137:15 release 48:1 released 46:9 117:14 relevant 44:11 remain 23:15 remained 23:4 remains 35:4 117:3 remember 66:11 69:7 remind 20:13</p>	<p>105:19 reminded 114:14 reminder 78:10 removes 71:3 140:9 repeat 9:5 10:10 report 93:20,21 98:18 114:13 reported 1:19 149:5 reporter 7:11 148:19 149:5 Reporter's 149:7 Reporting 1:19 reports 94:2 98:20 represent 59:20 64:8,11,17,19 112:15,21 represents 146:16 request 40:10 requested 125:13 requests 71:9 require 56:8 107:19 110:14 134:18 required 100:17 107:18 109:13 110:6 requirement 112:3 requirements 33:15 requires 109:14 research 43:3 113:12 117:9 130:1,5,16,19 131:3 132:14 133:8,21 140:11</p>	<p>145:13 researchers 131:4 resist 133:14 resistance 21:19 83:22 resistant 89:3,7 96:10 98:1 resolution 23:6 resolve 89:21 resources 23:18 76:9,10 103:6 respective 37:1 89:18 respond 30:12 54:18 70:14,15 143:22 responded 100:10 responding 122:17 response 9:13 116:22 responses 116:11 responsibilities 55:3 90:1 responsibility 114:18 rest 23:15 94:16 141:16 resubmit 70:17,20 result 34:1 40:7 52:12 89:8 102:4 resulting 74:17 results 26:16 51:18 resurrect 92:10 return 86:20 review 27:4 54:10 55:12 57:16</p>	<p>59:16,18 60:5,22 61:5,6 70:20 84:11 86:7 87:10 92:2 102:5 107:13,20 108:5,18 127:2 128:1 reviewed 42:18 44:21 61:20 98:15 124:16 reviewing 26:19 72:12 95:4 107:4 reviews 84:17 86:15 87:13 108:6 116:10,20,21 127:14 revise 55:20 67:8 revising 38:7 revisions 60:16 right-hand 68:6 rights 41:22 rigor 76:4,16 rigorous 13:1 73:11 ringtone 5:20 risk 4:4 27:10 35:14 42:6,19 44:8,9,12 45:1,5 46:8 47:22 54:21 55:2 62:15,18 64:10 77:7 86:17,18 90:12 106:17 118:5,16 120:21 123:21 124:18 127:2,4,6 Risk/Safety 41:11 risk-based 124:5 126:1 risks 32:8</p>
--	--	--	--

(866) 448 - DEPO

Capital Reporting Company
Stakeholder's Meeting 11-20-2013

Page 30

<p>River 1:14 Riverdale 1:15 36:22 road 1:14 106:12 robust 23:15 Rocky 5:20 role 12:6,11,15,16,19 16:16,19 19:9 21:12 22:1 roles 16:18 89:22 roll 107:8 rolled 52:11 room 6:1 7:22 8:5 10:3 19:20 52:18 79:16 143:20 147:9 round 129:2 route 116:14,16 routinely 66:6 68:1 69:22 rows 110:7,15,16 111:1 rubber 106:12 ruderal 110:12 rule 74:1 rulemaking 38:7 rules 49:6 113:21 run 23:10,11 99:1 103:2 running 105:16 runs 138:19</p> <hr/> <p style="text-align: center;">S</p> <hr/> <p>safe 137:13 140:5 safely 16:11 22:4 33:9</p>	<p>safety 42:11,19 44:12,20 45:5 46:4,8 47:17 50:9 139:4 140:4,6 Sally 2:10 3:10 37:14,19 40:4,5,14 50:1 sample 27:5 67:15 samples 133:9 save 21:13 99:16,18 100:6 120:15 134:17 saving 63:15 120:22 121:1 savings 60:8,9,20 61:3,15 62:11 75:3 98:15 saw 57:6 71:6 scale 104:20 scene 72:20 schedule 89:22 91:10 105:18 129:1 scheduled 9:6,13 119:11 schedules 83:18 85:21 89:12 91:5 schemes 42:1 science 2:11 3:11 16:6 37:15 110:2 111:8 130:3,20 Sciences 130:8 scientific 2:10 3:11 41:21 145:5 scientists 131:20 132:18 133:12 134:11 144:16 score 144:17</p>	<p>scratch 103:1 screen 8:14 9:2 135:10 search 102:20,21 searching 102:22 season 107:12 seats 5:4 106:7 Seattle 118:14 second 18:21 40:10 64:16 78:15 96:13,18,21 97:15,22 131:18 134:20 Secretary 11:18,19,22 13:21 17:16 25:11 29:11,13,16 136:8 Secretary's 13:20 17:15 19:7 sections 86:16 sector 15:3,4,6,7,15 43:15 sectors 14:15 19:8 Security 119:18 seed 15:4 41:10 42:1,17,18 43:10,12,20,21,2 2 73:8 110:12 139:7 seeds 47:5 seeing 40:1 105:8 seems 33:21 73:13 86:1 134:11 seen 11:9 15:21,22 26:19 38:22</p>	<p>53:15 72:7 sees 80:8 segment 146:10 select 126:1,5 selected 112:16,20 126:6 selecting 124:5 selection 125:4 self 111:9 send 61:6 70:13 71:7 sending 85:1 132:5 senior 11:18 17:16 79:15,22 81:18 83:1,4 sent 60:12 sentence 19:12 separate 77:11 separated 55:3 109:6 separately 64:15 separation 32:20 33:2,5,6 106:15 108:21 110:15,22 Sepp 17:14 September 46:10 132:4 sequence 134:16 sequences 131:14 134:15 sequesters 5:13 sequestration 24:10 series 14:14 80:10 seriously 30:13</p>
---	--	---	--

(866) 448 - DEPO

Capital Reporting Company
Stakeholder's Meeting 11-20-2013

Page 31

<p>servants 19:13,15,16 30:10</p> <p>service 1:6,14 2:15 3:6 23:4,22 36:8 147:7</p> <p>services 1:4 5:7 6:6 18:1,4,21 25:5 78:22 119:16</p> <p>session 4:7 9:7 10:4,13 105:20 129:4,6,7 146:12,21</p> <p>setting 46:6</p> <p>settle 86:11</p> <p>seven 27:6 43:13 57:18 58:12 59:9</p> <p>several 9:15 18:6 21:17 22:11 32:19 33:10 35:3,22 37:13 109:15</p> <p>sexual 109:7</p> <p>sexually 32:21 109:10 110:6,11</p> <p>share 4:8 10:16 80:3,6,17 122:14</p> <p>shared 36:22</p> <p>sharing 81:2,3 83:17 84:16 86:5,7 87:13 89:17</p> <p>Shea 2:14 3:5 11:7,9 19:4</p> <p>sheer 120:12</p> <p>ship 131:5</p> <p>shipment 39:1</p> <p>shipments</p>	<p>131:9,10 132:5,9 143:4,10,16,17</p> <p>shoot 115:19</p> <p>short 37:12,15 113:14</p> <p>shorten 25:19</p> <p>shorter 55:10 96:5 105:1 113:17</p> <p>shortly 55:4,13</p> <p>showed 59:19 67:19 68:2</p> <p>shows 38:17 68:11</p> <p>shrinking 49:15</p> <p>shutdown 22:21 85:20</p> <p>shutdowns 5:13</p> <p>Sid 2:2 3:18 4:10 51:20 78:20 90:5 91:21</p> <p>sides 75:10</p> <p>Sigma 25:12 26:11,13,14 29:2,4,6,7 31:11 52:12</p> <p>sign 6:12 9:21</p> <p>signed 9:19,20 95:18 105:21 129:12 134:21 135:4 142:16</p> <p>significant 20:12 27:7,20 28:11,14 37:16 39:11 74:5,7,12,17 75:5 91:7 98:11,16 100:16 101:8 103:4 130:13 143:15</p> <p>significantly 26:18</p> <p>similar 21:7 44:21</p>	<p>48:11 94:5 96:6,13,22 110:7 119:1 120:2 124:15</p> <p>simplified 132:4</p> <p>simplify 133:20</p> <p>simply 10:15 12:12 144:22</p> <p>single 28:10 32:5 64:10</p> <p>sir 46:21</p> <p>sister 42:10 81:9 82:17</p> <p>sisters 46:1</p> <p>sit 137:4</p> <p>site 119:4 125:4,18 126:2</p> <p>sites 32:6 106:15 111:17,19 112:2,11,14,16,2 0,22 113:4,11 115:13 125:20 126:6</p> <p>situation 23:8 29:10 35:7,12,15 43:2,14 44:9,14,15,22 45:9,11,20</p> <p>situations 43:7 45:14,18 110:11,20 133:4</p> <p>six 25:12 26:11,12,14 29:2,4,7 31:11 52:12 58:16 59:7 60:9 64:7 66:19 85:17 89:15 137:22</p> <p>sizable 7:4</p> <p>size 27:5 67:15</p>	<p>101:3</p> <p>slide 29:9 34:16 57:8 60:10 67:16 97:9,21 107:10 123:3,10 125:12</p> <p>slides 53:14 121:5</p> <p>slight 24:18</p> <p>slightly 55:10,17 65:20 90:16</p> <p>sloppy 76:19</p> <p>slowed 75:12</p> <p>slower 65:20</p> <p>slowing 65:5</p> <p>small 110:17</p> <p>smaller 66:1 69:6</p> <p>smooth 37:7</p> <p>smoothly 39:7 132:16</p> <p>Society 130:21</p> <p>soft 63:2</p> <p>soils 141:21</p> <p>solely 145:8</p> <p>solution 20:3 34:11</p> <p>solutions 19:19,22 21:15 22:5 34:14 39:6</p> <p>somebody 74:19 128:3</p> <p>somehow 76:2 136:3</p> <p>someone 73:21 83:5</p> <p>sometime 145:18</p> <p>somewhat 124:12</p> <p>somewhere 11:20</p>
--	--	---	--

(866) 448 - DEPO

Capital Reporting Company
Stakeholder's Meeting 11-20-2013

Page 32

<p>43:1 47:6 son 137:21,22 138:19 139:3,9 SOP 101:18 sorry 50:5 53:20 54:6 70:22 sort 10:14 53:11 63:2,5 64:12 68:3 71:15 74:13 75:7 76:10 77:3,10 90:7 102:10 134:13 sound 5:18 sources 45:1 soybean 111:22 speak 8:18,20 9:5 10:7,12 51:12 129:13 135:2 142:8 147:9 speaker 7:19 92:14 102:3 103:5 104:16 123:20 124:1 126:19,20,21 special 133:22 134:12,17 species 32:22 133:18 143:7,9,17 144:5,10 145:11,13 specific 12:11 35:1 49:4 83:21 136:8 145:13 specifically 84:4 specifics 73:22 specimens 133:13 sped 132:11 speed 114:11</p>	<p>speeding 61:8 62:11 65:11 spelled 24:5 spent 28:12 97:13 130:17 sphere 38:10 split 64:14 spoken 8:12 sponsored 130:2,5 spread 21:21 33:4 69:6 spring 107:22 squishy 62:16 staff 23:20 32:15 53:11 54:12 55:1,4 62:20 65:14,17 69:19 70:12 76:9,10 83:13,15 93:7,14,16,17 94:8,9,10,18 95:20 96:1,12 97:12 98:4,11,13,15 99:1,8,14,19 100:6,9,17,18 101:1,3,10,14 102:14 103:12,22 104:22 105:5,9 127:3,4 131:18 133:5 146:4 147:8 staffers 8:8 staffs 55:5 stakeholder 4:8 14:16 18:13 52:10 56:18 57:12 92:19 93:6 135:12,14</p>	<p>146:14 stakeholders 5:9,12 7:8 14:17,18 25:1 29:17 129:8 147:3 stand 129:16 standard 46:3,6 90:10 107:14 124:9 125:9 134:18 standardized 132:1 standards 107:18 108:16,19 109:4 110:4,10 111:13 standing 52:9 standpoint 124:18 stands 20:14 Stankiewicz 2:5 3:20 52:2 92:17 102:7 103:8,15 104:2,5,11 105:4,15 start 27:10,21 28:17 40:10 47:5 52:5 56:2,3 66:17 67:5 68:21 69:1 101:18,19 147:2 started 5:4,15 17:13 21:2 27:18 31:13 66:14 68:4,16 71:22 77:15 80:2 106:5,7 114:19 120:13 starting 69:5 87:4 102:17,19 103:1 state 33:13 118:9</p>	<p>statement 30:22 74:10 statements 30:20 States 21:14 35:9 36:17 82:21 118:8 120:20 126:6 137:1 station 127:13,18 132:7 stations 120:17 132:11,13 statistic 33:19 statistically 101:7 103:3 status 3:14 25:20 26:22 27:16 52:6 82:4,5 132:22 133:22 134:12 statute 86:22 stay 23:2 126:7 142:9 step 53:22 59:15,21 60:10,11,14,15 61:4,8 62:22 63:12,14,19,20 67:6 70:7 74:9,13 steps 25:17 26:21 27:1 29:5 53:10,13 54:5 55:5 56:13 57:5 61:16 62:5 72:11,20 84:15 100:12 137:12 Steve 6:7,9,10 31:15 127:10 128:11,13 stewards 117:9 stick 8:3</p>
--	---	--	---

(866) 448 - DEPO

Capital Reporting Company
Stakeholder's Meeting 11-20-2013

Page 33

<p>Stock 129:19 144:1</p> <p>straight 66:8,17</p> <p>straightforward 122:8</p> <p>strains 129:20 131:6,14 133:20 134:14 145:2,7</p> <p>strategic 81:8</p> <p>strategic/ operational 121:8</p> <p>streamlined 127:20</p> <p>streamlining 53:9</p> <p>strengthened 110:10</p> <p>stress 58:18</p> <p>strictly 25:3</p> <p>stringent 127:14</p> <p>strong 19:17 25:11,14 117:16</p> <p>struggling 79:11</p> <p>stuff 139:5</p> <p>sub-graphs 67:18</p> <p>subject 9:12 11:21 83:9 130:12 133:7</p> <p>subjective 94:21</p> <p>subjects 9:9 51:7,13 146:3</p> <p>submit 90:17 100:14</p> <p>submitted 112:9 122:15</p> <p>submitters 104:10,12</p>	<p>subscribe 34:3</p> <p>subsequent 53:16</p> <p>substantial 62:10 63:22 131:8</p> <p>substantially 69:3 132:12 133:8</p> <p>subtle 144:17</p> <p>success 123:7 131:3</p> <p>successes 121:15,16</p> <p>successful 89:16 107:11</p> <p>sufficient 56:7</p> <p>sugar 57:20 59:1</p> <p>suggest 133:19</p> <p>suggested 33:2,3 99:14,20</p> <p>suggests 133:6</p> <p>sum 61:21 108:19</p> <p>summaries 100:8</p> <p>summarize 86:20</p> <p>summer 107:22</p> <p>supplies 43:19</p> <p>supply 43:22</p> <p>support 16:2,3 42:6 90:6 99:18 102:8 104:3 118:5</p> <p>supported 100:11</p> <p>supporting 122:1</p> <p>supposed 11:5 56:1 74:21</p> <p>sure 6:14 10:3 12:12 13:2 15:8 21:20 22:4 23:6 27:2 33:14 39:7</p>	<p>73:20 77:14 78:1 85:8 88:5 98:22 108:12 110:19 113:21 114:17 121:1 125:7 126:7,11 143:5</p> <p>surprise 126:7</p> <p>surprising 101:6</p> <p>survey 10:19 99:3,6,9 145:18</p> <p>surveys 99:7 100:11</p> <p>suzukii 143:12 144:9,21</p> <p>switch 18:1 65:15</p> <p>sworn 148:5</p> <p>symptoms 22:11</p> <p>synchronicity 90:13</p> <p>synchronization 48:3</p> <p>synchronize 84:10</p> <p>synchronous 85:4</p> <p>synchronously 110:8</p> <p>syndicus 144:21</p> <p>system 6:9 12:9 13:1,9 17:3 20:1 24:4,9,19 25:2,16,17,18 31:22 33:19 60:17 71:19 118:20,21 131:20 134:4 137:2 138:3,17 140:3 141:10 143:13</p> <p>systems 81:19</p>	<p style="text-align: center;"><u>T</u></p> <p>table 5:22 6:12 51:2 108:21,22 109:3,20 110:3,9,18 111:14,15</p> <p>tactic 138:10</p> <p>taking 12:19 19:18 25:18,21,22 54:14 60:6 61:10 64:12,17,20 80:21</p> <p>talk 5:14 14:19 18:11 19:2 37:11 48:3 51:4 54:1 77:9 78:22 82:3,8,12 83:5 93:2 94:6,17 104:6 107:3 111:16 112:7 137:11,16 141:16</p> <p>talked 24:3 79:17 91:13 92:9 132:3 136:6</p> <p>talking 18:7 25:15 48:9 49:10 50:10 73:21 75:18 92:1 107:9 138:6</p> <p>talks 23:21</p> <p>target 28:3 53:22 59:17 61:9,14 62:4,15 67:14 69:3 115:20</p> <p>targeted 112:16</p> <p>targets 27:20,21 28:2 39:14 52:17 54:4 59:14 69:21,22</p> <p>Task 42:10</p>
--	--	---	--

(866) 448 - DEPO

Capital Reporting Company
Stakeholder's Meeting 11-20-2013

Page 34

<p>tasks 100:5,7 114:3</p> <p>team 83:13,14 118:3,4 121:6,21 122:15 123:4</p> <p>Tech 118:10</p> <p>technical 35:19 42:5 71:8</p> <p>technique 26:10</p> <p>technological 107:9</p> <p>technologies 13:4 87:3 138:18</p> <p>technology 14:2 15:20 137:12 138:20</p> <p>telephone 8:18 9:3 39:22 49:21 113:18 128:15</p> <p>templates 131:21</p> <p>ten 20:8,18 21:10</p> <p>tend 9:15 11:3 14:21 71:7</p> <p>Tennessee- Knoxville 118:9</p> <p>tephritid 144:14</p> <p>term 23:13 26:3,4 29:20</p> <p>termination 74:8 125:6</p> <p>terms 28:21 53:2 54:7 55:8 59:13,14 62:11,14 65:6 72:8,11,19 73:3 79:9 86:11 88:10 89:6 106:12 114:11,13,15,16 115:9 116:2,17,19</p>	<p>118:5 120:4 121:11,16,22 124:4,11,15,19,2 2 134:8 144:16</p> <p>Terrific 129:16</p> <p>test 85:13 89:14 106:15 107:17 113:9</p> <p>tested 32:21</p> <p>testimony 148:4,5,8</p> <p>testing 42:2 106:13 107:16 113:1</p> <p>tests 43:4 107:21 108:7</p> <p>text 8:15 9:2 10:5 78:14</p> <p>thank 11:2 16:21 17:8,11 34:6 35:15 39:18 40:7,14,16 46:19 49:18 51:5 52:7 60:22 70:3 71:17 75:20 78:17 90:5 103:8 104:19 105:14,15 106:3,6,8 114:7 115:3 123:4,8 134:19,20 135:7 142:7,9,10,14 143:18 145:15 146:9,12 147:11</p> <p>thanks 17:4 40:17 49:17 78:17 106:8 113:18 114:6 123:19 128:11,16 129:3,17 145:16</p> <p>that's 10:1,17 12:14,15,16 14:4 15:2,13 16:15</p>	<p>18:3,17 20:2 22:16 29:6 30:4 31:14 32:3 34:11 35:6 37:2,18 38:18 39:3 44:21 45:12 53:20,22 55:1 57:5 62:22 63:5 67:12,18 68:18,21 69:10 70:2 71:22 73:6,11,18 74:18,21 75:7 77:2,6 78:4,17 81:19 83:9 85:15 86:12 94:10 96:7,8 97:21 100:19 102:12 103:15 104:5 110:21 113:13,22 114:8,18 129:14 138:7,12 139:4,10,13,15,1 8 141:12 142:6 143:9 144:7 145:9</p> <p>theirs 91:10</p> <p>theme 5:19</p> <p>themselves 19:10</p> <p>thereafter 148:6</p> <p>there's 6:9,17 13:10 19:11 24:4 39:18,20 40:13,22 44:12,22 47:12 50:20 63:21 72:20 73:16 75:4,6,21 78:16 79:2,5 82:18 83:4 87:16,17 89:4,17,20 92:11 94:10 98:15,16 108:12 127:18 128:6 132:20</p>	<p>135:11 136:1 139:18 142:4,22 143:6</p> <p>they'll 125:3 129:13</p> <p>they're 5:14 15:5 22:5 48:12,13 49:14 66:16,18 73:17 79:8 83:18 97:6 104:7,14 107:19 108:2 113:21 117:10 128:8 134:10 143:8</p> <p>they've 44:5</p> <p>third 61:4 132:3</p> <p>thoughtful 106:22</p> <p>thoughts 107:2 129:9</p> <p>throughout 21:5 23:3 39:7 94:20 95:6</p> <p>throughput 59:10 66:2 69:15</p> <p>thunderous 129:2</p> <p>tier 126:4</p> <p>tightening 24:14</p> <p>tightly 15:5</p> <p>till 142:4</p> <p>tillage 141:19 142:2</p> <p>timeframe 93:11 96:7</p> <p>timeframes 67:5 93:10</p> <p>timeline 63:13,22 72:14,18 88:4</p> <p>timelines 56:13 66:5 67:2</p>
---	---	---	---

(866) 448 - DEPO

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Capital Reporting Company
Stakeholder's Meeting 11-20-2013

<p>69:15,19 84:5,20,22 98:5 timeliness 116:10 timely 39:15 76:11 85:1,2 88:6 89:17 108:5,7,8 116:22 121:3 140:8 title 41:8 today 6:19,21 7:2,11,15 8:8 9:6 11:11,13 14:5,11 23:21 51:17 52:9,13 59:3 69:10 78:22 81:17 93:2 94:17 95:9 106:20 129:18 135:20 today's 6:11 114:17 tolerant 79:8 82:10,11 83:12 87:10 91:1 92:3 tool 25:4 tools 92:21 134:10 145:12 top 8:14 9:2 20:8,18 21:10 72:10 101:11 126:7 topic 43:8 83:8,10,20 topics 87:3 total 57:14 59:3 61:21 touch 23:2 121:5 142:9 tough 78:4 138:21 139:15 toward 81:1 84:13</p>	<p>towards 24:8,14 27:21 35:21 48:8 69:20 117:16 track 101:16,17 113:14 114:16,18 128:17 tracking 28:22 track's 140:7 trade 37:7 41:21 46:1 49:12 50:19,22 140:13 142:22 tradition 147:2 traditional 128:4 Traditionally 110:5 train 47:20 training 33:10,16 trait 45:7 72:21 90:22 113:10 traits 72:15 112:6,19 113:2 transcript 7:13,17 149:6,8 transcription 149:1,9 Transcriptionist 149:15 transfers 50:10 transformation 134:1,9 transgenic 41:9 42:7,18 46:5 111:1 131:7,13 133:20 134:16 transition 57:22 65:18 105:7 transitioned 57:2</p>	<p>58:2,13,15 68:17 transitioning 26:4 transport 47:19 48:19 transposon 134:5 traveling 11:3 treat 47:20 treated 133:3 treats 46:7 trends 48:19 trial 124:21 125:6 trials 32:4,7,11,14,16 33:22 34:2 109:6 124:22 125:1 126:8 tries 44:4 trilateral 35:20 trip 8:4 trouble 73:5 truck 47:19 true 96:15 118:2 144:7 148:8 149:9 truly 138:1 Trust 131:1 try 8:17 10:11 39:4 77:19 86:9 87:12 142:9 trying 16:9 30:1 34:20,22 136:2 138:17 TTQ 48:19 turn 5:18 9:4,22 10:7 17:6 51:12 turned 24:14 26:17</p>	<p>Turner 4:3 106:16,19 113:19 turns 32:10 twice 104:22 136:19 two-and-a-half 119:11 type 8:15 9:2 77:4 78:14 100:9 124:8,20 typed 149:6 types 19:8 119:1 typewriting 148:7 typically 115:12 120:2 145:8 typographical 95:2</p> <hr/> <p style="text-align: center;">U</p> <hr/> <p>U.S 2:14 3:5 35:10,21 39:7 41:17 47:10 49:11 112:21 143:11 UC-Davis 119:12 ultimate 44:10 ultimately 21:13 unable 74:9 unapproved 35:5 unauthorized 48:1 underestimate 97:12 underscore 56:6 understand 26:14 32:13 48:7 49:7 87:16 114:2 135:9 138:9,14</p>
--	---	---	--

Capital Reporting Company
Stakeholder's Meeting 11-20-2013

Page 36

<p>understanding 49:13 80:16 127:1</p> <p>undertake 103:20</p> <p>undertaken 41:3</p> <p>unfortunately 81:16</p> <p>UNIDENTIFIED 92:14 102:3 103:5 104:16 123:20 124:1 126:19,20,21</p> <p>unified 38:15</p> <p>Union 131:1</p> <p>unique 5:12,14 32:7</p> <p>unit 22:15,17</p> <p>United 21:14 35:9 36:16 82:21 118:8 120:20 126:5 137:1</p> <p>University 118:9,10</p> <p>unmute 8:20</p> <p>unnecessarily 13:5</p> <p>unpredictability 140:11</p> <p>unreasonable 90:10</p> <p>update 52:17 99:21 100:2 106:14</p> <p>Updates 3:13 52:6</p> <p>updating 99:15</p> <p>upfront 75:3,7 128:1</p> <p>upon 74:15 115:11,21 127:7</p>	<p>upwards 117:13</p> <p>urge 133:14</p> <p>URL 30:4</p> <p>USDA 1:3 3:4 11:8 17:18 29:21 34:17 36:3 37:4 38:17 39:5 51:2 70:7 77:22 84:1 90:12,17 144:11</p> <p>USDA's 36:7</p> <p>useful 43:6 62:22 99:2,13,15,17,19 100:19 103:7 146:18</p> <p>user 22:17,18</p> <hr/> <p style="text-align: center;">V</p> <hr/> <p>valid 98:22</p> <p>validate 86:21</p> <p>validated 111:4</p> <p>value 81:9 122:3,6</p> <p>valued 30:7 99:5</p> <p>variability 29:6 69:9</p> <p>variable 53:2 68:5,7 95:20 99:12</p> <p>variables 93:16 95:7 101:5</p> <p>variation 72:19</p> <p>varied 14:19</p> <p>variety 26:21 33:3,17 41:21 43:12 44:19 45:1,10 48:20 50:17</p> <p>various 24:11 54:4 62:5</p>	<p>vast 109:1</p> <p>vector 134:9</p> <p>vectors 134:1,2,8</p> <p>verify 45:5 91:22</p> <p>versa 128:5</p> <p>version 53:18</p> <p>versus 55:6 57:3 93:17,20</p> <p>Veterinary 18:21 21:6</p> <p>via 7:8 114:9</p> <p>vibrate 5:18</p> <p>vice 128:5</p> <p>vigorously 133:14</p> <p>Vilsack 13:21 25:11</p> <p>Virginia 118:10</p> <p>virtual 30:18</p> <p>visible 7:5</p> <p>visibly 57:6</p> <p>vision 19:7 80:3,4,6,14,21 121:21 122:2</p> <p>visit 126:7</p> <p>volume 72:5,6 131:7</p> <p>voluntarily 117:7</p> <p>volunteer 125:7</p> <p>vulnerable 85:8</p> <hr/> <p style="text-align: center;">W</p> <hr/> <p>wait 71:12</p> <p>waiting 57:16 58:20,22 59:6,10 63:14 71:5</p> <p>walked 119:6</p>	<p>wandering 11:4</p> <p>Washington 36:22 79:17 118:14</p> <p>wasn't 11:15,16 13:19 26:7 94:22 96:19 102:6</p> <p>Watch 76:2 123:10</p> <p>watches 23:7</p> <p>watching 48:21</p> <p>water 5:22 76:2 123:10</p> <p>wave 6:10,16 17:14,15 65:13 66:3</p> <p>ways 8:11,22 29:20 30:2 33:4 39:4 77:9 116:8 119:19 122:22 141:15,17</p> <p>web 51:3 55:16</p> <p>webcast 7:1,8 8:19 30:15,17 78:11 145:21</p> <p>webcasting 6:21</p> <p>webcasts 31:3</p> <p>webinar 39:19</p> <p>website 6:20 7:14,17 30:13 33:1 38:15 46:11 108:20 111:14 112:12 131:21</p> <p>we'd 30:6 87:8 91:4</p> <p>Wednesday 1:10</p> <p>weed 89:3</p> <p>weeds 89:7</p> <p>week 15:4 39:1</p>
--	---	---	---

(866) 448 - DEPO

Capital Reporting Company
Stakeholder's Meeting 11-20-2013

Page 37

<p>136:19 weeks 7:14 119:11 welcome 3:2 5:2,5,8 16:13 17:5 104:14 146:6,7 we'll 5:4 6:16 8:16 9:4,5 10:3,6,7,10 18:7 25:2 38:4 39:22 52:1,5 66:5 78:12,15 85:16 86:3 88:2,3,4 89:15 90:2 105:12,13 106:3 123:7 135:2,6 147:10 Welland 131:1 well-funded 130:15 we're 6:21 7:7 8:8 9:7 11:13 13:11,12,16 14:21 15:9 16:9 19:18 23:14 24:20 26:3 27:19,20 28:1 29:1 30:20,22 31:13 32:16 37:8,13,21 38:10 46:15 48:17 49:3 50:10 52:20 54:2,14 55:9,17 59:13 60:20 61:13 63:15 64:3 65:5,20 66:1 67:15 71:4 72:12 76:11,19 81:2,3,21 83:11 84:10,22 85:1 86:2,5,9,10,12,1 5 87:1,4 88:2,18 89:2,5,14 91:16,17 92:16</p>	<p>94:15 97:17 100:1,22 101:15,17 105:8,16,17,19 106:5 107:9,21 108:8,10 109:9 115:17,19 116:14 120:19,22 123:6 130:5 135:17 136:19 138:13,17 139:14 140:16 143:15 145:20,22 147:5,6 we've 7:20 9:6,17 12:8 13:9,15 14:13,16 15:3,6,22 23:19 25:9,15 32:18 37:10 39:11 40:10 41:1 42:8 45:14 48:21 52:15,16 53:8 59:4 60:12 61:19 63:4 68:2 73:17,19 79:11 80:5,15 82:22 84:20,21 85:12,13,19 87:18,20 88:7 89:12,22 90:21 91:13 98:7 106:22 109:15 110:5,17 111:20 127:19 136:6 138:3,17 140:6,8,13,17,18 ,22 141:5,22 142:1 whatever 5:18,20 49:16 91:11 wheat 28:11 34:16</p>	<p>35:5 whenever 70:17 whereas 96:18 whether 44:11 73:16 74:4 98:13 109:15 125:19 127:5 140:3 141:3 146:1,2,17 white 11:4 whole 24:4 39:5 89:7 135:14 136:14 139:2 140:15 whom 148:2 who's 73:8,21 83:2 whose 148:4 wide 112:17 widely 129:22 wife 135:19 137:22 wild 110:12,21 Willing 123:8 window 43:21 windy 139:6 wise 74:13 wish 31:9 wishes 16:22 withdrawal 22:11 withdrawn 58:9,12 witness 148:4,6,9 wives 136:18 wonder 76:2 wonderful 21:16 wondering 123:10 work 10:17 14:6 15:3 16:8 22:4</p>	<p>23:18 30:2 32:9,15 36:7 37:8 38:20 39:13 40:6,19,22 42:5,8,9 47:1 51:1 58:9 60:9 74:22 76:4,19 77:6 79:12 80:17 81:1 84:9,19 85:9 86:5,8 87:4,12 89:15 91:5 93:17 100:21 104:16 125:10 130:15 136:16 141:14 worked 22:14 35:21 45:16,19 86:6 87:18 88:11 131:18 137:3 workflow 25:4 working 3:10 17:1,9 18:16 22:2,8 23:5 28:21 29:1 30:20,22 32:18 35:4,20 37:13 38:11,16 39:5 40:15 42:3 50:17 77:5 81:21 82:2 83:6,11,14,15,16 ,20,21 85:22 88:2 89:6 96:2 97:13,16 101:15 114:1 121:6 140:16 143:8 144:16 145:21 workload 132:12 workloads 86:12 works 17:4 36:4 74:1 107:10 137:2 138:22 139:15</p>
---	---	--	---

(866) 448 - DEPO

Capital Reporting Company
Stakeholder's Meeting 11-20-2013

<p>work's 15:16</p> <p>workshops 117:22 118:7,15 119:6,10,13</p> <p>world 39:8 46:1 48:4 73:6 138:12 140:17 141:1 143:6</p> <p>worlds 16:10</p> <p>worried 109:9</p> <p>worse 104:22</p> <p>wow 73:18</p> <p>wrap 46:12</p> <p>wrapping 34:22</p> <p>write 10:5 30:4</p> <p>written 8:12 10:1</p> <p>wrote 98:13,14</p> <hr/> <p style="text-align: center;">Y</p> <hr/> <p>yellowish 68:14,19</p> <p>yesterday 49:9 135:20</p> <p>yet 13:11 27:20 37:8 39:10 56:10 67:2 87:7 92:6,7 101:22 140:21</p> <p>York 21:17</p> <p>you'll 14:5 20:1 21:4 23:21 26:12,20 27:7 32:1 33:1 37:14 39:12,22 53:18 54:3 56:22 93:9 96:7</p> <p>Young 1:19 7:12 148:2,19</p> <p>yours 135:5 136:2</p> <p>yourself 8:7</p>	<p>you've 26:19 43:19 44:1 48:14 50:9 72:7 84:14 136:13</p> <hr/> <p style="text-align: center;">Z</p> <hr/> <p>zaprion 144:21</p> <p>zaprionus 144:11</p> <p>zero 113:16,17 128:15</p> <p>zone 109:16,17</p>		
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