

UNITED STATES DEPARTMENT OF AGRICULTURE (USDA)
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
(APHIS)

+ + + + +

BIOTECHNOLOGY REGULATORY SERVICES (BRS)

+ + + + +

STAKEHOLDER MEETING

+ + + + +

WEDNESDAY
NOVEMBER 15, 2017

+ + + + +

The Meeting convened in the Oklahoma City Memorial Conference Center, 4700 River Road, Riverdale, Maryland, at 1:00 p.m., Dick George, BRS Communications Branch Chief, presiding.

PRESENT

DICK GEORGE, BRS Communications Branch Chief
MIKE FIRKO, APHIS Deputy Administrator for BRS
IBRAHIM SHAQIR, APHIS Associate Deputy
Administrator for BRS
DAVID HERON, BRS Biological Scientist
CARRIE MCMAHON, Consumer Safety Officer, U.S.
Food and Drug Administration
BILL DOLEY, BRS Government Relations Specialist
SUBRAY HEGDE, Branch Chief, Plants Branch
ALAN PEARSON, Branch Chief, Plant Pests and
Protectants Branch
NATHAN YATES, Branch Chief, Compliance
Evaluation and Enforcement Branch
CHESSA HUFF-WOODARD, Branch Chief, Policy,
Program and International Collaboration
Branch
LINDA PARDOE, Lead IT Specialist

I N D E X

AGENDA ITEM:	PAGE:
WELCOME.3
BRS: REFLECTIONS ON FY17 AND A LOOK FORWARD TO FY188
"AM I REGULATED?" - BUSINESS PROCESS IMPROVEMENT REPORT	23
INTERNATIONAL OUTREACH FY17.	37
QUESTION AND ANSWER SESSION.	56
BIOTECHNOLOGY UPDATES FROM FDA	66
ENHANCING COMPLIANCE118
BIOTECHNOLOGY QUALITY MANAGEMENT SUPPORT PROGRAM127
NEW PERMITTING DATA SEARCH TOOL DEMONSTRATION138
COMMENTS AND QUESTIONS SESSION146
ADJOURN.174

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

2 (1:04 p.m.)

3 WELCOME

4 MR. GEORGE: Thank you. Good
5 afternoon. I'm Dick George, Communications
6 Branch Chief here at Biotechnology Regulatory
7 Services. I'd like to welcome you to our 2017
8 Stakeholder Meeting.

9 Each year at this meeting we get
10 feedback from you on how to make everything
11 better, and we do a lessons learned for the next
12 year. And last year somebody took me aside and
13 said, Hey, Dick, you know it's wrong with you
14 meeting, don't you?

15 And I was like, What?

16 And the person said, Well, I don't
17 know how to tell you this but I don't want to be
18 the bearer of bad news.

19 And I'm like, What? What? What is
20 it?

21 And finally they said, Well, Dick, the
22 meeting is kind of dull.

1 And I'm like, Dull? We have one
2 glorious PowerPoint after another for several
3 hours, hundreds of beautiful slides, some with
4 color-coded charts and graphs. Some pictures
5 even. Delivered by our highly-educated, deeply
6 knowledgeable scientists on guaranteed-to-please
7 subjects. Like, volunteer monitoring,
8 supplemental permit conditions, regulated articles
9 -- how could that be dull?

10 This person's like, Okay, Dick, don't
11 shoot the messenger.

12 But I took their comments to heart and
13 I resolved to spice it up this year with music.
14 And not just any music but the music of John
15 Philip Sousa. This music has energy and motion
16 and I don't know what it is, but I know what it
17 isn't. It isn't dull. So I hope you enjoy it.
18 We'll be getting to our music as we go in and out
19 of the breaks.

20 And that was Starts and Stripes
21 Forever, by the way, his biggest hit. But he had
22 numerous others.

1 A few housekeeping details. Please
2 set your cell phones to vibrate. We have coffee
3 and water on the table in the back. Please help
4 yourselves.

5 Down the hall, out this door to the
6 right, and then the first hallway to your left is
7 the cafeteria if you'd like to get something else
8 to eat or drink during our break.

9 As usual, we are webcasting our
10 meeting. So we must remember that we have people
11 who are not visible but nevertheless very much in
12 attendance.

13 I would ask all attendees here today
14 to wait until we get a microphone to you before
15 you make a comment or ask a question so that our
16 webinar audience can hear. And I would ask
17 everyone to please identify yourself and your
18 organization, if you represent one, before you
19 speak, whether you're here in person or via the
20 web.

21 We have a court reporter here today,
22 Toby Walter, the guy with that magnificent beard.

1 He will be making a transcript of this meeting
2 that will be posted to our website within a few
3 weeks. And that, again, is why we need you to
4 please always wait for a microphone before you
5 speak, and identify yourself. And spell your
6 name, especially if it's anything unusual or
7 complicated, so we get it right in the
8 transcript.

9 With one exception that I'll get to in
10 a minute, we ask that you please hold your
11 questions until each speaker has completed their
12 presentation. Then, as I mentioned for those of
13 you in the room, wait for a microphone before you
14 speak so your words will be recorded.

15 Those of you online, well, we're kind
16 of working out the technical details right now,
17 but if you're online and would like to make a
18 comment, there will be instructions in the
19 webinar box. We'll communicate those
20 instructions to you.

21 It may be the same as we've done in
22 the past, which would be press 1, then 0 on your

1 telephone keypad. But it might be a little
2 different. That depends on how we work out this
3 little technical detail that we're working on at
4 the moment.

5 But if you're online and you'd like to
6 ask a question or comment when we come to that
7 part of the meeting, please refer to your webinar
8 where there will be instructions on how to do
9 that.

10 There's also a comment box on the
11 webcast where you can put a comment and hit
12 "Enter" and send that to us, and then we have
13 someone monitoring that and they will get that to
14 us.

15 Also, we have time allotted at the end
16 of the day for comments and questions. So if we
17 run short of time at the end of the presentation
18 we have time then to take those questions.

19 We even have an old fashioned comment
20 box in the back of the room if you'd like to
21 leave us a written comment. We're glad to have
22 that as well.

1 One last thing. After the meeting
2 you'll receive an email questionnaire about this
3 meeting. If you would, please just take a few
4 minutes to fill that out. We welcome your input.

5 So, let's get started. At this time,
6 to take a look at the year just past and the year
7 to come, I'd like to introduce our APHIS Deputy
8 Administrator for BRS Mike Firko.

9 For Mike's segment only, please hold
10 your questions until our longer Q&A period at the
11 end of the day where we'll have more time for
12 questions, comments, and discussion.

13 BRS: REFLECTIONS ON FY17

14 AND A LOOK FORWARD TO FY18

15 MR. FIRKO: Thank you, Dick.

16 Can folks hear me in the back? Is my
17 mike okay up here? Okay, good.

18 Dick, I'm the first one that's going
19 to say I'm going to violate your policy: I'm not
20 going to put my personal phone on vibrate, I'm
21 going to start a 30-minute timer right now so I
22 know when I need to shut up. I tend to run on.

1 MR. GEORGE: I can help with it.

2 MR. FIRKO: Okay, you'll help me with
3 that. Okay. But I need the slide program. Up
4 here?

5 Okay, I want to start with Secretary
6 Purdue's USDA model, a relatively new model that
7 he's been talking to everyone about within USDA
8 and outside. Do right and feed everyone. That's
9 a model that is very easy for us to live by here
10 in APHIS and BRS. So you'll probably be hearing
11 that a lot over the next week.

12 I want to start with a report of some
13 of our regulatory activities over the past year.
14 So this slide carves out authorizations and
15 release sites by crop. And you'll notice this
16 section only has corn, soy, and cotton. And
17 you'll see why in a minute. Corn, soy, and
18 cotton in terms of the number of authorizations
19 that we've issued and the number of release sites
20 where outdoor plantings of genetically engineered
21 regulated crops are conducted. 94 percent of all
22 sites are corn, soy, or cotton, and 71 percent of

1 the authorizations.

2 They're not on this chart because they
3 would be so far high that you wouldn't be able to
4 see them. You see that the highest for
5 everything other than these crops, 50, and the
6 number of release sites for cotton is 162 and for
7 corn it's 2000-plus. So that lets you see how
8 corn, soy, and cotton dominate the regulatory
9 work that we do. And it gives you a feel for
10 some of the other major crops that we regulate.

11 Other is a whole variety of different
12 things that occur in different numbers. If you
13 have questions about what some of those are you
14 can speak to one of our branch chiefs in the
15 Permitting Group, Subray Hegde or Alan Pearson,
16 and they can give you more details about this.

17 So this is pretty busy, but I also
18 wanted to give you a breakdown with respect to
19 notifications which can be for import only,
20 interstate movement only, or release field
21 trials. And this category I've lumped
22 notifications that are for interstate movement

1 and release combined, and for those which are
2 just for release.

3 And you see that the total number of
4 authorization requests that we received,
5 notifications, was 801. 13 percent of those were
6 withdrawn, 2 are still pending. I collected
7 these data several weeks ago. Some of that 2
8 percent has been done, but we've received new
9 requests since then. So it's a snapshot in time.

10 3 percent were denied for one reason
11 for another, and 82 percent were authorized. But
12 you see the main reason that a notification is
13 not authorized is because it's ultimately
14 withdrawn.

15 So this is for notifications.

16 For permits the pattern is similar.
17 The numbers are much smaller. The total number
18 of permit applications we received was 408. 17
19 percent withdrawn; 9 percent pending.

20 And, of course, the time frame for
21 notifications is much smaller for permits of 120
22 days. So at any one time you've got a higher

1 proportion that are pending.

2 Some of these have been processed.
3 And we've received new ones during that time. 9
4 percent are pending; 2 percent were denied; 71
5 total were authorized.

6 And, again, the primary reason an
7 application is not authorized is it's withdrawn.

8 This gives you summary data for just
9 releases. And same pattern I've been showing you
10 for the past couple of years. The numbers are
11 down a little bit. The number of release
12 authorizations that we issued: 356 at 3,724
13 sites, and 45,000-plus different genetic
14 construct for crop-trait combinations. A couple
15 different ways that you can characterize that.

16 So I have to mention Puerto Rico a
17 little bit. Many of the folks in the room have
18 activities in Puerto Rico. We have a BRS
19 employee stationed permanently in Puerto Rico.
20 He lives there. He's lived there for many years.
21 He's very active with the field trials that occur
22 in Puerto Rico. And obviously this was

1 devastating for our activities and devastating
2 for any kind of agriculture in Puerto Rico.

3 Our goal is to keep very good contact
4 with all the folks conducting field trials. We
5 have reports from everyone conducting field
6 trials in Puerto Rico.

7 Our employee in Puerto Rico Victor
8 Valentin has not been able to visit every site.
9 There are gasoline issues. It's tough to get
10 gasoline. Some of the roads are not clear enough
11 to travel yet. There's still a lot of, a lot of
12 issues with getting around in Puerto Rico. But
13 he is getting to the different locations as soon
14 as he can.

15 So, let's talk about various
16 accomplishments over fiscal year 2017. First, we
17 published a proposed rule for revisions to 7
18 C.F.R. 340. The abbreviation of 7 C.F.R. Part
19 340, the whole title is listed there. That
20 proposed rule was published January 19th, 2017.
21 Interesting date I know. That's when it was
22 published.

1 We conducted three public meetings
2 during June in Kansas City, Missouri; Davis,
3 California; and here in this room. We received
4 208 comments. And you'll, you'll hear us refer
5 to these things differently. Two hundred and
6 eight is the number of individual submissions
7 that were given. But the number of individuals
8 who commented, either by signing documents that a
9 number of people signed also, that's more in the
10 order of tens of thousands. But the number of
11 individual submissions was about 208.

12 There was a specific request to
13 provide some feedback on the comments that we
14 received. So I have some pretty general comments
15 about that. I should say that all of these
16 comments are available to the public on
17 regulations.gov. They're still up. So you can
18 go in and look at each of these, do your own
19 assessments, your own analyses.

20 Here are some of my general
21 assessments. Many of the comments did praise
22 APHIS for acknowledging and dealing with advances

1 in science.

2 For the Noxious Weed Authority it was
3 about half and half. About half said, no, you
4 shouldn't do that. And about half said not only
5 yes, but you need to do a lot more with it.
6 There was a lot of concern about the up-front
7 risk assessment that we proposed.

8 And as is typical in a biotech
9 situation, there was concern about the new scope
10 of regulations, both with respect to it
11 constituting under-regulation, and with respect
12 to it constituting over-regulation. And there
13 was concern about too much regulatory relief.

14 So another accomplishment was we
15 withdrew the proposed rule last week. I was out
16 in my cabin in New Mexico. And the reasons for
17 the withdrawal, two primary reasons, because of
18 comments that were received. As is typical, very
19 different viewpoints on the proposed rule. And
20 an overall interest in additional stakeholder
21 engagement.

22 So, other accomplishments. During the

1 fiscal year we granted deregulation to three
2 requests: a product from Simplot, a potato with
3 late blight resistance and low acrylamide. We
4 did that in eight months. It was an extension.

5 We granted non-regulated status to the
6 Scotts/Monsanto glyphosate resistant creeping
7 bentgrass. And even though that was an
8 Environmental Impact Statement we did that in 15
9 months, which is the time that we -- that was our
10 targeted time for Path 2 with an environmental
11 assessment. So we did that in very good time.

12 And then the most recent one was a
13 Bayer male sterile/glufosinate resistant canola;
14 11 months. That also was an extension, but
15 because of the age of the NEPA documentation that
16 existed for that particular deregulation we did a
17 new EA on that to make sure that we had the most
18 current information in the environmental
19 assessment.

20 So we're going to be hearing more
21 about this later on perhaps, but we are working
22 very closely with FDA on an education and

1 outreach project. There was not only authority
2 but funding provided by Congress to FDA for this
3 work.

4 Those of you who listened in to EPA,
5 FDA, and APHIS testifying before the Senate Ag
6 Committee a few years ago saw those folks wag
7 their finger at all three of us, why aren't you
8 doing more to educate the public about genetic
9 engineering and genetically engineered food, and
10 things like that. So in the most recent
11 appropriations they gave money to FDA to lead
12 that effort.

13 And, well, here I'll say that there
14 were public meetings November 7th and yesterday.
15 Yesterday in San Francisco, last week in
16 Charlotte. And Doug McKalip, who is a new BRS
17 staff member who is in the audience, attended
18 both of those. I'm sure he'd be happy to talk to
19 you about how those meetings went if you didn't
20 listen in, give you a report about them.

21 This year we, we in APHIS, really
22 strengthened our relationship with the

1 Agricultural Research Service. And it's not just
2 biotechnology regulatory services, it's across
3 APHIS. Our collaborations with ARS over the
4 years, maybe haphazard is a little too strong a
5 term, but it hasn't been as, as formal as would
6 be appropriate given the scope of APHIS programs.

7 So Ibrahim Shaqir, our new Associate
8 Deputy Administrator, is, since he's from ARS, is
9 a natural fit for helping us reinvigorate our
10 collaboration with ARS. And others in APHIS are
11 working very closely with ARS to make sure that
12 the research that ARS is doing in support of
13 APHIS mission areas is exactly what we need. And
14 there's good management across to make sure that
15 the work that they're doing is what we need, and
16 the things we need we're getting.

17 So that's a big effort that we've been
18 working on for the last year or so. And it's
19 working out very well.

20 You'll be hearing later on from Linda
21 Pardoe about the new search tool that APHIS
22 created for release data. Many of you for years

1 have been accessing a site that we funded that
2 was maintained by Virginia Tech. All of the data
3 that were presented on that website are still on
4 our websites. But we created a new tool in an
5 effort to emulate some of the services that
6 Virginia Tech had provided. We expect to
7 continue making improvements to that.

8 Right now it's a little low on the
9 graphics. We're going to increase the graphics
10 and the summary data and things like that over
11 time. But everything that was available on the
12 Virginia Tech site remained available during the
13 transmission.

14 GE petunia. I've got pictures for
15 this one. So actually let me tell you about
16 these pictures first of all.

17 The day after we first became aware of
18 this Rachel Windsberg, who is in the audience,
19 went to a graduation ceremony. And what did she
20 see on the table at this graduation ceremony,
21 these beautiful orange petunias. And if I'm not
22 mistaken, I think these turned out to be

1 genetically engineered. She really wanted to
2 take a sample but her boyfriend wouldn't let her
3 apparently.

4 But this is, this is a big example of
5 a non-regulatory solution that APHIS took. There
6 was no APHIS "investigation." Now, I've got that
7 word in quotes because in APHIS this term has a
8 very specific meaning. It means that we went to
9 Investigative and Enforcement Services. And the
10 Director's sitting here. I see you there, Steve.
11 It means I went to Steve and said, Steve, we need
12 an investigation into this.

13 And he gets his folks with badges out
14 and they go make visits and they interviewed
15 people. And they got subpoenas. He didn't do
16 anything like that.

17 We sometimes do what's called fact
18 finding. We didn't even do that.

19 What we did was from day one we
20 engaged with the petunia industry and we worked
21 very closely with them while they withdrew
22 unauthorized GE petunias from the marketplace.

1 And it went really well. They took care of all
2 of that.

3 A few days into this they asked us,
4 What should we do with GE petunias that we find?

5 And we said, Well, you should destroy
6 them. Either that or get a permit, you know, so
7 you can move them around. Because we'll give you
8 a permit for these things.

9 And they said, No, we want to destroy
10 them. How should we do that?

11 So at their request we put together
12 this destruction information, which has been
13 posted on our website. But, again, that was at
14 the request of the industry. There were no
15 regulatory actions whatsoever taken by APHIS.
16 There was no mandated destruction. There was
17 nothing like that. The industry said they would
18 take care of it, and they did.

19 I just show this. You know, at the
20 beginning we, and I think a lot of folks, thought
21 this was all about orange petunias. And the way
22 that this was originally found was somebody in

1 Finland I think was walking down the street, a
2 scientist or a petunia breeder or somebody, and
3 he saw these orange petunias. Wait a minute,
4 there's no such thing as an orange petunia.

5 So they started looking into this.
6 What it turned out is that the genetics for this
7 color had been moved into a large number of
8 different varieties, and they range all the way
9 from orange to a pretty deep purple. These are
10 all genetically engineered. None of them are on
11 the market in the United States. Like I said,
12 the industry chose to pull those from the market.

13 So this year we updated BQMS, which
14 now has a slightly different title. The word
15 "system" has been replaced by "support."
16 Biotechnology Quality Management Support. There
17 will be a presentation about this a little bit
18 later from Chessa Huff-Woodard.

19 We made progress on eFile, APHIS
20 eFile. This will be a replacement to ePermits.
21 I don't have a date for you about when that might
22 be rolled out. Who in the audience thinks that

1 huge IT projects happen on time and under budget?
2 Anybody? Right; I don't. Yep, yep.

3 Progress is being made though. We're
4 still heading in that direction. The system is
5 looking better every day. Thanks to everyone who
6 participated in the demo that we provided and the
7 feedback that we received. We're going to
8 continue working on that.

9 "AM I REGULATED?" -

10 BUSINESS PROCESS IMPROVEMENT REPORT

11 MR. FIRKO: We also had a formal
12 business process improvement. It's still ongoing
13 for our Am I Regulated process. I'll show you
14 some data in the few minutes about our Am I
15 Regulated process and you'll see the numbers that
16 we deal with.

17 And, you know, several years ago some
18 of those things were two, three, maybe even four
19 years old. They'd been -- we'd had the request
20 in house for a long time.

21 About two years ago Sid Abel, who's
22 somewhere, our Assistant Deputy Administrator who

1 sort of manages this for us, said, you know, I'm
2 really unhappy with the fact that these are
3 taking too long. So we started doing a lot of
4 work to speed these up. Our averages over the
5 last year or two have been much better. But
6 we're really trying to take it as far as we can
7 to improve the process and to make it as timely
8 as possible.

9 You can see all of the answers that
10 we've given since 2011 on our web page. Anybody
11 who gets my business card will notice that on the
12 back is the URL for the Am I Regulated site. And
13 there's cards on the back table, too, that
14 provide the URL to the Am I Regulated site. So
15 you can see all the incomings that we've
16 responded to over the last six years and all of
17 our outgoing responses.

18 GE diamondback moth. So, I don't know
19 how many of you are aware of this damaging pest.
20 It's a major pest in New York and many other
21 states. And some folks at Cornell University
22 have been working with a genetically engineered

1 Diamondback moth for a few years. And this year
2 we completed an environmental assessment in
3 support of a permit that we issued to a professor
4 at, at Cornell, to do full-scale releases of
5 genetically engineered Diamondback moths on the
6 campus, Cornell University, Geneva.

7 The bottom bit shows damage. But
8 needless to say, this was fairly controversial.
9 You can think of this as biological confinement.
10 It has a sterility gene in it. That's the whole
11 purpose. Some people think of this as a form of
12 biological control.

13 The field season is over in New York
14 at this point, but the releases did take place
15 this summer under permit.

16 Well, eucalyptus, freeze tolerant
17 eucalyptus. So this is, as you'll see in a few
18 minutes, this is a petition that we received in
19 2011. About two-and-a-half years ago we sent our
20 draft EIS and our biological evaluation under the
21 Endangered Species Act over to Fish and Wildlife
22 Service. And this year we decided to just go

1 ahead and publish that draft EIS.

2 We're still waiting to hear from Fish
3 and Wildlife Service, still waiting for their
4 biological opinion.

5 Our decision about whether or not to
6 deregulate freeze tolerant eucalyptus will be
7 based on whether or not it is a plant pest. But
8 I'm probably subject to more laws than any of you
9 are, and I have to complete the NEPA process
10 before we can complete our deregulation.

11 This year also we initiated an
12 Environmental Impact Statement and a Pest Risk
13 Assessment in support of a permit for Florida-
14 wide release of genetically engineered citrus
15 tristeza virus as a biological control of citrus
16 greening disease.

17 Now, as you all know, too, citrus
18 greening is just a horrendous disease of citrus.
19 We've been hearing from the citrus industry for
20 the last couple years that they're struggling to
21 keep their head above water.

22 APHIS has an annual meeting with

1 members from the citrus industry sector. We had
2 one just a few weeks ago. And, you know, they
3 were just starting to get their head above ground
4 a little bit and then Hurricane Irma hit. And
5 that sort of knocked them back down again.

6 They are in desperate need of some new
7 ways to control citrus greening. My commitment
8 to the developers of the genetically engineered
9 citrus tristeza virus is we will not hold you up.
10 In fact, we've had to slow down because the
11 science hasn't allowed them to proceed as quickly
12 as they would like to have proceeded.

13 We originally intended to issue them
14 a permit during calendar year 2018. Now they're
15 saying there's no way they're going to be ready
16 until January of '19 at the very earliest. So we
17 don't want to complete all of our analyses too
18 far ahead of them. We want to make sure our
19 Environmental Impact Statement and our Pest Risk
20 Assessment are based on the most current
21 information possible at the time of permit
22 issuance.

1 The permit that we anticipate issuing
2 is for release anywhere in Florida. It covers
3 all counties in Florida. Florida is in desperate
4 need of some relief from citrus greening disease.
5 Initial data indicate that this genetically
6 engineered citrus tristeza virus, which will
7 essentially deliver a spinach defense gene to the
8 citrus trees, notice that this is not a
9 genetically engineered tree, think of it as kind
10 of a therapy. Genetically engineered trees are
11 much further down the road.

12 I spoke with all of the labs who are
13 doing regulated work to create a genetically
14 engineered tree for resistance to citrus
15 greening. Spoke to all of them this year. The
16 most optimistic estimate I got was five years
17 from now. So that's a little ways off. This GE
18 CTV is a little bit, it's going to happen a
19 little bit sooner, and not too soon for the
20 citrus industry in Florida, that's for sure.

21 There's a whole section after me about
22 our international engagements, our extensive

1 international engagements that we do throughout
2 the year. I just highlight here a couple of the
3 main ones: OECD. Sally McCammon on our staff and
4 several others on our staff are very active
5 working with all of the OECD countries.

6 Typically about 40 countries participate in these
7 meetings, these government-to-government meetings
8 three or four times a year.

9 We talk about gene editing. We talk
10 about environmental considerations for risk
11 assessment. Ibrahim has attended some of those.
12 I attended some of those in my previous position.

13 Let me look at my time. How am I
14 doing? Five minutes. My timer, where's my
15 timer. I don't have my -- see, I left my clock.

16 And, of course, we have annual face-
17 to-face with China. And we have quarterly
18 meetings with Canada and Mexico, and annual face-
19 to-face with the Trilateral Technical Working
20 Group.

21 APHIS Weed Risk Assessment. So, last
22 year in the afternoon of the stakeholder meeting

1 we, we showed you Version 4.0 or our weed risk
2 assessment tool. Thank you very much for all of
3 the comments that you provided. We now have
4 Version 5.

5 You know, there's papers showing up in
6 the scientific literature now, a Weed Science
7 Society of America publication, you know, and
8 people are saying, you know, these tools that are
9 out there for weed risk assessment, they really
10 don't help with the GE plants. And something
11 else is really needed.

12 So we're doing our best in the APHIS
13 to fill that gap.

14 So, back to Am I Regulated a little
15 bit. That's the short version of does my GE
16 organism meet the definition of a regulated
17 article under 7 C.F.R. 340. I reported last year
18 on the 13 data -- 15 data, we did 13 of them in
19 2016. We did 13 this year. In '17 we answered
20 14 of those requests. All of those are up on the
21 web page. We've already done some -- Did we do
22 one in '18 yet? No, not in '18 yet. We better

1 get busy.

2 We currently have six that have, that
3 are in house, and they've all been received
4 recently. So we're, we continue to be as timely
5 as we can on these.

6 Let me talk a little bit about
7 authorizations for products created through
8 genome editing. Now, keep in mind that these
9 authorizations were issued because somebody asked
10 us to be regulated. They came to us and said,
11 Here's a notification. I want authorization.
12 Or, Here's a permit application. I want
13 authorization.

14 So these are situations when people
15 asked to be regulated. This is a busy slide, but
16 really what I wanted to show you here is that
17 starting over on the right we've got our first
18 zinc finger nuclease product in 2008. It peaked
19 in '12 or '13. Haven't seen any for a couple of
20 years.

21 For TALENs, we got our first one in
22 2011. Maybe it peaked in '14. It does seem to

1 be falling off.

2 Of course CRISPR is a totally
3 different issue.

4 Now, these show per year. The next
5 slide is cumulative, and you can see that CRISPR
6 is just taken off and shows no sign of slowing
7 down. We all know the potential for CRISPRs.

8 We do, however, instead of people
9 coming to us saying, "I want to be regulated,
10 here's my permit application," we also get people
11 saying, "I made this thing. I used CRISPR
12 techniques. Is this regulated?"

13 So we've had 19 requests, not just for
14 CRISPR but also for meganuclease, zinc finger,
15 TALEN. We have so far answered 16 of those. All
16 of the 16 have been, no, you're not regulated.

17 So we're -- we've really stretched
18 these. You know, 10 years ago our answer might
19 have been, yes, you are regulated. We've taken
20 some novel approaches to these. And all of these
21 responses are available on our web page. I will
22 note, however, that all of these have been SDN-1.

1 I know that's a lot of jargon there
2 but it has meaning for many folks. Any of the
3 folks in biotech can talk to you about those if
4 you're interested.

5 The bottom just shows some of the
6 recent products that we have done.

7 So, looking forward to '18, APHIS'
8 primary mission is to protect animal and plant
9 health. In BRS it's protecting plant health.
10 That drives everything we do. Our authority
11 comes from the Plant Protection Act, so this is
12 the first and foremost consideration in our
13 regulatory activity.

14 We will continue to improve our
15 inspection process both with respect to what we
16 inspect, how we inspect it, how we respond to
17 findings. And you're going to be hearing a
18 little bit more about that from Nate Yates a
19 little bit later in the session here.

20 We currently have five petitions for
21 non-regulated status. Our old standby, ArborGen
22 freeze tolerant eucalyptus. I would dearly love

1 to see this done before I retire. Every week I
2 get a little more depressed about that.

3 Bayer herbicide resistant cotton,
4 that's currently out for 60-day comment. Closes
5 26th December.

6 This morning we published for comment
7 a petition from Verdeca for an increased yield
8 soybean. And we received two additional
9 recently that have not yet been published. We
10 anticipate that the petitions will be published
11 for public comment very soon.

12 You know, we've got that one from
13 2011. Everything else we've got is six months
14 old.

15 There's my 30 minutes, Dick. And I
16 think I'm pretty close.

17 So we, I think we're doing a good job
18 of living up to the commitments we've made with
19 respect to giving answers to petitions quickly.

20 We're going to continue to improve
21 APHIS risk assessment for both plant pests and
22 noxious weeds. We work very closely with PPQ,

1 the largest part of APHIS. And the other part of
2 APHIS that works pursuant to the Plant Protection
3 Act and worries about plant health, we work very
4 closely with PPQ on both of these issues.

5 We've been improving permit
6 conditions. We've had a very active program to
7 improve those, both in terms of transparency,
8 inspectability, et cetera, and we'll continue to
9 do that.

10 I don't think we've talked about this
11 before, but we've been systematizing our use of
12 IT solutions for FOIA requests in the production
13 of administrative records. I mean, in this day
14 and age, you know, when there's 9 million emails
15 that might be germane to a particular topic you
16 can't rely on human beings to be going through
17 all of those.

18 We're using eDiscovery products, in
19 particular a product called Clearwell. BRS has
20 been the leader on this. We've now been training
21 the Office of General Counsel, three or four
22 other APHIS programs like PPQ and Wildlife

1 Services. We've been training the agricultural
2 marketing service on the use of this technology.

3 Everybody sees the value of it. It
4 allows us to be much more responsive and much
5 more-timely when we get FOIA requests or when we
6 have to create an administrative record.

7 And we will absolutely continue our
8 intensive program of meeting with and hosting
9 international regulatory counterparts, trading
10 partners.

11 Okay, we'll have questions and answers
12 at the end. Thank you.

13 MR. GEORGE: Thank you, Mike. If you
14 have questions or comments for Mike just jot them
15 down and we'll get to them later when we have a
16 little more time.

17 I do want to mention that to all of
18 our speakers there's water up here. Please help
19 yourselves when you get thirsty. Under the
20 podium and also behind me.

21 We have 70 people on the webinar which
22 I think is a new record. So, welcome to

1 everyone, those of you in the room and also I
2 want to make sure those of you that are listening
3 in know this. We're very aware that you're with
4 us and we're very glad that you are.

5 It's been a busy year not only on the
6 domestic front but also internationally. Here to
7 tell us about it are two members of our
8 international team. First, our APHIS Associate
9 Deputy Administrator Ibrahim Shaqir, who heads up
10 our International Group, will provide an
11 overview, followed by BRS Biological Scientist
12 Dave Heron, who will give more detail about the
13 international meetings themselves and the
14 subjects other companies -- other countries want
15 to talk to us about, as well as global groups BRS
16 participates in and the subjects being discussed
17 there.

18 First, Ibrahim.

19 INTERNATIONAL OUTREACH FY17

20 MR. SHAQIR: Thank you, Dick. Can you
21 hear me? I can use this? Okay, very good.

22 Thank you very much for the

1 introduction. And it's good to be here with you
2 today this afternoon.

3 And so you asked us and we're here to
4 basically provide you with an overview of some of
5 the fantastic work we do here at BRS domestically
6 and, of course, we're going to elaborate on the
7 international engagements that we do.

8 So we have a great team within BRS
9 that works exclusively engaging with our agencies
10 within government that deals with all aspects of
11 agricultural issues, particularly on the biotech
12 side and trade and so on. So, we work closely
13 with FDS; USTR in DOS, Department of State; FDA;
14 EPA; and then the coordinated framework.

15 So, we do really go above and beyond
16 in terms of what we do, how we engage
17 internationally to ensure that we are conveying
18 basically the great work when it comes to
19 regulatory approaches and so on.

20 So what I will do is to briefly give
21 you an overview, quick overview of some of the
22 international engagements and approaches we have

1 here by way of conducting our engagement. And
2 then Dr. Dave Heron will elaborate more on some
3 of the specifics. So I hope that's not, you
4 know, prosaic. And I hope that it's engaging and
5 you find it informative. Okay?

6 So, with that I -- the way we approach
7 international engagements is, you know, as Dr.
8 Firko mentioned, our core main area of interest
9 internationally is to ensure that we're
10 protecting plant health. So we engage
11 internationally by providing, having, you know,
12 coordinated efforts when it comes to engagement
13 and conveying and collaborating on the
14 international side with our friends who do a
15 fantastic job communicating and ensuring that
16 working with our subject matter experts to ensure
17 the plants are protected here in the U.S. and
18 abroad when it comes to our review of the right
19 course.

20 The other thing that we do, and we do
21 very well, is to support international trade. As
22 I mentioned, we work closely with sister agencies

1 within government: Foreign Ag Service. IS, we
2 also have a strong international programs within
3 APHIS. We work closely with USTR, the Department
4 of State and, as I mentioned, the sister agencies
5 within government that are under the coordinated
6 framework with FDA and EPA.

7 We do also provide great deal of
8 interaction and capacity building when it comes
9 to training and outreach. And Dr. Heron, Dave,
10 will provide you great detail on some of these
11 activities throughout the year.

12 So, with that I will go ahead.

13 So, when it comes to the plant,
14 protecting plant health, as I mentioned we do
15 regularly engage with our, with partners from all
16 of, several countries that are interested in
17 learning about how we do -- how we approach our
18 regulatory aspect of ensuring that basically, you
19 know, our friends meet on a regular basis here
20 and overseas to help other countries understand
21 how we regulate this on science and risk and help
22 them build the capacity to regulate based on the

1 same principles.

2 And I think I do believe that this is
3 important that we share and we have an open and
4 transparent way of communicating so as to ensure
5 there is no ambiguous or lack of understanding on
6 how we do and conduct our business.

7 The technical and regulatory
8 information sharing, and I think this is what
9 works by multiple ways. We do, as part of Mike
10 mentioned the OECD, that's an important global
11 platform, that we do take advantage of having Dr.
12 Sal McCammon from our team, she chairs the Global
13 Harmonization. And we make sure that we are
14 basically conveying and sharing and learning
15 about the other and conveying our thinking on
16 things that are of concern to us as a regulatory
17 agency and learning from other partner countries
18 on the things of concern to them, and also share
19 and disseminate information.

20 Looking at the horizon scanning
21 ensuring that our system is based BRS to what,
22 you know, international outreach can help with

1 the regulatory gain information about what traits
2 and products are entering the foreign regulatory
3 system which gives an early understanding of what
4 might be reaching our shores in the future. And
5 that's an important way to basically have an
6 understanding and be proactive in our approach.

7 So, as I mentioned, the harmonization
8 of biotech regulatory system we take advantage of
9 our multiple engagements on the international
10 side. And we have to ensure that we have shared,
11 you know, open and based on our deciding
12 practical science.

13 I also identify practical solutions to
14 barriers to trade. And that, so as much as
15 possible we do have our team tries to mitigate
16 some of these important issues. And I do believe
17 that they will elaborate on some of these things.

18 Information sharing with foreign
19 counterparts that I, you know, as you can see
20 they're all basically cross and complement each
21 other in many ways.

22 So, finally I just want to mention, I

1 mentioned earlier on that the visitors that one
2 of the important things that we do is of course
3 enhancing capacities in countries. And we do so
4 by participating and inviting regulators from
5 other nations to come to the U.S. and participate
6 with us. And this is coordinated effort with our
7 Foreign Ag Service, also with International
8 Services here within APHIS, and other sectors and
9 private entities in the U.S.

10 So we have about 17 countries from --
11 we have visitors from 17 countries with over 107
12 visitors. And I find that this is really a
13 fantastic opportunity for us to maintain
14 engagement. We've had visitors that actually
15 provide us with questions in advance on
16 particular issues that visited. We had visitors
17 here from Japan, and they are very much
18 interested in our things, also of great interest
19 to us. And so we had an open discussion about
20 some of the issues that interested them and
21 concern.

22 Visitors from China. We've had

1 multiple visitors from China, South Korea. And
2 Dave will elaborate on some of that.

3 Finally I will mention, also,
4 something about we talked about our engagement
5 and the cross-collaboration with the TTWG, with
6 the Trilateral Technical Working Group on
7 Biotech. That's with Mexico and Canada. And
8 through that engagement it takes basically great
9 pride in sharing with our trading partners.

10 With the Canadians, for example, they
11 were very much interested in our extension
12 process we have here at BRS. We shared that with
13 them in 2016 at the 2016 Annual Meeting. And now
14 we are at a point where that meeting they might
15 think of adopting this system approach in the
16 near future.

17 They also asked about the Am I
18 Regulated process. And we shared our Am I
19 Regulated process last year. And this was of
20 great interest to both Canada and Mexico.

21 So with that I'll just, as I
22 mentioned, I'd just give you a quick update here.

1 And Dave will give you much more detailed
2 information about some of the specific activities
3 and initiatives we have in place.

4 Thank you.

5 MR. HERON: Thanks, Ibrahim, and hello
6 to everyone. As Ibrahim said, I'm going to go
7 into a little bit more detail on some of these
8 activities and the topics that we cover in the
9 international outreach.

10 In the activities area these three
11 main areas come into play: capacity building with
12 foreign government; bilateral and trilateral
13 working groups; and support also for
14 international trade.

15 The foreign government capacity
16 building you'll see ranges from relatively simple
17 short-term to longer, more intensive interaction.
18 But when we look at the visitors -- and Ibrahim
19 gave you the total, 107 people from 17 different
20 countries in the past year, we have this
21 interesting diversity among the people who come
22 to see us.

1 We have legislators, parliamentarians.
2 We have government regulatory officials who are
3 responsible for implementing their national
4 system. We have scientists, both people engaged
5 in the research and development, and also
6 scientists from countries who are called upon to
7 serve on advisory committees or in review
8 committees, interested in understanding both the
9 interface between regulations and their work, and
10 then also how they would work as part of a
11 government that has to essentially borrow
12 scientists to periodically serve on review
13 committees, unlike the luxury that we've had in
14 the United States to have permanent and full-time
15 employees for our scientific reviewers in our
16 agencies, in APHIS, EPA, and FDA.

17 We also have a lot of interest in the
18 visitors with importers, people involved in grain
19 trade. We know that agricultural products are in
20 an international market, so they're interesting
21 in understanding how the U.S. system works on a
22 day-to-day practical basis.

1 And we still are getting visitors,
2 journalists, public relations people in
3 government. And this percentage has gone down in
4 recent years, but we still get a few people who
5 are interested in communicating the complex
6 issues in ways that the general public can
7 follow.

8 The types of topic that we cover, we
9 run the gamut. Most of them are focused on the
10 role that a government agency plays. In our
11 case, our role is looking at the safety. And so
12 we're looking at the regulatory tools that
13 governments are using, whether they're using
14 regulations or guidelines. The implications for
15 if you have regulations and binding requirements.
16 How do you verify compliance with those
17 requirements? And how this becomes a dynamic
18 interaction when countries are looking about how
19 this would be set up and implemented on a day-to-
20 day basis in their country.

21 Regardless of the regulatory approach
22 with regulations or guidelines, the issue of

1 safety and how it's evaluated is -- comes up in
2 virtually every new technology and biotechnology,
3 with no, no exception there.

4 We typically are interacting with
5 people at this level perhaps more frequently in
6 workshops that we're involved with, and in some
7 cases when we have visitors, especially the
8 Japanese visitors that come every summer. With
9 the regulatory agencies and their researchers who
10 serve on their review panels we get a chance to
11 dig into some of the details on how our risk
12 assessments are done.

13 And the third major area for the topic
14 concerns the international obligations the
15 countries need to keep in mind when they're
16 developing and implementing their domestic
17 systems. So most countries have obligations
18 under international agreements such as those
19 under the World Trade Organization, and how the
20 domestic measures fit into those international
21 obligations is another topic that's been of great
22 interest.

1 And you'll see some of these threads
2 through some of the other activities I'll be
3 talking about today.

4 In years past we did a top ten number
5 of questions. I've shortened the list this year
6 just to give you a little bit of a flavor of the
7 types of questions that we get from visitors.
8 And perhaps the one that is most surprising to
9 Americans is the question Do Americans eat food
10 from genetically modified plants?

11 And there's widespread misinformation
12 around the world that the U.S. doesn't actually
13 eat this. They may feed it to their animals or
14 they export it, but we don't eat it. So we
15 always make sure that even if groups are a little
16 shy about bringing this question up we make sure
17 that we provide this information when we're
18 meeting with them.

19 The other question that is of great
20 interest is the way that our three agencies,
21 APHIS, EPA, and FDA coordinate with one another
22 and how does this relate to the legal structure

1 that we're operating under. We're operating
2 under separate statutes. And yet in describing
3 the coordinated framework from over 30 years ago
4 the agencies will have opportunities where
5 there's some overlap and need for coordination.

6 And the fact that I think something
7 that was not foreseen 30 years ago, that the
8 agencies would be able to do so much in a
9 collaborative fashion and not require some body
10 above us in the executive branch to force us to
11 get together.

12 This is always of great interest
13 because this is the problem in most governments
14 with the stovepiping, with one ministry not
15 interacting well or talking well with others.

16 The question always comes up what
17 resources do you have. Resources are a limiting
18 factor in virtually every country. So they're
19 always interested to see how we do these, how
20 many people are involved, and so on.

21 And the topic that you'll hear in
22 other discussions today is what about some of

1 these newer techniques? How do they fit into the
2 picture we have today. Mike was talking earlier
3 about this Am I Regulated. Again, reminding
4 people that you go back as an agency to the
5 parameters that you've been given in laws or
6 regulations, the guidelines, and the text is your
7 starting point for being able to sort this out.

8 So there's been lots of interest in
9 that. And also interest in where things are
10 going to go in the future.

11 This is another question with the
12 coexistence in agriculture that I know at the
13 departmental level has gotten a lot of attention
14 over the last 8 or 10 years. And still in other
15 countries when they look at what the government's
16 role is in day-to-day agriculture they are trying
17 to grapple with what the government's role will
18 be in their country. And they're sometimes
19 surprised to hear that it's primarily coexistence
20 in the U.S. We have multiple production systems.
21 And it's worked out on a local level between
22 growers for the most part. And the government

1 actually does not step in and mandate who grows
2 what, in what fashion, in which location.

3 Now let's switch now to one of the
4 areas where we have had ongoing trilateral and
5 bilateral discussions. The discussions in North
6 America go back, the questions with Canada and
7 APHIS go back to the early '90s. So that's 25
8 years. In about the year 2000 we added Mexico
9 into the mix.

10 And the way that we approach this is
11 we -- it's focused on a technical level, not
12 policy based. And we're sharing our expertise.
13 We have an opportunity to talk about what is in
14 the R&D pipeline that we're seeing currently with
15 field testing and so on. And we cover the two
16 main areas, both in the food and feed safety
17 evaluation side of the house and the
18 environmental side of the house as well.

19 The long range goal in all of this is
20 to increase the harmonization, recognizing that
21 most of these products are going to be traded
22 across borders. So we talked about the approval.

1 We talked about the scoping, the horizon scanning
2 report from the National Academy, and we talked
3 about our activities with international
4 organizations.

5 In terms of bilateral discussions
6 we've had technical discussions with our Chinese
7 counterparts in the Ministry of Agriculture, now
8 going back to about a decade. And we again are
9 sharing our expertise both on the environmental
10 side and food and feed safety.

11 The most recent meeting that was held
12 in China was this past year, and we focused
13 primarily on Chinese amendments to their
14 guidelines for safety assessments, and also the
15 Chinese research in the area of animal
16 biotechnology.

17 China is probably one of the leading
18 countries in the animal biotech research.

19 As Ibrahim mentioned earlier, there's
20 a lot of collaboration with other agencies -- we
21 won't go into details here -- both in capacity
22 building and longer term, more intensive

1 interactions, risk assessment, and also in this
2 whole area of synthetic biology that's being
3 discussed in international fora, especially under
4 the Convention for Biological Diversity.

5 Looking at some of the topics,
6 probably the two leading topics are both the new
7 breeding techniques and how they fit into a
8 regulatory scheme, and the presence at low levels
9 of GE products that have not yet approved -- been
10 approved in your country but they've been
11 approved somewhere else. So that's essentially
12 the definition used under the Codex Alimentarius
13 for food safety.

14 There was a Global LLP Initiative that
15 was set up in 2011. Fourteen countries got
16 together to talk about what might be some
17 practical approaches on this at that meeting,
18 looking at some, recognizing that there could be
19 different legal approaches but looking for
20 something that's practical.

21 In all of these there is the
22 involvement of government and industry in the

1 discussions about how this can be addressed.

2 And this is also closely related to
3 the discussions under another group of countries
4 that are trying to look at some issues related to
5 low-level presence genome editing and agriculture
6 innovation in general, again trying to minimize
7 trade disruption.

8 The theme in all of this is to what
9 extent can we have consistent or harmonized
10 approaches to avoid trade disruption? And this
11 has been one of the approaches used in the OECD
12 discussions that go back more than 25 years. In
13 the whole area of biotechnology we have two
14 agency leads, FDA leads the harmonization group
15 for food and feed, and APHIS leads the group for
16 the environmental safety.

17 And coming up in the coming year we'll
18 have our workshop, or OECD will have a workshop
19 on health and environmental safety in genome
20 editing applications in agriculture. So that's
21 something to think about for the future.

22 And with that, if we have a little bit

1 of time is this where we pause for questions?
2 I'll ask Ibrahim to come up.

3 And it should be related to the
4 international outreach.

5 QUESTION AND ANSWER SESSION

6 MR. GEORGE: It's actually good news
7 because what it means is that the system's
8 working. So, of course, if you're in the room
9 please wait until we get a microphone to you if
10 you have a question.

11 If you're online one way to ask a
12 question is on the webinar there's a comment box,
13 so you can put a comment there and we'll get
14 that. Or you can press 1 and then 0 on your
15 telephone keypad and we will see that and we'll
16 open the mike.

17 So having said that, if you have
18 questions for these guys, please let us know and
19 we'll get a mike to you.

20 MS. SCHMIDT: Thank you. Daria
21 Schmidt, the Ag Division of Dow-DuPont. I have a
22 question for, for both of you and perhaps a

1 little bit for Mike as well.

2 With regard to international
3 stakeholders around the globe how are you going
4 to be addressing the recent actions on Part 340?
5 And what are some of the -- are you getting any
6 questions from some of the other government
7 regulators as to what, what's going to happen
8 next with that? If you can share that, that
9 would be wonderful.

10 MR. SHAQIR: I will let Mike answer
11 that.

12 MR. HERON: 340 and international.

13 MR. SHAQIR: 340 and international.

14 MR. HERON: You want to do that now or
15 during your session later?

16 MR. SHAQIR: Later.

17 MR. HERON: Okay. 340 related things
18 later with Mike.

19 MS. SCHMIDT: And international.

20 MR. HERON: International. He's
21 jotting it down right now.

22 MR. SHAQIR: Well, yeah, I mean

1 international and national we take what basically
2 will be the same approach. And we will -- I hope
3 we'll address your question during Mike's
4 session.

5 OPERATOR: Yes. Someone asked how the
6 foreign governments are chosen for capacity
7 building projects.

8 MR. HERON: Most of the selection for
9 capacity building projects is done by other
10 agencies. State Department and the Foreign --
11 USDA's Foreign Ag Service are the two leading
12 ones. So there's formal programs under the
13 Cochran Program, the Borlaug Program. Those are
14 set up. And those are probably the most frequent
15 two programs that are set up. And those are both
16 administered through the Foreign Ag Service of
17 USDA.

18 OPERATOR: Okay. And a second
19 question from a webinar participant. How does
20 the USDA propose to let average citizens,
21 biohazard and safety scientists, know that
22 they've been deregulated?

1 MR. SHAQIR: It's in the Am I
2 Regulated.

3 MR. HERON: So this is sort of a
4 perennial question for any regulator: how do you
5 tell people what their obligations are under the
6 laws, the regulations?

7 So, Mike maybe can go into this a
8 little bit more. But Am I Regulated is probably
9 the most formalized approach we've used. And, of
10 course, we provide lots of information online.

11 I believe there would probably be some
12 mention in the BQMS portion of the program about
13 outreach organizations, too, especially public
14 sector researchers along those lines.

15 MR. SHAQIR: Terry.

16 MR. MEDLEY: Terry Medley from Reg Bradley, LLC.

17 David, could you maybe mention a
18 little bit more about the upcoming genome editing
19 seminar or workshop at OECD? Do you know what the
20 major objectives are?

21

22 MR. HERON: The details on that

1 actually the working group is still working on
2 this. It's primarily to share experiences and
3 sort of taking stock of where things are.

4 In recent meetings held under OECD in
5 previous years what the group has been doing is
6 sort of allowing each other to hear what their
7 experiences are and what issues are coming up.
8 So that's the primary function for it.

9 MR. MEDLEY: Just to follow up, I
10 know that OECD normally will have, they'll set up
11 kind of a program of work for the next three
12 years or so. Is this a major part of that
13 program of work or is it discussed in that
14 context?

15 MR. HERON: As I understand it -- and
16 Sally's really the expert here on the OECD --that
17 is part of the program of work. And this is an
18 issue, for those of you who have not been
19 following this, this has been in active
20 discussion among countries for about the last
21 seven years, trying to sort out how do, how do
22 some of these newer techniques fit with existing

1 systems and approaches.

2 And OECD is trying to bring groups
3 together to have some discussions around this,
4 again going back to OECD's primary goal to
5 minimize trade disruption.

6 OPERATOR: Someone asked if the OECD
7 genome editing workshop will be in the USA?

8 MR. HERON: That's a great question.
9 I'm not sure where it's -- we can, there will be
10 information about that. I think it's going to be
11 in Paris actually.

12 MR. SHAQIR: It will be in Paris.

13 OPERATOR: And someone asked if you
14 could describe how China's safety and regulatory
15 standards are being harmonized with the U.S.
16 expectations for GM crops for U.S. exportation?

17 MR. HERON: This is a great, this is
18 a graduate level question. So what we probably
19 should do is during the break those who really
20 want to hear the answer to this can hear the tip
21 of the iceberg.

22 We're in the early stages of even

1 though it's now about ten years that we've had
2 technical discussions with our Chinese
3 counterparts we're still in the early stages of
4 talking about the day-to-day implementation, how
5 you bring the best available information,
6 scientific information into play with the
7 reviews.

8 Some of the challenges that they have
9 in the Chinese system, they are actually making
10 some changes in recent years, structural changes,
11 so that they can have a cadre of permanent people
12 in the Ministry of Agriculture who are more
13 conversant in the risk assessment side of the
14 house, instead of having to go out to scientists
15 in the Chinese Academy of Agricultural Sciences
16 and research institutes, and bring those in using
17 the National Biosafety Committee.

18 This is a very quick gloss on this,
19 but those are some of the most pressing issues
20 that we're focusing on on the technical side.

21 The discussions with the Chinese
22 government in this area are in two main groups,

1 one of them a technical side that APHIS is
2 leading, and on the trade side it's USDA's
3 Foreign Ag Service that's leading that.

4 The Foreign Ag Service discussions are
5 focused more on the systemwide issues in the
6 Chinese system. The technical working group
7 discussions that we're having are to focus more
8 on the technical issues that would come into play
9 in any country's implementation of their system.

10 So, no more discussion about Chinese
11 at break time. No, I'm just kidding.

12 MR. SUSSMAN: Hi. I'm Mike Sussman
13 from USDA AMS.

14 Even you've got a line on one of your
15 sites about whole genome sequencing. How are you
16 using that?

17 MR. SHAQIR: That's a very good
18 question. Yes, well the whole genome sequencing
19 actually kind of shared with us their guidelines
20 on the whole genome sequencing from the Canadian
21 perspective. And if you want an answer on this
22 topic, is John here? John Turner?

1 John will give you a nice response to
2 this. Well, I will give him, quickly ask him to
3 do that.

4 MR. TURNER: Thank you. As you know,
5 in recent years whole genome sequencing is a
6 technique which has advanced very rapidly. So
7 we're now in the third generation of things. And
8 we're starting to get additions for non-regulated
9 status of that whole genome sequencing as a
10 replacement for what used to be our dominant
11 southern blocks.

12 Our basic questions are when we get
13 this kind of data are what's the impactness of
14 the insert? What went in that's been rearranged?
15 Are there things that you didn't want in, things
16 like the backbone of the class that we're
17 starting to use whole genome sequencing for that.

18 That being said, we're still in the
19 process of defining exactly what sort of data we
20 want and how it should be used in petitions for
21 us to do the analysis. We know it's coming but
22 we don't have a lot of guidance. So that's why

1 we were so interested in the guidance that Canada
2 put out.

3 But and it's been published. I'll say
4 this: it's not very specific on exactly what
5 techniques. It didn't say what sequencing depth.
6 It says, it talks about the kind of questions,
7 the type of quality, why do you have -- why did
8 you choose the techniques you chose, and the
9 quality of the data is there such that it can be
10 interpreted.

11 We're very interested in following up
12 on this, but we don't have specific guidance on
13 whole genome sequencing. But, again, the
14 applications, the nexus of whole genome
15 sequencing is us, it's for plants when they come
16 in for non-regulated status and we need to know
17 what the insert looks like.

18 MR. GEORGE: Okay, thanks. I think
19 we're going to cut it off there in the interest
20 of staying on schedule. Thank you for the
21 interest. And as I mentioned, we're going to
22 have a little more time at the end of the day for

1 the group to handle other, other questions.

2 As most of you know, we regulate
3 biotechnology in conjunction with EPA and FDA as
4 part of the coordinated framework for the
5 regulation of biotechnology. We are very
6 fortunate to have with us today a representative
7 of the FDA to talk about their activity in regard
8 to biotech.

9 Our guest is Dr. Carrie McMahon,
10 Consumer Safety Officer of the FDA Center for
11 Food Safety and Applied Nutrition in the Office
12 of Food Additive Safety. That's a long title.

13 Carrie, thank you very much.

14 BIOTECHNOLOGY UPDATES FROM FDA

15 DR. McMAHON: Thank you for inviting
16 me. I appreciate USDA's invitation to include us
17 in the meeting today. They've done so for many
18 years. And we do try to have this wonderful
19 coordinated framework, coordinated working space.
20 And I think it speaks really well when we meet,
21 as was just spoken about, these international
22 groups and we hear the struggles that their

1 governments have working across agencies as a
2 partner. And we don't really have those too
3 much.

4 So, again, my name is Dr. Carrie
5 McMahon. I am with the Office of Food Additive
6 Safety at FDA. I've been a part of the
7 biotechnology team for the last 15 years. And as
8 was explained on the BRS stakeholder meeting
9 website, you know, the purpose of being here
10 today is for us to take a look back at 2017 and
11 to look forward to 2018.

12 Where's my slides? Aha, you've strung
13 them together. Clever. Thank you.

14 So, given the short amount of time
15 that I have what I would like to do is focus in
16 eight slides on three subjects. Hopefully we can
17 keep entertained for those slides.

18 And I want to talk about the
19 biotechnology consultations we've finished since
20 the last stakeholder meeting.

21 I would like to talk about the request
22 for comments that FDA issued earlier this year

1 and where we stand with that for information on
2 genome editing of plants intended for food use.

3 And I'll wrap up with a little bit of
4 information which has been raised already with
5 the biotechnology education and outreach
6 activities as we're coordinating with the FDA.

7 So if you've been to our website
8 lately -- I hope you visit frequently -- we do
9 post updates on the consultations as we complete
10 them. And since last year about this time we've
11 completed four consultations.

12 We've completed a consultation for
13 canola that has both a male sterility trait
14 throughout for hybrid seed production, as well as
15 herbicide tolerance for maintenance of that
16 sterile line. That consultation was completed
17 just last month in October. And it took about 14
18 months from the time that it was submitted.

19 We've also completed a consultation on
20 soybean. And this is from Verdeca, as we've
21 mentioned earlier. They brought in their soybean
22 with altered growth properties. This is the HB4

1 transcription factor from sunflower. And the
2 purpose here is to give it better resistance to
3 environmental stresses that would reduce or
4 suppress crop yields.

5 That one was concluded in August. And
6 that one also took about 14 months from
7 submission to sending our response letter to the
8 company closing the consultation.

9 J.R. Simplot brought in two potato
10 lines. And these were retransformations of
11 earlier transformed events where they were adding
12 additional traits. And the new line is the Y9
13 and Y17. And what they really did here was add
14 another gene RNAI product to further suppress
15 reducing sugars, which are a part of the spare
16 gene and acrylamide production. And they also
17 added pest resistance to late blight where they
18 added the Rpi-vnt1 gene. And those were to lines
19 that were Burbank Russet and to Atlantic
20 potatoes.

21 And, interestingly, we had a fruit
22 this year. We had pineapple. And the trait of

1 the pineapple is that it's pink. And the pink
2 pineapple is created by using RNAI as well as
3 introducing a synthase to drive the beta carotene
4 biosynthetic pathway up to the production of
5 lycopene and then stop it. So you actually
6 accumulate an intermediate.

7 And lycopene, for the non-chemists in
8 the group, is the red component of tomatoes. So
9 you get this beautiful pink pineapple.

10 That one was completed in December of
11 last year. And that one took about 25 months for
12 us to complete.

13 And I also want to mention about a new
14 protein consultation we've completed. Hopefully
15 you're familiar with this program but it's a
16 little bit maybe under the radar because it's not
17 as heavily used by developers. But we do think
18 it has a lot of merit and value.

19 And the new protein consultations
20 program is for non-pesticidal proteins that are
21 under development in plants intended for food
22 use. And this is a very early stage base

1 evaluation. And we implemented it to help
2 address concerns of low level presence while
3 maybe a developer is working on a plant and had
4 gotten it into the field.

5 I think it has a double benefit: it
6 informs the agency but it also helps the
7 developer understand whether there might be
8 safety or legal concerns, questions that would be
9 raised which gives you an opportunity to resolve
10 those if they're resolvable, or maybe to redirect
11 your business processes if they're going to be
12 insurmountable.

13 We completed one this year for
14 isopentenyltransferase which was submitted by
15 Arcadia Biosciences. And the gene comes from
16 *Agrobacterium tumefaciens*. And I suspect a
17 little transferase is part of the cytokinin
18 pathway. And so it increased drought tolerance
19 when paired with the proper promoter.

20 This program is wonderful in that we
21 complete it typically in under four months. And
22 this particular consultation was completed in

1 two-and-a-half months. The focus here is on
2 concerns for food safety, so toxicity and
3 allergenicity are the first ones. It's a very
4 focused assessment. And so the data package is
5 very focused as well and it doesn't take us long
6 to complete.

7 From here I'd like to move on to some
8 of these new technologies we've been hearing
9 about discussed earlier today. And I want to
10 talk about what FDA is doing in terms of
11 developing a policy for how we would want to
12 approach these new technologies with respect to
13 our authority under the Federal Food, Drug, and
14 Cosmetic Act.

15 And I want to start here by making
16 sure that we're all on the same page because
17 there's a bit of a misconception. And I believe
18 this is generated in part by reports from the
19 media that once you've been through APHIS' Am I
20 Regulated and APHIS sends out this wonderful
21 letter that says, you know, under our
22 considerations of what your product is you don't

1 -- we've determined that you don't fall under 7
2 C.F.R. 340.

3 Then at the bottom of that a very nice
4 phrase that says but you may be regulated by
5 other agencies under other authority. But the
6 media hasn't picked up on this. And so there may
7 be a misconception that the letter from APHIS
8 means they're not regulated by the U.S.
9 Government.

10 And I want to clarify that all food
11 comes under the authority of the Food and Drug
12 Act. So it is important that we consider whether
13 there are safety or regulatory questions for
14 crops that are developed through genome editing
15 that may not fall under and within APHIS'
16 oversight.

17 And FDA really is keen on making sure
18 that we move forward and engage in the right way
19 with stakeholders about products they're
20 developing through genome editing techniques.
21 And a step that we took to do this is by issuing
22 a Request for Comments in January of 2017. And

1 that went up on -- into the docket on
2 www.regulations.gov. I've listed the docket
3 number here. You can go and look.

4 It was open until June. And our
5 comment period is closed.

6 There were four very specific
7 questions in that Request for Comments if you're
8 not familiar or haven't read it. And the first
9 one really focused on something very basic: are
10 the food safety risks the same or different for
11 plants developed through genome editing compared
12 to plants developed with any other technique --
13 traditional breeding, mutagenesis, irradiation,
14 transgenic? Simple question.

15 The second question, are there
16 categories with a scientific basis to conclude
17 the foods in this categories are unlikely to
18 present risks that are different or greater?

19 And then we kind of have the flip side
20 of the coin. Are there categories in which there
21 are scientific bases to conclude that the food
22 from these categories are more likely than

1 traditionally bred plants to present a food
2 safety risk?

3 And in both of these questions 2 and
4 3 we asked for details, for descriptions, not yes
5 or no. And so we really are looking for
6 information from, from our stakeholders, from
7 you, from academics, from plant developers in the
8 community that have information to share with us
9 to make sure we take all of this in consideration
10 to determine how best to engage. Because really
11 that's the ultimate goal.

12 And you see that in question 4: What
13 steps can we take to help firms engage with the
14 FDA about questions related to food safety?

15 FDA has a 20-year history of engaging
16 with plant developers over bioengineered crops.
17 And we have a 100-year history of engaging with
18 all developers of food over safety and regulatory
19 questions. And we want to make sure that that
20 engagement is science based and that we're asking
21 for the right information and have the right type
22 of consultations for the safety and the

1 regulatory processes for the products that are
2 being developed.

3 If you go to regulations.gov and look
4 at the docket you will see there are 583
5 published comments. If you haven't gone there,
6 please go and read them. This is what we're
7 thinking about right now at the agency. We're
8 sorting these comments and considering the ones
9 that answered the four questions, and what
10 information they've provided.

11 Next year at the stakeholder meeting
12 I hope we'll have more information on where we
13 stand with that consideration and what type of
14 approach we may be looking at. But it takes some
15 time to give these serious thought.

16 And we have another project under way
17 where we are seeking public comment and
18 information to help inform our activities. And
19 that, as has been raised, is the Biotechnology
20 Education and Outreach Initiative which derives
21 from Congress' awarding, appropriating \$3 million
22 for FDA to work in coordination with USDA to

1 provide information and educate the public about
2 agricultural biotechnology and about foods
3 derived from biotechnology.

4 In this initial phase, as has been
5 mentioned, what we have done is to have two
6 public meetings very recently. And we opened a
7 docket. And that docket we were actually
8 accepting comments till November 17th. So you
9 have two days, you have until Friday as a
10 consumer, you know, put in your thoughts.

11 We have three questions. The
12 questions relate to, you know, what topics,
13 questions, information would you find most useful
14 about agricultural biotechnology and food derived
15 from these products?

16 How and where do you get your
17 information?

18 And how can FDA and in coordination
19 with USDA best provide the information that
20 you're looking for?

21 You can follow this initiative. We
22 have a website. And I have it listed here. I'm

1 happy if you want to see me afterwards, I can
2 give you my email address. If you contact me
3 I'll send you my slides so that you can get all
4 of these addresses and contact persons. But I
5 encourage you to follow these things, see what
6 other people are submitting, what their comments
7 are. It's very informative. And provide your
8 own.

9 With that I'll wrap up with just a
10 reminder, and that is that FDA really strives to
11 be science based. And we do this with help from
12 all of our stakeholders. We're approachable. At
13 least I've been told we are. And our costs for
14 consulting with us, for meeting with us and
15 discussing these regulatory questions are zero.
16 It doesn't cost. We have no fee for you to come
17 and talk to us about something you're working on
18 to get an idea of what might be the safety or
19 regulatory question.

20 Or if you're developing a new
21 technique and you want to share with us that new
22 technology so that we're aware and informed. We

1 invite that type of interaction as well. Or you
2 can reach out to me and I can arrange meetings,
3 virtual or in person.

4 Thank you. And I'll take any
5 questions you have.

6 OPERATOR: I have a question from a
7 webinar participant.

8 How does FDA become involved with
9 transgenic mosquitoes?

10 DR. McMAHON: You know, this goes back
11 to the coordinated framework. And the purpose of
12 the coordinated framework, when the Office of
13 Science and Technology Policy first said, you
14 know, we have new science here, how are we going
15 to oversee it? Do we need new laws?

16 And they asked the three agencies to
17 sit down and say, Do we need new laws? And do
18 you have the authority to oversee products of
19 genetically engineered plants back in the 1980s.

20 And they're doing this again; right?
21 Just within the last couple years OSTP has said,
22 You need to rethink about it; we have new and

1 different products.

2 So the agencies work together when we
3 have these products to try to determine who is
4 the right agency with the right expertise and the
5 right legal authority to oversee their species.

6 With mosquitoes we have a FDA guidance
7 out that outlines how we work with our partner
8 agencies to divide up that line for who, which
9 agency oversees which.

10 And if the person online is
11 interested, I can certainly provide them more
12 information, a contact name and a website where
13 they can follow that guidance and what's going
14 on.

15 Okay, thank you.

16 MR. GEORGE: Thank you very much,
17 Carrie, for that informative session about FDA's
18 activities.

19 We're going to take a break now.
20 It's, why don't we get back here at a quarter to.
21 And we'll sort of get back on schedule just a
22 little bit. So we'll see you in about 12, 12

1 minutes or so.

2 Thank you.

3 (Whereupon, the above-entitled meeting
4 recessed at 2:33 p.m., and reconvened at 2:48
5 p.m.)

6 MR. GEORGE: Okay. About six years
7 ago, we created our Am I Regulated process, and
8 recently we've taken a good look at how to make
9 it better. Here to tell us about it is BRS
10 Government Relations Specialist Bill Doley.

11 MR. DOLEY: I got it. Oops. Good
12 afternoon. Some of you -- many of you are
13 familiar with the Am I Regulated process. Mike
14 talked about it some this morning. And some of
15 you have probably used the process. And what I'm
16 going to talk about today is over the past year.
17 So, starting in January, we conducted a business-
18 process improvement project to enhance our Am I
19 Regulated process.

20 So, before I get into the project we
21 did, let me give you a little background about Am
22 I Regulated and what we've done up until we

1 started the project in January. Here we have the
2 benefits, which is, it keeps organisms out of the
3 regulatory system that aren't regulatory
4 articles. So, the idea here is that it's -- it's
5 a win-win. We don't spend time analyzing things
6 that shouldn't be regulated, and you don't spend
7 time having things regulated there's no need to
8 be regulated.

9 So, the way it works is, if you would
10 like confirmation that your new product is --
11 whether or not it meets the definition of a
12 regulated article, you can send us a letter. And
13 it has certain components, which are outlined on
14 the website. And then we'll respond to your
15 letter.

16 Starting in 2011, we've answered 55 of
17 these. The very first one, which came out in
18 July 2011 was a response to Scotts regarding
19 Kentucky bluegrass. So, if you look on our
20 website, that's all of our lists. The one at the
21 very bottom is Kentucky bluegrass. Also, some of
22 these relate to what are referred to as new plant

1 breeding techniques.

2 And I'll say a little more about that.

3 If you look on the website, we have a listing of
4 all of the inquiries and responses. And this is
5 a new view here. It used to be, you had to
6 scroll down to look through and find the one
7 you're interested in. Now we have a searchable
8 format here. And this is a new format. So, if
9 you have any feedback on how to improve this,
10 we'd be interested in making this a -- more to
11 meet your needs. But it is searchable in terms
12 of the crop and the company now. So, that's a
13 big improvement.

14 So, basically, this is a legal
15 analysis of whether or not what you describe in
16 your letter is a regulated article. And the
17 definition of regulated article from 7 CFR 340 is
18 rather lengthy, but it has two key components.
19 Is it altered or produced through genetic
20 engineering, and is there a donor, vector, or
21 recipient of plant pests? So, it needs to be
22 both of these things to be a regulated article.

1 So, you think about that. It comes down to, if
2 the answer to those two questions is yes, well,
3 yes, you're a regulated article.

4 When we go back a little bit here.
5 The second question, is the donor, vector, or
6 recipient a plant pest? If that's a no, then
7 you're not a regulated article. So, those are
8 kind of general conclusions.

9 What's complicated this is the
10 nucleases. And let's just look at this list of
11 EU new plant-breeding techniques. When this list
12 came out, they actually had eight things on it.
13 The last one's synthetic biology. I don't use
14 that one, because they're still looking for a
15 definition. And the first one, says zinc finger
16 nucleases. Well, since then, we have TALEN and
17 CRISPR. So, the technology evolved hugely, just
18 in the last five years. So -- so, we have the
19 site-directed nucleases. We have these other
20 techniques. And we've been answering these Am I
21 Regulated inquiries related to these techniques.

22 These ones I just put the green stars

1 up are ones where we've answered in a positive
2 manner, you're not regulated. And the three
3 stars on the top line refer to zinc finger
4 nuclease, TALEN, and CRISPR. So, we've answered
5 inquiries for all three of those. Unfortunately,
6 one person got a negative response that they were
7 regulated. It's cisgenic apples from the
8 Netherlands. In that case, they introduced all
9 their apple bits and pieces, agro bacterium.
10 Agro bacterium is a plant pest. So, they were
11 regulated based on using a plant pest as a
12 vector.

13 This table is a summary of all the
14 fifty-five inquiries we responded to. And it has
15 the genetical modification plant pest component
16 as two separate sections. And this is the way it
17 used to be. We were looking for a yes plus yes,
18 you're regulated. And you can see in the second
19 row there, there's a bunch of yeses on the right
20 side, but some of those things are not regulated.
21 And those are the no-insertion category, I call
22 it. Before we talk about that, let me just point

1 you to the first row of the table, where about
2 half of all these responses are no plant pest.
3 That means these are actually genetically
4 engineered plants. And mostly they are made with
5 biolistics, but no plant pests components were
6 used. So, they are genetically engineered
7 plants, but not regulated articles. In the
8 second column, in the second row, these no
9 insertions -- these are all the result of site-
10 directed nucleases. And in many cases, the
11 process proceeded by creating a regulated
12 article. And then, that was self-produced
13 progeny, where the regulated aspects of the
14 article were segregated out, and all that
15 remained was a deletion. And, so, that's what
16 all those are, is targeted deletions, where
17 there's no inserted genetic material from the
18 genetic engineering.

19 On that same line of thinking, or --
20 the first one we struggled with there was TALEN.
21 And TALENS are derived from plant pests. So, you
22 can imagine why that was difficult for us. So,

1 we were presented with new regulatory scenarios
2 when these -- when these nucleases came around.

3 There's some other columns, rows there
4 we don't need to get into. Well null segregant
5 was interesting. The third row. Most of them
6 are true null segregants, but two of them were
7 epigenetic. So, epigenetic are not changing the
8 DNA sequence. So, we consider that a null
9 segregant.

10 So, now, the Business Process
11 Improvement project. The -- down on the bottom
12 right, you can see the logo of Six Sigma. We
13 used Six Sigma techniques as we went through this
14 project. You can see the phases there, define,
15 measure, analyze, improve, and control. So, I'll
16 talk a little bit more about that.

17 The purpose of the project was to make
18 the response time more predictable. As Mike
19 mentioned earlier, some of the responses took a
20 little bit too long. There was a fair amount of
21 range. We've been doing better lately, but --
22 so, we want to reduce the total amount of time

1 and also the variance in the time to respond.
2 And we'd like to have consistency in our
3 responses from technical and problems standpoint.
4 And this is more consistent. I think they've
5 been consistent, but we want to make sure we
6 maintain that consistency that we've had up till
7 now.

8 So, these -- is going through the
9 phases a little bit. So, in the define phase, we
10 formed a team, developed a team charter. And
11 this is tied to Six Sigma. We had an as-is
12 process map. So, you make a flow-chart map of
13 everything you're doing today, so you can analyze
14 what could be improved.

15 So, when we get into the measure
16 phase, we went through the Am I Regulated that we
17 did over the last three years and collected data
18 for different points in the process to try to --
19 so we have measurement, quantitative data of
20 about how different steps took. And we also did
21 interviews called Voice of the Customer. So,
22 this is an important aspect of the Six Sigma

1 Business Process Improvement project, because you
2 need to know what the customers expect. And this
3 is both internal, external. So, we -- we ask
4 some questions of some external customers who had
5 been recipients of Am I Regulated responses and
6 also internal customers like Mike. We had to ask
7 Mike what he expects of us.

8 And when we got to the analyze phase,
9 we started identifying root causes, like what are
10 -- what are the things that can go wrong, and
11 what are the things that you can change to
12 prevent those things from going wrong?

13 Then we get into the improve phase,
14 which we're still actually wrapping up. So, we
15 prioritize the solutions. We conduct a failure
16 modes and effect analysis. So, that's thinking
17 about all the things that could go wrong and why
18 they go wrong and what you can do to solve them.
19 And then, finally, you have a To-Be Process Map -
20 - is the new process, after you -- after you've
21 implemented some of the solutions that you
22 prioritized. Oh. There we go.

1 So, right now we're in the control
2 phase. We are doing some of the things that are
3 listed as improved now. And I'm going to just go
4 through a few of the improvements that we have
5 concluded are going to make our process better.

6 So, first of all, we're going to have
7 improved guidance for developers. We're going to
8 update what's on our website. We have had delays
9 due to confidential business information (CBI)
10 issues. Initially, the website didn't have any
11 information about confidential business
12 information. We always had to go back and ask
13 for your CBI justification and things like that.
14 So, now we have that up there.

15 Another aspect of delay has been,
16 sometimes we have requested additional
17 information to characterize the described
18 product. And we're going to provide additional
19 guidance on that. I can tell you now though that
20 -- of mostly these delays have been due to --
21 there have been cases where it's a -- it's a
22 targeted deletion, and we would like a little bit

1 of data to show that the final product does not
2 contain any of the inserted sequences that were
3 in the parent plant that was initially made.
4 That was a little confusing, but the idea is that
5 the final product that has a targeted deletion,
6 we want to be sure nothing was inserted. So, if
7 you could send us some data to show that with
8 your letter, things will go quicker.

9 We also are going to implement a
10 triage committee. This is a small group to look
11 at these things when they first come in to
12 identify any potential scientific or policy
13 issues that might hold up the process, so we can
14 sort of nip them in the bud.

15 We have a new SOP for internal use, so
16 that everybody has better instructions on their
17 role in the process. And we have some new
18 templates and checklists to go with that. And
19 we're going to develop a tracking system.
20 Probably in the past, you've heard about our
21 petition-tracking system, which was implemented
22 to keep the petition on time, which was a

1 previous BPI we implemented. And we are thinking
2 pretty much the exact same thing on a smaller
3 scale, so that we can track when each step is
4 completed and each person knows when it's their
5 turn to do their step in the process. And that's
6 all I have to say besides answering questions.

7 MR. GEORGE: So, we have a question
8 here. And while we're getting a microphone
9 there, I will remind those of you that are on the
10 phone, if you have a question, please press 1 and
11 then 0 on your touch-tone phone. And when it's
12 your turn, we'll unmute you, and you can ask your
13 question. In the meantime, please go ahead, sir.

14 MR. DOVER: So, hi, Bill. This is Ray
15 Dover with Monsanto. So, there's already
16 specific guidance with regard to information
17 expected in those letters of inquiry. And that's
18 on the web. So, are you anticipating changing
19 that?

20 MR. DOLEY: There's a list of -- of
21 bits of information that we want you to have in
22 your letter. And, so, we're not really changing

1 that list, but we might add one item, which is to
2 provide data which demonstrates that the final
3 product does not contain the inserted material.
4 In the -- especially in the case of the nucleases
5 where you create a genetically engineered plant
6 and then it spits out a plant with a targeted
7 deletion.

8 MR. DOVER: So, but right now the
9 process is largely prophetic. So, you could have
10 a prophetic --

11 MR. DOLEY: Right.

12 MR. DOVER: And so, actually, there
13 wouldn't be specific data. So, how do you intend
14 to address that?

15 MR. DOLEY: Well, that's correct. So,
16 there's basically two forms. There's the form
17 where you write a letter saying, I'm planning to
18 create this new product. And then you couldn't
19 have any data. Versus, I have already made this
20 product. And, so, there are two formats.

21 MR. GEORGE: Do you have a question,
22 Ms. Operator?

1 OPERATOR: Yes. A webinar participant
2 asked, if the vector is disarmed as a bacterium,
3 would it still be regulated?

4 MR. DOLEY: As of today, all agro
5 bacterium is still considered plant pest and
6 makes you subject to regulation. Okay. Should
7 turn that thing down, if we could.

8 Dr. Smith.

9 (Laughter.)

10 MR. GEORGE: Great. Thank you very
11 much, Bill. One of our fundamental activities in
12 BRS is permitting. And here we have updates on
13 supplemental permit conditions in general and
14 permit-specific supplemental conditions for wheat
15 -- are Alan Pearson, Branch Chief of our Plants,
16 Pests, and Protectants Branch, followed by Subray
17 Hegde, who heads up our Plants Branch.

18 MR. PEARSON: I'm glad to be able to
19 talk to you today about our work on supplemental
20 permit conditions. Last year, we told you about
21 a joint project between Biotechnology Risk
22 Analysis programs and the Regulatory Operations

1 program to join efforts to revise our standard
2 supplemental permit conditions. This year, I'm
3 going to provide you with an update on that work.

4 Just, as I already mentioned, it's a
5 joint project between BRAP and ROP. In BRAP, we
6 assign supplemental permit conditions, and ROP,
7 as you know, goes out and does inspections for
8 compliance, including compliance with those
9 conditions. And that's why this is a joint
10 effort between the two programs in BRS.

11 Also, by way of background, just to
12 remind you or inform you, there's three different
13 kinds of permit conditions that will appear in
14 permits. There's, first, sort the standard
15 permit conditions. And these are really already
16 listed in the regulations themselves. They apply
17 to all permits. So, they're just standard. They
18 never change.

19 Then there's a set of what we call
20 standard supplemental permit conditions. And
21 these are permit conditions that are developed
22 for various different types of -- of products and

1 activities. So, they use standard language, but
2 they may differ, depending on the type of product
3 or permit. For example, we have a set of
4 standard supplemental conditions that apply to
5 movements of plants. Different set for movements
6 of microbes. Different sets for releases,
7 microbes versus plants. The single-year release
8 versus a multi-year release, and so on.

9 Right now, we actually are working on
10 the 22 different sets of what we call standard
11 supplemental conditions. And then, on top of
12 those, we will make -- we will put permit-
13 specific supplemental conditions there, depending
14 very specifically on what the crop-trait
15 combination is. We may add additional
16 supplemental conditions.

17 What I'm going to talk to you about
18 today is the standard supplemental permit
19 conditions.

20 So, starting in 2015, we undertook a
21 thorough review of our supplement -- of our
22 standard supplemental permit conditions and of

1 our recent compliance history, and we realized
2 several things. First that some permit
3 conditions -- and we realized this also in ROPs
4 really just in going out and conducting
5 inspections, but sometimes the permit conditions
6 aren't completely clear to the permittee.
7 Sometimes there's ambiguity and even uncertainty.
8 And there's been confusion between the permittee
9 and the inspector going out in the field in terms
10 of what BRS's expectations are. And this has led
11 to enforcement and oversight challenges. We've
12 also found that there's inconsistencies between
13 some of these different sets of permit conditions
14 that we need to address.

15 And, so, what we're really aiming at
16 with this work is to revise our supplemental --
17 the standard supplemental permit conditions with
18 three goals in mind. First that they are very
19 clear to both the permittees and the inspectors.
20 Second that they are enforceable, according to
21 our regulatory authority. Third that they're
22 commensurate with risk.

1 And, so, our focus, then, in general
2 -- just to speak about the changes, but thinking
3 about generally, has really been on establishing
4 consistent language across all of these different
5 sets of conditions that let both the agency and
6 the permittee acknowledge that the expectations
7 that we're putting on you as permit holders are
8 clear to everyone. We've also streamlined the
9 conditions. We're aiming to streamline them so
10 that they only contain language that we can
11 actually enforce, not language that wouldn't be
12 something we can enforce. And where we moved
13 language is really along the lines of guidance to
14 a separate guidance document.

15 And, finally, by working
16 collaboratively between BRAP and ROP, we're
17 helping ensure that the conditions are
18 commensurate with risk. At the moment, we've now
19 reduced those 22 different steps or conditions
20 down to 11. Not -- we have not yet sort of
21 pushed the button on implementing them. It's not
22 where we're at.

1 I'm just going to show you a few
2 examples of some of the changes that we've made.
3 So, this is the first one. It's an example of a
4 supplemental permit condition that will be
5 deleted. And it basically just says, you know,
6 that although we're issuing a permit, you -- our
7 issuance of a permit doesn't eliminate your legal
8 responsibilities that you might have under other
9 regulations. Well, that's really information.
10 That's not a condition. So, that's an example of
11 the kind of information we'll provide in a
12 separate guidance document.

13 Another example here is a permit
14 condition that will be amended. It has to do
15 with the use of the material that's being grown
16 for food or feed. So, currently, we say you
17 can't use it for food or animal feed unless
18 you've gotten approval from FDA, and in some
19 cases EPA and so on. And we're basically
20 amending that to say, you can't use it for food
21 or feed unless it's first been devitalized, or if
22 you haven't first been devitalized, then all the

1 food, feed, and waste that comes out of the
2 animals has to be treated as regulated material.
3 And that -- with that amendment, that really more
4 accurately reflects our authority, which is, we
5 need to make sure that regulated material stays
6 confined. So, we don't actually have the
7 authority to say, you can't use it unless you've
8 gotten approval from some other agency. And, so,
9 again, that's guidance. We're letting you know,
10 you may need to get approvals from elsewhere.
11 But that would go into a guidance document.

12 Here's an example of a supplemental
13 permit condition where we're aiming to clarify
14 the condition. So, in this case, we've got a
15 condition where we're saying, this permit
16 authorizes the use of the regulated material only
17 as described in the permit, in the permit
18 conditions and any associated design protocols or
19 SOPs that you've submitted with that permit. And
20 if there are discrepancies or disagreements
21 between those various different things that we've
22 referred to there, then the permit conditions

1 take precedence. So, at the end of the day, the
2 permit conditions themselves will take
3 precedence. This condition itself also allows
4 us, if we haven't modified any of the permit
5 conditions, to simply make your design protocols
6 or SOPs the condition that you've submitted and
7 said, this is what you're going to do -- and
8 we're saying, yes, we're referring to that,
9 rather than getting long, lengthy permit
10 conditions that basically just recapitulate what
11 you've put in your SOPs.

12 So, adding this condition, we think
13 will clarify both to the permit holders and to
14 the inspectors the procedures and the conditions
15 under which the release must be conducted. We'll
16 be using this same approach for dealing with
17 issues around confinement and volunteer
18 monitoring and so on.

19 Finally, just a brief slide on our
20 next steps. So, we're planning to conduct more
21 in-depth stakeholder outreach on our -- on the
22 revisions to the supplemental permit conditions

1 that we're proposing. We'll do a stakeholder
2 announcement. We hope to have some webinars set
3 up and sort of have this next step by the end of
4 January. And then we're seeing sort of a two-
5 phase process written these changes. We'd like
6 to implement some of the revisions that won't
7 involve any changes to record keeping or
8 recording on the part of permit holders,
9 hopefully by the end of June of next year and
10 implement and revisions that may involve changes
11 in record keeping or reporting by January of next
12 year. And we know that -- that all of you have
13 various IT systems and so on that may need to be
14 modified in order to accommodate any changes in
15 record keeping or reporting. And we certainly
16 need to leave time for those modifications to
17 occur. So, this is our notional plan. Then our
18 next step's on moving ahead with the need to set
19 the supplemental permit conditions.

20 And, with that, I'm done. I'll turn
21 it over to Subray, who will talk more
22 specifically on questions related to the other

1 type of supplemental permit conditions I talked
2 to you about, which are the more specific
3 supplemental permit conditions. And then we'll
4 take questions at the end.

5 MR. HEDGE: I think Alan gave you an
6 overview of permit conditions. It's very
7 general. And he used the word consistency,
8 clarity, and also depending on the risk, you
9 know, we put permit conditions, what we call some
10 kind of deductive reasoning, from the general to
11 specific. I will go other way. I will take the
12 specific conditions of a particular crop and how
13 we apply these conditions, with the biology and
14 ecology of crops. And I'll make a general
15 statement, like in an inductive reasoning.

16 I'm going to cover three topics here.
17 I just -- a couple of very critical control
18 points where things can go wrong or can be
19 potential for hazard. I'm not saying that it's a
20 risk, but I just took two critical points to show
21 that, you know, how exactly we put special permit
22 conditions to prevent the hazard, and a potential

1 hazard of the -- a potential for persistence and
2 dissemination of the regulated article. And
3 there are some on this. And I want to make a
4 very general statement. Sometime, you know, why
5 do you put specific permit conditions which are
6 so different between crops? So, why we do that
7 one, so that way, you know, you guys know --
8 because we get the question, why is this
9 different? It is because of the biology and
10 ecology of crop lands.

11 If you remember, in 2016, January, all
12 notifications for wheat feed science always you
13 know, should a permit into their notification.
14 And it is simply because a notification, we
15 cannot put any specific permit conditions. And
16 there are a couple of incidences where feed were
17 not confined. You know, then we decided that the
18 only way to prevent such incidents with feed was
19 to have enough permit conditions that we know
20 that, you know, where things can go wrong, we can
21 really control those critical points, prevent
22 dissemination.

1 So, I just wanted to give you the
2 difference between notification and permit,
3 where, you know, we can put that specific
4 condition, based on the biology and ecology of
5 crop lands to prevent dissemination and
6 establishing.

7 And, I'm just taking in a couple of
8 points. One here is -- taking the wheat as an
9 example. It can occur with any crops, but since
10 we are experience with wheat, you know, I took
11 this example, where things can go wrong. You
12 know, just for example.

13 Equipment cleaning. This is one of
14 the areas, we thought, you know, things can go
15 wrong, especially if you use a huge combine. You
16 use combine and then you use it for harvest, what
17 happens is, you can clean inside, but still, you
18 know persist. And when you use this combine to
19 move your other seeds, if it is non-regulated,
20 there is a potential for dissemination. And this
21 is common to the farmers, because they use
22 combine, and they clean, whenever -- to get, you

1 know, wheat seeds, just like in our regulated
2 material.

3 So, we have now two-phase cleaning.
4 The first one is, after the harvest is done,
5 before moving, it should be cleaned in the
6 regulated area, so that you're not -- even if you
7 have a regulated material in the combine, it
8 should fall into the ground, because the
9 regulated area, you have post-harvest monitoring.
10 It would take care of it.

11 But later we came to know that this is
12 not very practical. One of the stakeholders, a
13 permittee contacted us saying that this is
14 sometimes very hard. He cleans as much as
15 possible, but he cannot get rid of all the seeds,
16 because we have to dismantle this combine to get
17 rid of all the seeds. So, somehow, we are to move
18 all of the seed and take every part and clean it.
19 So, that -- so, if you have a second one, you can
20 move it, but clean as much as possible. But when
21 you move it, you know, move to a shed or a storage
22 place, you dismantle it,

1 you clean it. That is a condition. If you have
2 concrete base, then you can just sweep and
3 devitalize all that regulated material. But if
4 it's a bad sign where you do it, then you have to
5 do all interior managing, because there's the
6 chance that, you know, regulated material, will
7 persist in the soil and can germinate.

8 So, that's why now there's a two-step
9 cleaning, whenever you use combine to prevent
10 dissemination.

11 So, the second one is this
12 persistence, which is very common in crop plants.
13 If you look at, you know, some of the regulation,
14 it's very clear that regulated material should
15 not persist, and its progeny should not persist
16 after the harvest. It should volunteer -- if
17 there's a volunteer, it should take care of this
18 volunteer before it flowers.

19 So, what we have done for wheat is,
20 earlier, you know, wheat was in the notification.
21 So, they used to do volunteer monitoring for two
22 years. And it worked probably because, if it is

1 -- so, this is a wheat volunteer feed.

2 And, so, we say, you know, there is no
3 shattering. Yes. That is true, but when we say
4 no shattering, it is 33 percent. When you use a
5 combine, two to three percent of the seed is
6 really high percentage, so you can have millions
7 of seedlings coming as volunteers.

8 If the soil is moist, okay, most of
9 them germinate, because our domesticated crops.
10 And, so you can get, you know, volunteers easily.
11 So, that's part of an understanding. Right? But
12 -- see, this is what happens. What we perceive
13 is an average performance of the trait under
14 ideal conditions. And a high, you know,
15 temperature and moisture stress, it includes the
16 seed dormant. That means, years there are
17 extreme conditions, which is, you know, because
18 of the exception -- biology is not an absolute.
19 It behaves different, is it has done the genetic
20 variation, which we don't have complete control.
21 Though, we make a general statement. The
22 domestic do not have any of these seed dormancy

1 and shattering.

2 Okay. And not just the literature.

3 We also have internal data. So, just think, this
4 can happen. There's an incident with which,
5 where -- and it was in a notification. And we
6 had a two-year volunteer managing. And permit
7 and whatever, you know, they did a good job, you
8 know -- they were volunteers. But because of the
9 unusual weather condition -- there were two years
10 of very dry weather and the dryland condition.
11 And the volunteers started showing up after two
12 years. See that means, yes, this can happen.
13 That is despite an understanding of crop biology.

14 I wanted to show that, you know,
15 because most of us have a very general statement,
16 the highly domesticated crop. But under extreme
17 conditions, evolution always favors survival,
18 because evolution doesn't want to favor death,
19 right? Because that's happens. So, everybody
20 knows, you know, Dr. Malcolm, yes. It's always
21 find a way to survive. Right? And even, you
22 know, you can see the plants in your -- a place,

1 where it's not supposed to come, but still it
2 comes. Because, then, how did it come?

3 There is a genetic variation for
4 survival, they show up. That's why now we have a
5 -- when it came to the permit, when we turned in
6 a notification to permit for wheat seed trial.
7 So, we said, okay, if you can do irrigation after
8 first harvest, you can get most of the
9 volunteers.

10 So, yes -- if it's an irrigated
11 condition, you can do it. But, if it's a very
12 dry land and there is no irrigation, then, you
13 know, we have a four-year volunteer monitoring,
14 because we have data to support here. Volunteers
15 show up after four years. Maybe more.

16 Okay. Now, I'm coming to the general.
17 That is from specific to general. What we know
18 is, you know, a final phenotype, and taking the
19 seed dormancy. It's a very common practice. You
20 need just one year. And we have two years, but
21 need, you know, three years based on the trait,
22 what we understand is the normal conditions.

1 But what we do not understand is this
2 one, gene to interaction. We don't have, you
3 know, control over this one. What we know is the
4 person populates the genetic variation. Yes.
5 Most of the time we know.

6 Corn for example. We know how it
7 behaves. What we do not know is the second part.
8 Sometimes in the genetic breeding program, you
9 cross material, different genotypes. For
10 example, in wheat, you can cross things that are
11 different. Do you really know where it has a
12 product, how exactly genotype changes? I don't
13 think so, unless you really make a design to
14 study the genetic variation in the hybrid
15 population. So, we don't know.

16 The third one is variation. Most of
17 the time, where our knowledge comes from, in an
18 ideal condition, how the plant behaves. But
19 there are conditions that are beyond. Like, in
20 extreme conditions, we have plants behave
21 differently, which we don't have control. So,
22 what -- that's why, you know, what we are doing

1 is case by case permit condition.

2 So, we have different conditions.

3 Like, it's just really risky, like some of the
4 perennials, for example. Okay. So, we have a
5 different permit condition for volunteer
6 managing, compared to an annual, highly
7 domesticated. So, there is a general message, a
8 take home message, that we have to change this
9 condition based on our knowledge, based on the
10 data, based on our compliance. That's why, you
11 know, these things change.

12 Oh, just wanted to say, when we made
13 a notification permit, a lot of people asked, oh,
14 we don't want to do it, because it is so
15 complicated. It takes 120 days, and you may not
16 be able to do it. But in 2016, Mike Firko, when
17 we came to a permit condition, our administrator
18 said, you know, we will do it our best. We
19 probably will do it in two months. And they have
20 120 days.

21 I just want to show and assure this.
22 I know exactly how we did in 2016. How we had 11

1 permits. We did it in 50, 60. And in 2017, so
2 far, we have three -- or four. We did it forty
3 days. I put an asterisk by one, because it took
4 141 days.

5 But the permittee was not really
6 interested to get these permits. You know,
7 whenever we have the question repeatedly, he
8 couldn't provide data on whatever needed, in a
9 permit -- the body of the permit. So, that's why
10 it took more time. It's not because of, you
11 know, we delayed it. It is because we did not
12 get responses from them, the applicant. So,
13 that's why it took more time. Otherwise, yes, we
14 did it in 40 days. Just wanted to show that,
15 yes. If your application is complete, it will
16 take time, just because of the permit.

17 Thank you. Alan.

18 OPERATOR: Okay. We have a webinar
19 question. Someone wanted you to define
20 devitalize. Two other people answered it within
21 the webinar chatbox, but I thought it'd be nice
22 to get your definition.

1 MR. HEDGE: Very simple. Just killed.
2 It means get rid of -- devitalize means, you
3 know, that you don't have any life left. So,
4 there are different methods people use. They
5 burn it, and they cook it in high pressure, or
6 they bury it, in a deep burial. Yes. There are
7 different methods, depending on the crops or the
8 GE regulated article.

9 OPERATOR: Okay. And somebody typed
10 in while you were speaking. They said, but most
11 of the devitalization mechanisms on the back of
12 wheat combines only devitalize 97 percent of the
13 wheat seeds and grains. There's still an
14 opportunity for wheat.

15 MR. PEARSON: That's why we have
16 conditions around volunteer monitoring.

17 OPERATOR: Yes.

18 MR. PEARSON: Right. Because we know
19 that volunteers will come up, and so -- and
20 that's why all of you are doing he volunteer
21 monitoring, so that when they come up, they can
22 be pulled out or in other ways killed.

1 OPERATOR: It looks like we have some
2 people in the webinar typing some questions. So,
3 I'm going to check the phone real quick.

4 Another person asked for you to
5 comment on the need for design protocols for
6 permits versus communicating all requirements in
7 the standard or supplemental conditions.

8 MR. PEARSON: So, we ask, in the
9 permit -- there's a section in the permit where
10 we ask specifically how you're going to address
11 issues around confinement and devitalization and
12 so on. Many applicants will also submit
13 separately an SOP or design protocol. Many
14 applicants will, in those fields of the permit
15 application, put in the information that they've
16 submitted as design protocols for notification.
17 And, you know, applicants basically need to
18 answer those questions in the permit application.

19 Beyond that, we will set permit
20 conditions. Often applicants provide a very
21 extensive list of procedures they're going to be
22 using to do things like volunteer monitoring, and

1 there's all kinds of different variations and so
2 on. Many of those things, you know, we've
3 already looked at and approved and so on. And
4 that's that one condition I've showed you, where
5 we -- where we basically cite to the design
6 protocol or the SOP in that case.

7 We're just making that information
8 which you've provided and which we've reviewed
9 the condition, rather than itemizing all of those
10 different variations in the condition itself.

11 I hope that answers the question. But
12 there is certain basic information that an
13 applicant is expected to provide in the permit
14 application. There's not the need to be a false-
15 weighted design protocol or SOP.

16 OPERATOR: So, we have two different
17 folks on the webinar -- our network hiccupped a
18 little bit during Subray's part. And they would
19 like to know when they can get the slides made
20 available to them.

21 MR. GEORGE: Sure. All of the slides
22 from today will be on our website within the next

1 couple of days. Yes.

2 OPERATOR: And then we have one more
3 question. Under what circumstances would
4 autoclave validation still be required, since it
5 appears to have been removed as part of the
6 streamlining?

7 PARTICIPANT: What?

8 OPERATOR: Under what circumstances
9 would autoclave validation still be required,
10 since it appears to have been removed as part of
11 the streamlining?

12 MR. PEARSON: I have -- we didn't show
13 you all of the different permit conditions. So,
14 I would not -- the fact that you didn't see
15 anything about autoclave validation in there,
16 doesn't mean that autoclave validation isn't
17 still in there where appropriate. I mentioned
18 that we are planning to do a stakeholder
19 announcement and webinar on our methods to
20 provide much more detailed information to
21 stakeholders about what the actual permit
22 conditions will be in the future if this kind of

1 venue doesn't provide us with the time or the
2 opportunity to really go through in a detailed
3 way. So -- but, we will definitely be putting
4 that information out.

5 OPERATOR: All right. And one more
6 question we have is that, will all the slides be
7 posted? And, yes. All -- all slides will be
8 posted.

9 MR. GEORGE: Yes. They will.

10 Okay. Thank you very much, guys.

11 Nathaniel Yates is our BRS Branch Chief for
12 Compliance, Evaluation and Enforcement. He's
13 next with a report on compliance enhancements in
14 the last year and in the year to come.

15 Nate.

16 ENHANCING COMPLIANCE

17 MR. YATES: Thank you, sir. Good
18 afternoon, everyone. As he stated, I am the
19 Branch Chief of Compliance, Evaluation and
20 Enforcement, and I want to talk to you about some
21 of the things that we have done today, some of
22 our accomplishments over the last year, also some

1 of our process improvements as we've gone forward
2 throughout the year, how we've dealt with some
3 incidents that we've seen, as well as how we're
4 going forward, as it relates to compliance
5 oversight.

6 We continue to go through our process
7 for improvement, which includes -- one of our
8 goals this year was to develop and implement a
9 database to improve BRS management and tracking
10 of reports submitted by regulated entities. That
11 includes our planting reports, field test report,
12 volunteer report. In that, we have developed a
13 tracking access database to better track the
14 receipt of these reports, as well as for us to
15 review and analyze volunteer monitoring reports
16 over the last year. Information can be entered
17 manually into the database and then imported via
18 e-Permit, which allows us to track and analyze
19 information for multiple sources in one location.

20 It's also designed to synchronize with
21 a general BRS email, which allows us to easily
22 send emails to multiple regulated entities at one

1 time. So, we are becoming more efficient, as you
2 can see, through our processes.

3 Another one of our goals was to
4 increase the number of inspections that we were
5 doing. So, from 725 -- I'm sorry. Up five
6 percent. But also that we would conduct 50
7 percent of those inspections. As of November
8 1st, of this year, we have conducted 755
9 inspections. 55 percent of those we, BRS
10 personnel, actually performed. And 10 percent of
11 those were unannounced inspections. The
12 remainder of those that we didn't are
13 accomplished under a continued partnership with
14 our PPQ and State partners.

15 As relates to incident response,
16 you've seen, and we've all acknowledged that
17 we've had an elevation in the number of
18 hurricanes we had to deal with. And on our end,
19 we had to make sure that we could coordinate and
20 communicate to make sure there was no
21 unauthorized release or loss of containment of
22 regulated articles.

1 We've been able to do that. We've
2 been able to account for the different trials by
3 communication. We've engaged some of our
4 regulated entities more so to ensure that we can
5 do that. But also, as Mike mentioned earlier,
6 we've had engagement in other types of incidents
7 as well.

8 Specifically, Mike mentioned that we
9 had, but in that case, it was a non-regulated
10 solution, which is one of the things that worked
11 greatly to our benefit this year. So, we were
12 able to implement that plan for our incident
13 response plan.

14 Speaking of engagement with our
15 regulated entities, we have had a year of Notices
16 of Finding that raise some concerns. With that,
17 we have engaged with the feedback from the
18 regulated community. And we reviewed our
19 processes. And what we came up with is a better
20 understanding of how things are accomplished on
21 both ends.

22 We've engaged to see how certain

1 coordinates -- because our greater concern was
2 GPS coordinates of field trial. And what we
3 found is -- out is how you actually conduct or
4 take those coordinates and what it means to you
5 versus what we were seeing. As a result of that
6 engagement, we have actually reduced the manpower
7 hours on our end, because we were able to engage
8 during the process. We've also saved the time on
9 review of those items in the process, by becoming
10 more efficient in that way, which has obviously
11 made our timing and our handoff reduction -- we
12 reduced our handoff.

13 So, our inspectors go out. They can
14 see what's going on. We can get the information
15 we need and make an adequate assessment right off
16 the bat, as opposed to handing it off and then
17 going back and having to review that information
18 across different hands and at different times.
19 This has reduced our cost, but it's also
20 increased our quality, efficiency, and
21 effectiveness in doing our mission as regulators.

22 Going forward, there are some things

1 that we continue to pursue. And one of those
2 things is increased transparency. Some of you
3 may be aware that you can call in, and we can
4 discuss different matters. However, we are going
5 to make an effort to make sure that everyone is
6 aware of appeals process as it relates compliance
7 and termination. This is not new. We've always
8 been open to hearing and engaging on issues to
9 see what's going on. However, we do want to make
10 sure that those who have not used the process are
11 aware of that process. And that will help us in
12 our transparency, but also in your understanding
13 of how we make determinations on a number of key
14 things.

15 We are also in the process of
16 developing a new monitoring and evaluation
17 process for oversight. And what this allows us
18 to do is to still be able to come out and see
19 what's going on at a site, even during the months
20 where there may not be things coming out of the
21 ground. Imagine where there's snow covering the
22 ground. It does not mean that we can't look at

1 items such as equipment cleaning records, stores
2 and disposition of harvested materials records,
3 review of plans and volunteer monitoring, as well
4 institute a feedback loop into inspection process
5 for the 2018 planting season. Both of these, as
6 you can see, are geared toward more
7 communication, which allows us to do our job more
8 effectively.

9 Inspection selection. As you can see,
10 we might be wondering why we have a big parfait
11 up here. Not because we're hungry. It's because
12 we recognize that there are different levels and
13 different things that go into play when we make
14 our inspection selection.

15 As you can see, we evaluate different
16 things. Persistence risk, crop biology, trial
17 specifications. What's going on with that
18 specific trial? But also compliance history.
19 These are some of the factors that go into how we
20 manage. Where we're going to inspect, how we're
21 going to inspect, and things of that nature.

22 The overall drive is that we're really

1 looking at a more risk-based process. That's one
2 of the things that we want you to take away, is
3 that we're looking at that. We're not picking on
4 people, but we do want to make sure that we are
5 assessing the risk and ensuring that we don't
6 have any issues going into the future.

7 So, that's pretty much what we have to
8 bring for compliance oversight. We've
9 accomplished some great things this year. We've
10 improved our processes. We've improved our
11 communication. We've dealt with incidents, and
12 we've had very little concern in that process.
13 And going forward, we intend to engage more
14 thoroughly with you in order to provide the
15 necessary oversight.

16 Any questions?

17 MR. GEORGE: I remind people, if
18 you're on the phone and you'd like to ask a
19 question, press 1, then 0 on your telephone
20 keypad, and we'll see that. We see there's a
21 question coming in on our webinar.

22 OPERATOR: So, we have a question.

1 Has engagement with biosafety increased? Are
2 there plans for engaging biosafety officers
3 during inspection?

4 MR. YATES: Can you give me that
5 again?

6 OPERATOR: Has engagement with
7 biosafety increased? Are there plans for
8 engaging biosafety officers during inspection?

9 MR. YATES: So, our inspections have
10 not changed. How we do our inspections, as it
11 relates to being on the field, they have not
12 changed. However, our overall engagement has
13 improved. We do engage with our regulated
14 entities before we make determinations and also
15 throughout the process and afterward.

16 MR. GEORGE: Question? No? Okay.
17 All right. Thank you, Nate. Thank you very
18 much.

19 Some years back, BRS saw the need to
20 help people learn how to comply with our
21 regulations, and the result was the Biotechnology
22 Quality Management System program, which has

1 recently been updated with a more modular and
2 user-friendly approach. Here to tell us about it
3 is our Acting Director of our Resource Management
4 program, Chessa Huff-Woodard.

5 BIOTECHNOLOGY QUALITY MANAGEMENT SUPPORT PROGRAM

6 MS. HUFF-WOODARD: Wonderful. All
7 right. How's everyone doing? Okie dokie. So,
8 I'm going to try to be -- do multi-tasking here.
9 Again, my name is Chessa Huff-Woodard. I am the
10 Acting Director of our Resource Management
11 programs with BRS. However, in my everyday role
12 prior to my detail, I am the Branch Chief for
13 Policy program and international collaborations.
14 And it's my honor, my duty to discuss with you
15 all today the Biotechnology Quality Management
16 Support program.

17 Let's see. All righty. Great. So,
18 the -- what I want to explain to you today is
19 that BQMS -- and their acronym has remained the
20 same, has three critical components or three
21 building blocks. The first building block is our
22 modules. Our modules are now available on the

1 BRS website. We have a specific module for BQMS,
2 and what those modules consist of are templates
3 that are with modules to help you understand as
4 stakeholders and regulated entities what the --
5 what the intent is behind the use of each module,
6 and it helps you to understand whether or not you
7 will need to utilize them for your own purposes
8 or to either use those to check your own
9 documentation to ensure that you have a quality
10 management system in place.

11 The second component of our program,
12 our workshop. This year, what we have -- I'll
13 discuss those a little bit later. But there are
14 two components to our workshop. We have
15 foundational workshop, and then we also have
16 compliance assistance workshop, which we call
17 building up. What those essentially do is, after
18 you have established your foundation of quality
19 management, and specific to 340, your BQMS, that
20 you're able to put up the walls and the windows
21 and the doors that we're using the house building
22 acronym in order to help you understand more

1 those critical components of whether or not
2 they're critical control points or other aspects
3 of quality management that are related to our
4 regulations at 340.

5 And the last part is targeted
6 compliance assistance. We now have the
7 flexibility to work with individuals and
8 regulated entities on specific issues related to
9 quality management. I don't want to put any
10 parameters of scope around these, but it's to
11 help you understand a little bit more the tools
12 that we have available for your use.

13 And -- but, if we do find that some
14 of your questions are really geared towards
15 issuances, our branch, we do work in a
16 collaborative format. So, we will refer you to
17 the proper entity or -- excuse me, group within
18 BRS, whether it's BRAP or ROP or another group,
19 if necessary.

20 So, before I dig a little bit deeper
21 into the building blocks of BQMS, I do want to go
22 a little bit over the background of how we got

1 here to the current BQMS. So, in 2006, what BRS
2 did was engage with stakeholders to figure out
3 how we could provide a little bit more robustness
4 to our compliance. And really what we found is
5 that there was an area where we could fill in the
6 gap with compliance assistance.

7 And through having pilot projects and
8 really determining how we could focus on
9 compliance assistance, we implemented the BQMS
10 program in 2007. We operate that program
11 successfully, having recognized entities. But we
12 noticed that the program was very rigorous in the
13 sense that it had mandatory components and a lot
14 of requirements. And, so, we engaged with our
15 stakeholders in about 2015 and learned that
16 amongst other things that BQMS was not within the
17 reach of a lot of our universities and small
18 developers because of the resource intensity that
19 the program had.

20 So, in 2017, after a brief hiatus, we
21 did announce through a Federal Register Notice
22 the BQMS program transitioning from the

1 Biotechnology Quality Management program to the
2 Biotechnology Quality Management Support program.
3 Small evolution in the wording, but it made a big
4 difference, and we hope that's making a big
5 difference to you all as our stakeholders.

6 So, a little bit about the BQMS
7 program as it currently exists. The BQMS program
8 has always been voluntary, but it's a lot more
9 flexible in the sense now where you all have the
10 ability to reach out and touch all of our access
11 points on the BRS website and to decide whether
12 or not you actually want to utilize the modules
13 and templates that we have or if you just want to
14 use them as a resource just to ensure that you
15 have a succinct quality management system that's
16 unique to your requirements at 340.

17 So, again, this is accessible to and
18 available to anyone who would like to access
19 them, as long as you're related -- well, not as
20 long as you're related to, but specifically for
21 those who are related to developing agricultural
22 biotechnology products and engaged in research.

1 So, we have two primary objectives for
2 the BQMS program as it is. The first one is to
3 enhance the compliance with our regulations at 7
4 CFR part 340. And the second part is really to
5 help you all understand your responsibilities
6 pursuant to our regulations at 340, and also to
7 understand APHIS' practices, as it relates to the
8 implementation of the regulation.

9 So, let's take a little step back.
10 When we talk about quality management, what
11 exactly is that? Quality management systems in a
12 sense are comprised of your procedures and your
13 policies that ensure quality management.
14 However, they're overlaid on a continual
15 improvement paradigm, and we've kind of
16 distinctly had this chart here, which shows you
17 the plan do at and check module -- paradigm.
18 And that's improving it.

19 So, what you do, is you plan your
20 activities, your policies, and your procedures
21 pursuant to 340. You do those things, whether or
22 not it's an actual test run or if it's a -- or a

1 test run or an actual implementation of your
2 policies and procedures. You check them against
3 what it is that you said you would do, and then
4 you figure out your findings. And where those
5 gaps are, you act on those.

6 The goal is for you to take those
7 findings, to reinsert them into your processes to
8 improve them, and then to start this process over
9 again. The beauty about the BQMS system as it is
10 now, you have the flexibility to decide on how
11 often you do the cycle and how formally or
12 informally you do it.

13 Now, we'll talk a little bit more
14 about the components of the BQMS. As you see, we
15 have four primary categories that we use to
16 categorize what BQMS is. The first one is
17 document control. The second one is internal
18 control. The third are your critical control
19 points. And the fourth is continual improvement.

20 And what we will focus on today, and
21 what we have done, is to focus on your critical
22 points, which are relative to our regulations at

1 340. So, I won't go over all of the list of our
2 critical control points, but these are a listing
3 of the succinct modules that we have for our
4 critical control points with BQMS to help you see
5 how they correlate to a lot of the things that
6 you've heard from our colleagues earlier that
7 relate to how we operationalize our regulations
8 at 340.

9 What you won't find is a one to one --
10 necessarily, component to every line in the
11 regulations. But what they do is they operate.
12 Well, they are meant to fit in with how we
13 operationalize 340 and for you to understand what
14 your responsibilities are and what we're looking
15 for in regard to your document and what you
16 consider in creating a quality management system.

17 So, about the BQMS modules. I don't
18 want to be a little too redundant today, but they
19 are hands-on, they're flexible, and you are able
20 to adjust them to fit your needs. As I said
21 before, you are able to use them as either a
22 reference tool or as a template format to create

1 your own documentation.

2 But the beauty behind this is that it
3 does have an inquiry-based approach, where it
4 asks you questions along the way to help you
5 figure out whether or not you have these
6 processes in place or procedures in place and
7 where to put them into the document if you don't
8 have any idea, or if you would like some guidance
9 on how to put those together in order to create
10 succinct documents. That, again, overlaying to
11 the critical control points in the other modules
12 related to what we would consider a quality
13 management system pursuant to the regulations at
14 340.

15 So, the second component of our
16 building block for the BQMS program -- and you
17 see here we have the strong foundation. So, we
18 want to continue to reiterate that aspect of our
19 workshop. This year, I'm proud that my staff, we
20 were able to work with our colleagues within BRS
21 to execute our first BQMS foundation workshop.

22 That was in September of this year.

1 We had over 40 registrants and participants who
2 were here in headquarters and also participated
3 via webinar. What this did was it gave us the
4 opportunity to explain the tools as they have
5 been -- as they have evolved with the BQMS
6 program, as they are. And we also gave some
7 valuable feedback to you all as our stakeholders.

8 And this year we anticipate the we
9 will be able to host at least two compliance
10 assistance workshops, one that's geared at CBI
11 and compliance -- or, excuse me, and BQMS. And
12 CBI is confidential business information. And
13 it's really important that you all understand
14 what that is so you can justify and explain to us
15 as the regulators how to protect your information
16 so that you do not have any competitive harm.

17 And the other program -- or, excuse
18 me, workshop that we'll have is the Building Up.
19 And the reason that we're calling it the Building
20 Up right now is that we're going to use the data
21 that we get from our colleagues to see trends and
22 figure out what areas of -- are of the most need

1 from you all, our stakeholders. But we'll also
2 take your input to help us inform how we shape
3 that training and also our curriculum as we move
4 forward.

5 And the last part, as I spoke earlier,
6 is our targeted compliance assistance. This
7 really is an opportunity for you to contact my
8 staff and others in BRS to get more detailed
9 information and guidance in regard to the how to
10 establish a QMS related to the regulations at
11 340. We definitely encourage you to email us at
12 the email address listed here, and someone will
13 contact you and work with you in order to
14 identify what's the best way forward, the best
15 way to meet your needs is or are.

16 So, with that, I'm going to ask, are
17 there any questions?

18 OPERATOR: So, I don't know that this
19 is a question, but we have a comment that says,
20 in some strange way, I missed the old system, but
21 it was costing APHIS a lot of money.

22 MS. HUFF-WOODARD: Noted. Thank you.

1 Okay. All righty. Thank you all for your time.
2 Have a good one.

3 MR. GEORGE: Thank you very much,
4 Chessa. For many years, BRS worked with Virginia
5 Tech to make our release permitting data
6 available to all via their website. In
7 September, that all changed. Here to tell us
8 about it is our BRS lead IT specialist, Linda
9 Pardoe. The clicker's right there.

10 NEW PERMITTING DATA SEARCH TOOL DEMONSTRATION

11 MS. PARDOE: Okay. Thank you, Dick.
12 My name is Linda Pardoe. I am the lead IT
13 specialist here at BRS. And I have the honor of
14 standing between you and Dr. Firko and your
15 questions. So, I will try to do this as
16 expeditiously as possible.

17 So, I'm going to tell you about new
18 search tools for our permitting data, available
19 on the APHIS website. Okay. So, the BRS
20 permitting data includes permits and
21 notifications that have been submitted to us
22 since 1985. Yes. Our data goes back that far,

1 to 1985. And it's part of our goal of making our
2 regulatory actions transparent.

3 The data on the website for our
4 permitting data is refreshed every business day.
5 Many of you probably know, the BRS first
6 published our permitting data on the Virginia
7 Tech website in the 1990s. In 2007, BRS
8 implemented the ePermits system, and we have
9 posted the data for that system and all previous
10 data on the APHIS website since then.

11 I want to highlight a recent change
12 that Dick mentioned. As of this September, BRS
13 permitting data is exclusively hosted on the
14 APHIS website, and the Virginia Tech website has
15 closed. We developed these changes with in-house
16 staff, and we made the changes to improve
17 efficiency and also to provide improved searching
18 capabilities.

19 So, here is the previous check-status
20 page from prior to September. You can see in the
21 top-most red box, these were the prior links
22 directing folks to the Virginia Tech website,

1 where they could research our release data. I
2 did want to note that Virginia Tech only housed
3 our data for our release permits in those
4 occasions. We have other actions and movement
5 and import, and they have always been housed just
6 on the APHIS website.

7 And then, in the second red box, you
8 see the previous way that we used to provide
9 search capabilities on the APHIS website. We
10 have uploaded -- updated those means, and I will
11 show you that in future slides.

12 Okay. So, this is the old Virginia
13 Tech search-data page with the many fields that
14 you can search on for our release data. This was
15 then the resulting data page after the users
16 entered their search criteria, the data would be
17 presented as such.

18 So, to briefly review the time frames,
19 our APHIS agreement with Virginia Tech ended
20 September 15th. We announced this change to our
21 stakeholders on the APHIS website on September
22 1st. And Virginia Tech has graciously offered to

1 redirect anyone who's bookmarked links to their
2 old site -- to redirect them to our site. And
3 they will -- you'll be able to do that until
4 about March. We also encourage you to bookmark
5 links to our updated site.

6 So, there are several reasons for the
7 change. We have recently developed the in-house
8 capability to provide the permanent data on our
9 website. We have also added new features,
10 including the ability to search across all fields
11 in the table, and the ability to download data
12 selections in spreadsheet format. We have also
13 built the new search tables to run well on
14 multiple screen sizes. So, they will display
15 just as well on the laptop as on your smart phone
16 and tablet. And with the new search tables,
17 users can continue to search with the fields that
18 were previously available. And we've added new
19 searching fields.

20 Okay. So, here is the first page of
21 updated content. That's available now. Has been
22 available since September 1. In the red box

1 there, you see that we've divided the data into
2 three separate tables. Due to the large amount
3 of data dating back to the 1980s, we have chunked
4 it into three pieces. So, we have one table for
5 the release permits in those occasions. The
6 first one, a separate one for the movement
7 actions, and a third one for the courtesy
8 permits.

9 We are working to further improve
10 this. Eventually, users will be able to add --
11 enter their search criteria first and then be
12 shown the specific data that they're looking for.
13 Right now, when you click on one of these links,
14 it will fully load this table. So, we also
15 advise you to give it a minute or two, because,
16 depending on the speed of your internet
17 connection, it may take -- it may take a while to
18 load.

19 Also on this page, you see the red
20 arrow down the lower part? It shows the link to
21 download all of our data in a format that's
22 easily usable with a spreadsheet software. And

1 that file does contain all of our data. The link
2 right below that gives documentation. It will
3 give the data definitions for the fields in our
4 data.

5 This is just an example of what the
6 downloadable spreadsheet looks like when you open
7 it in Excel. It's hard to see, but those little
8 down arrows are the data filters. And as many of
9 you know, Excel provides many ways to analyze,
10 search, and filter on data.

11 So, this is what the new data tables
12 look like. This is the one for releases. Each
13 table has three sections. You see the blue bar,
14 the filter, search, and download. With the
15 filter, you make selections via the drop-down
16 lists. So, for status, you can pick acknowledged
17 or pending, et cetera. For type, you can pick
18 permit or notification. Then, for the middle
19 section, you search on text-box fields.

20 So, you enter a particular article
21 you're looking for in search article, and the
22 results would show that article. You can also

1 combine your search fields in one search, so you
2 can select pending as a status and enter a
3 specific article and see those results. Last
4 thing, you can download your selected data in
5 popular formats that work well with spreadsheet
6 software.

7 So, this screenshot shows the data.
8 Note the blue plus sign to the left of each row.
9 You see that all the data fields don't display,
10 don't fit horizontally on the screen. So, when
11 you click the blue plus sign, the data will fully
12 expand. And we see here on this example, the
13 data for the first row is fully shown.

14 As I mentioned, the APHIS data tables
15 are now optimized to run on multiple screen
16 sizes. So, this will work the same way on your
17 tablet and your smart phone.

18 So, we are always working to improve
19 the website. We want to add a way for users to
20 first enter their search parameters and then
21 present the data they're interested in. This
22 will also speed up the delivery of the data.

1 We're also working on other ways to speed up the
2 data delivery and eventually want to have one
3 table with all the data, so you can search it all
4 at one time. Lastly, we are working to add
5 summary charts.

6 So, here's a sample chart. This is a
7 work in progress. It shows the number of release
8 sites effective in 2016 for the continental US.
9 You can see that data. You see that we're not
10 yet showing Hawaii, Virgin Islands, and Puerto
11 Rico. So, we'll be adding additional data here.
12 We also want to add some interactive capabilities
13 so folks could see this data over time, in
14 addition to other charts such as on our top-ten
15 release article and basic numbers of our release
16 authorization, effective every year.

17 And I'm done. Any questions?

18 MR. ERICKSON: This is Neil Erickson
19 from the Ag division of Dow Du-Pont. I think I
20 may have already addressed this with you guys all
21 previously to the meeting, but the old site
22 actually used to show us statuses and -- kind of

1 as it was working its way through the process
2 with the state review as well. Are there any
3 plans that kind of add that to the search tool or
4 no?

5 MS. PARDOE: Well, we have thought
6 about that, and we think that the states really
7 are the best source of information, the most
8 accurate and up to date to advising you on their
9 review times. So, at this point, we will
10 recommend that you go to the states to get the
11 best answer to that question.

12 Thank you. Okay.

13 COMMENTS AND QUESTIONS SESSION

14 MR. GEORGE: Okay. Thank you very
15 much, Linda. So, we have some time here at the
16 end of the day for other questions. And I'll ask
17 Mike to come forward. I know we have one person
18 who has asked to make some comments. That's Leon
19 Corzine. And I would invite you to come forward
20 and make your comment. And then, Mike, if you
21 want to take questions, or however we want to do
22 this afterwards, that's fine.

1 MR. FIRKO: I do have some questions
2 that I got. And I'll handle those in a few
3 minutes, but I did want to comment that a few
4 days ago I got an email from Mr. Corzine asking
5 me, could he make a statement. I said, well, we
6 always have a question and answer session. How
7 about if we just have you come up, make your
8 statement as the first part of the Q and A. So,
9 Leon Corzine, who is a corn farmer from Illinois
10 -- you know, APHIS' mission is to protect animal
11 and plant health. And in doing so, we're
12 primarily protecting farmers and agricultural
13 producers. And Mr. Corzine is an agricultural
14 producer. He's one of the people we're
15 protecting.

16 MR. CORZINE: Okay. Thank you. I
17 want to offer greetings from the heartland and
18 thank -- special thanks to both Mike and Dick for
19 allowing me this time to bring a few comments
20 from the farm. It's a great opportunity for me.

21 And I really want to start out to
22 offer support to you all and your teams and also

1 talk a moment about the real importance that you
2 are and the things that you do that affect not
3 just me, but also my farm, my family -- I farm
4 with my son and my wife. But also to -- I'm an
5 Illinois guy. The state of Illinois. You can
6 expand that to our country, and I would submit,
7 even to the world, because of the things we're
8 able to do with the new technology that you all
9 help bring forward. So, not only you help
10 protect us, but you also provide the pathway for
11 these new tools that really help us.

12 We just finished harvest, and with my
13 son and wife -- and we have a helper that helps
14 us -- but it was my 44th harvest, which, I'm
15 thinking, holy cow. I started really young. I'm
16 not that old, right?

17 Our yields were our second best ever,
18 and by country numbers, USDA is going to come in
19 pretty close, a new record harvest. And you may
20 or may not be aware, we had Mother Nature throw
21 the term, everything but the kitchen sink at us.
22 You know, we -- when we were planting -- right

1 after we started planting, we had record
2 rainfalls, followed with cold weather, which is
3 the worst for corn germination. We replanted
4 more corn than we've ever replanted on our farm.

5 We then had -- during and right after
6 pollination, we had heat. Then we had dry
7 weather. I think after somewhere around
8 September 1st, I'm not sure it rained again.
9 Maybe a little bit. Then we had an extended cool
10 period, which, I think at the end of the day,
11 helped us. And here we are with yields, in my
12 part of the world, now we are natural water, if
13 you will. We don't irrigate. We have some of
14 the best soils in the world, and I'm just well
15 blessed, five generations ago or six, family
16 happened to hop off of the train at the right
17 place in central Illinois. But to have record
18 yields and to be able what we're able to do, we
19 have literally doubled, since I started farming,
20 what our yield goals are.

21 And that's a great story, that I don't
22 think we tell well enough or often enough. And

1 in that -- you know, in that adversity, these
2 yields and what our seed technology -- now, our
3 other technologies with our equipment and what
4 we're doing with the soils is part of that too.
5 But to do that is just plain awesome. I'm not
6 sure there's another word for it, that we do need
7 to talk more about.

8 And with that, what that helps us do
9 -- we're getting better nutrient utilization as
10 well as we are also continuing to improve our
11 sustainability in the stewardship of our soils.
12 And we aren't having to infringe on those fragile
13 lands to get the kind of production we need. In
14 fact, we have -- in a sense, in prices we've
15 over-produced just a little bit.

16 Now, with that, I think -- I really
17 want to appreciate also, when I started coming to
18 these meetings or got involved, we had somewhat
19 of a backlog of all the things coming at APHIS
20 and BRS. And, you know, you've really moved
21 through that. And I really applaud that. That's
22 important, because those kind of delays keep --

1 if we do get into delays, there is a cost, not
2 just in time cost to whoever the biotech provider
3 might be, but also to us on the farm, because all
4 of these things are able to do and to keep moving
5 forward for my next generations is -- we can't
6 have those delays.

7 We need the tools available, because
8 things evolve, science helps us evolve, and as we
9 -- if we have backlogs or undue delays, you know,
10 there's that cost that we -- it's a lost cause --
11 if you get what I mean. So, we need that new
12 technology. We need to keep coming forward. US,
13 they're the leaders in this, and there's a reason
14 why.

15 So, I also want to mention that for a
16 moment I thought I should also talk about, as we
17 have new tools, new science, I really appreciate
18 the efforts that have been made or the work that
19 has been done on the rewrite of Part 340.

20 I know there were some issues, I saw
21 them on it, but I think it is a -- it is a great
22 thing to do. It's something we need to do. My

1 hope is we don't put it on the shelf and let it
2 sit there. I think, because -- I think it does
3 need to be done. I think there's some things
4 that stakeholders have some questions and maybe
5 didn't fully understand even in some parts. So,
6 I guess the question is, you know, what is the
7 process as we go forward?

8 And also, an ask would be, can we
9 include stakeholder groups, whether it's the ag
10 groups, in the process early on so we do have an
11 understanding and maybe can provide some input as
12 we move forward in that process?

13 So, those are the only two questions
14 I ask. And I do appreciate the time. I could go
15 on and on about the farm for a while, but, you
16 know, I'm going to get us late in the day. So, I
17 will stop at that. So, once again, thank you
18 again for the opportunity. And it's great to be
19 here. I was able to dust -- get the dust out of
20 my hair and get on an airplane for a couple days.
21 So, thank you.

22 MR. FIRKO: Thank you very much.

1 Questions for me or anyone who gave
2 presentations.

3 John.

4 PARTICIPANT: Thank you, Mike. In
5 your presentation, you were talking about giving
6 authorizations or notifications for a variety of
7 CRISPR-type organisms.

8 MR. FIRKO: Yes.

9 PARTICIPANT: Is that correct? Okay.
10 And yet telling us in our Am I Regulated process
11 and through some of the letters that should have
12 been submitted there, that developers are not
13 regulated using similar or the same sorts of
14 technology.

15 MR. FIRKO: Yes.

16 PARTICIPANT: You see an inconsistency
17 there in how you're approaching the regulation of
18 some of the CRISPR organisms?

19 MR. FIRKO: Nope. Let me tell you
20 why.

21 PARTICIPANT: Okay.

22 MR. FIRKO: A lot of these products of

1 CRISPR technology are indeed regulated articles.
2 We -- if someone asks to be regulated, if someone
3 asks for a permit, we assume they know what they
4 did and how they made it and that it's a
5 regulated article. Others who have used CRISPR
6 techniques and they're not certain whether or not
7 it's a regulated article, they can ask us a
8 question, and we'll give them an answer.

9 And the primary difference there --
10 and I have some online questions that will get to
11 this too is, what did you do, how did you do it,
12 and what's left over? In the cases of the
13 products created using CRISPR technology that we
14 have said, no, you're not regulated, like I said
15 before, those have been all SDN-1, which means,
16 maybe a plant pest was used during the process,
17 but the resulting product not only has no trace
18 of any plant pest material that may or may not
19 have been used during the process, but there is
20 not inserted material whatsoever.

21 So far what we've seen is single base-
22 pair deletions. You know, very minor gene

1 editing processes. So, there's nothing there
2 that we can say, oh, well, there's a plant pest
3 there, so we have it barred. And it all boils
4 down in the Am I Regulated to, do we have the
5 authority or don't we have the authority. Now,
6 again, in our proposed rule, we propose to ask
7 those questions every time somebody submitted a
8 permit. That's not our process now. We propose
9 to do that. That rule is withdrawn right now.

10 PARTICIPANT: Okay. Thanks.

11 MR. GEORGE: Mike, we have an online
12 question.

13 MR. FIRKO: So, we got some online
14 questions earlier. Maybe I should address those
15 first?

16 MR. GEORGE: Do those first.

17 MR. FIRKO: Okay. First one from Dr.
18 Joshua Terse. I think it's Terse. He's asking -
19 - he's asking about the slide where I showed the
20 number of authorizations for release, the number
21 of sites, and the number of genetic constructs.

22 And he asked the question, does the

1 genetic -- does the number of genetic constructs,
2 is that elevated? And I hope I get this right.
3 I hope he's still on.

4 Is it elevated because particular
5 genetic construct is tested in multiple
6 locations, and therefore it counts it twice or
7 three times or four times? The answer to that is
8 no. The one possibility of some redundancy is
9 that the search tools that we use right now to
10 generate those numbers looks per authorization,
11 per application. So, it is possible. And it
12 goes by event name. So, it's event by event.
13 So, if a particular applicant requested a
14 particular event, and then during that same
15 fiscal year asked for that same event, it might
16 get counted twice. But we can -- we think that's
17 a pretty small -- it probably occurs, but we
18 think it's not very likely and it's not very
19 often. But what we can do for next year is try
20 to enhance our search capabilities to tease those
21 out, so that we can really look at the number of
22 unique events or unique constructs.

1 We had a question. It's from Don
2 Enley. He asked, now, I mentioned that the 340
3 rule was withdrawn based on comments received.
4 Can I be more specific?

5 A little bit. One of the reasons I
6 spent some time talking about the general nature
7 of the comments that we receive is that if you go
8 in and you look at the comments that we receive,
9 it's a head-scratcher, because if I were to
10 characterize the number one thing, there is a
11 whole group of commenters who said, oh my gosh,
12 this is so much more regulation. And then
13 there's a whole 'nother bunch of people. And if
14 you count people, it's a much larger proportion
15 to say, this is dramatic underregulation. You're
16 not going to be regulating anything.

17 So, somewhere in our communications,
18 different groups of people are interpreting our
19 proposed rule very differently. So, that's why
20 we need to engage with stakeholders more. Try to
21 figure out what was going on there, why different
22 groups of people viewed our proposed rule so

1 dramatically differently. And that's what the
2 new stakeholder engagement is intended to
3 address.

4 Also had a question. And this goes
5 back to the CRISPR business. Again, Dr. Joshua
6 Terse. And I'm not sure I got the exact
7 transcription of his question, but what I read
8 here is, why BRS decided that CRISPR-modified
9 organisms should not be regulated?

10 Now, two things about that. And if
11 this was not the exact wording, I apologize to
12 Joshua. First of all, we didn't decide that all
13 CRISPR-produced organisms will not be regulated.
14 We decided that those particular products that
15 were put before us would not be regulated.
16 CRISPR is a very powerful tool. It may very well
17 be possible that we will soon see a product
18 produced with CRISPR technology where we would
19 say, oh, yes, that falls within our regulatory
20 authority, under our current regulation.

21 So, I want to make it clear that our
22 decisions haven't been about all products

1 produced with CRISPR technology -- only those
2 that we've seen so far.

3 And then the other one -- and, again,
4 I might be parsing words a little too much, but I
5 can be type-A sometimes -- should not be
6 regulated. So -- and I've seen this in the media
7 as well. We're not answering the question,
8 should something be regulated. We're answering
9 the question, do we have the authority to
10 regulate it. That's a different question. And
11 when we give an answer, we're saying, we don't
12 have the authority or we do have the authority to
13 regulate it.

14 And then -- actually, Margaret Allen
15 had answered my question. She said, were the
16 not-regulated CRISPR products not regulated
17 because genes were not added? Yes. That's why.

18 Okay. So, I think I -- Yes. So, the
19 new online one.

20 MR. GEORGE: Okay. Yes. I have one
21 online. What were the reasons for the January
22 proposed rule was withdrawn?

1 MR. FIRKO: That's in my presentation.

2 MR. GEORGE: Okay.

3 MR. FIRKO: Yes. The two primary
4 reasons are -- and I just spent some time talking
5 about that. It's hard to make sense of the
6 disparate comments that we got. And we clearly
7 need to do additional stakeholders engagement to
8 try to figure out how it can be interpreted so
9 differently by different people.

10 MR. GEORGE: And I also want to make
11 sure we get to Leon's question about whether farm
12 groups and so forth can be involved in whatever
13 development might be. And answer to that one
14 too.

15 MR. FIRKO: Sure. Absolutely. You
16 know, we -- I got your comments and proposal.
17 Thank you. People can go ahead and read what you
18 said to that.

19 OPERATOR: So, while we're on the
20 subject of the proposal, we had a question. What
21 are the next steps for the withdrawn proposal?

22 MR. FIRKO: So, we in BRS have been

1 talking about that for a while. The Secretary's
2 office has been talking about that. I don't
3 think the Under Secretary has engaged. He's
4 brand new, and USDA is a bureaucracy. I guess
5 he's been here for about a month. Mr. Ibach.
6 He's the Under Secretary for Marketing and
7 Regulatory Programs. Maybe five weeks.
8 Something like that. I think most of his time up
9 to this point has been dealing with getting a
10 security clearance, getting his link pass -- you
11 know, figuring out what it means to work for the
12 federal government.

13 So, I personally have not met Mr.
14 Ibach since he started. I've been engaging with
15 him for many years as he was a NASDA member.
16 National Association of State Departments of
17 Agriculture. And APHIS engages with NASDA very
18 regularly. But I have not engaged with him since
19 he started, and he is my Under Secretary.

20 And, you know, I'm not in a position
21 to be saying, here's what we're going to do until
22 I've engaged with Mr. Ibach, my Under Secretary,

1 and had those discussions with him. And although
2 everybody's been thinking about this and
3 everybody's got ideas and everybody's got plans,
4 there's nothing to be released at this point
5 about exactly what that's going to look like.

6 You can interpret from the language
7 about we need to engage with stakeholders. I
8 would hope that we will be engaging as broadly as
9 is humanly possible with interested stakeholders.
10 You may remember two years ago, at the -- at the
11 stakeholder meeting two years ago, we have the
12 opportunity to any interested person to meet one
13 on one with me or other BRS leaders. And we did
14 that. We had 20 or 30 one-on-one meetings with
15 individuals or groups.

16 Apparently, we didn't get our message
17 across very well, because I know that I met with
18 people that were on one side of that bimodal
19 distribution that I talked about and others who
20 were on the other side. So, we need to find a
21 different way to communicate what our intentions
22

1 are and what we were actually proposing.

2 OPERATOR: Do you have an aspirational
3 goal of when you would like to make the formal
4 changes to the proposed rule?

5 MR. FIRKO: I have -- well,
6 aspirational? Tomorrow.

7 (Laughter.)

8 MR. FIRKO: When do I think it might
9 happen? I -- you know, I would -- I'd have to
10 get my crystal ball out, and my guess would be no
11 better than anybody else's. You know, there's a
12 lot of work we've got to do. First of all, we
13 have to decide whether or not there's going to be
14 a new proposed rule. And then, secondly, we have
15 to decide what the path to a new proposed rule --
16 if we go that direction, what that pathway's
17 going to be. I hope it happens quickly.

18 Our -- our regulation that we have
19 now, in a field that is absolutely dependent on
20 modern science is 30 years old. It's based on
21 the science from 30 years ago. I'm embarrassed
22 by that. It's time to have new regulations.

1 There have been some tweaks over the years, but
2 essentially, it's based on the same regulatory
3 trigger, and it hasn't changed fundamentally.
4 Now you can do petitions. Now you can get
5 notifications, couple little things like that.
6 But it's fundamentally the same regulation that
7 was written 30 years ago.

8 Yes.

9 MS. HOUSTON: Virginia Houston,
10 American Free Trade Association. I wanted to
11 follow up on our comment earlier about
12 international engagement. If BRS receives any
13 questions from international stakeholders,
14 partners or post about the withdrawal 340 and to
15 that hot talking point that has been provided.

16 MR. FIRKO: So, there's a couple
17 things there. Yes. We -- we did a little bit of
18 engagement ahead of publication of the proposed
19 rule, letting them know it was coming, because
20 that was in the public domain, and we wanted to
21 make sure they were aware of that.

22 As I discussed last year at this

1 stakeholder-meeting, you know, once you get into
2 this ex parte communication, Administrative
3 Procedures Act business, you can't really talk
4 details with anybody, regardless of whether
5 they're domestic or international. Now, as folks
6 have come in, as these visitors have come in and
7 we've met with them or we've gone to China or
8 we've gone to Paris and met with OECD, we've
9 relayed to them what we can.

10 In terms of what's been released, in
11 terms of requests from international trading
12 partners since the withdrawal, no. In terms of
13 what we will be doing, nothing until we have a
14 public-releasable outreach program and a plan for
15 going forward. It will include international
16 outreach though. The public releases say that,
17 and I see no reason why that wouldn't happen.
18 Obviously, the US domestic regulations, which is
19 what we're talking about, has impacts on our
20 international trade and export of US products.
21 So, it's critical that we deal with foreign
22 governments but also remember that we are not a

1 trade agency. Foreign Ag Service is the trade
2 agency, and we support the Foreign Ag Service.

3 Daria, you had a question that we --
4 was that it? Or--

5 MS. SCHMIDT: So, Mike, thank you for
6 that. And, also, I will raise a concern, because
7 -- because the US is looked to, as it should be -
8 -

9 MR. FIRKO: I missed that. Say it
10 again.

11 MS. SCHMIDT: I do have a concern.
12 So, I'm going to roll into -- into my concern a
13 little bit.

14 MR. FIRKO: Yes. Definitely.

15 MS. SCHMIDT: Because the US is looked
16 to quite a bit --

17 MR. FIRKO: Oh. Looked to. That's
18 what I missed. Sorry.

19 MS. SCHMIDT: I'm not enunciating.
20 There are questions already being raised --

21 MR. FIRKO: Yes.

22 MS. SCHMIDT: -- around the globe with

1 what happened. And we can interpret, and we can
2 try and help our individual folks overseas, but
3 it's really effective if -- I would suggest it'd
4 be really effective for -- actually to begin as
5 soon as we can for those next steps and we can
6 say that. And now that you can have those
7 dialogues.

8 MR. FIRKO: Yes.

9 MS. SCHMIDT: There are a number of
10 venues that are coming up. I would ask that BRS
11 consider how they can help the rest of the
12 regulators around the world to understand what's
13 next.

14 MR. FIRKO: Yes.

15 MS. SCHMIDT: And as much as we can
16 help with that, let us know, but it's really more
17 effective if it would come from y'all.

18 MR. FIRKO: Like I said, my
19 aspirational goal is tomorrow.

20 MS. SCHMIDT: Tomorrow. Well, and I
21 do understand that, but I'm still trying to find
22 out where the cafeteria might be.

1 So, we appreciate the effort. So, I'm
2 going to restate. Because we really appreciates
3 these efforts to modernize the regulatory
4 framework. Your point of a 30-year-old system is
5 well taken. We believe that significant portions
6 of the draft will go well-intended. Science-
7 based and supportive of continued innovation.

8 There were components of the draft
9 ruled out, were unworkable, and we talked about
10 that. We strongly encourage BRS to engage with
11 stakeholders at the earliest possible opportunity
12 on how to modernize part 340. Would you believe
13 that now is the time to modernize regulations
14 that's covered biotechnology?

15 And the momentum must not be lost, as
16 we keep that right balance and delivery
17 effective, efficient, and risk-proportionate, and
18 science-based regulations for the United States.
19 US farmers are and will continue to be in need of
20 innovative solutions to provide for both the
21 domestic and international.

22 In order to do so, we believe that

1 modernization of the specific aspects of the
2 regulatory framework is the right path to
3 continue to lead as the US Department of Ag to
4 shape the global discussion and work toward that
5 international harmonization.

6 MR. FIRKO: Thank you. I didn't hear
7 a question in there. Right?

8 (Laughter.)

9 MR. FIRKO: Okay. I just didn't want
10 to miss one. Thank you.

11 OPERATOR: Speaking of harmonization,
12 somebody said, we heard about discussion that
13 OECD on global harmonization. Is there any
14 progress with global harmonization on gene
15 editing regulations?

16 MR. FIRKO: Do you want to get that?

17 MR. SHAQIR: Well, concerning the gene
18 editing regulation, we're looking to the U.S. for
19 leadership. And the other -- so, we have been
20 really thinking about, you know, the best
21 approach is to share with them what we have done
22 so to date and what they have shared so far is

1 how we're dealing with their inquiries with the
2 Am I Regulated.

3 And, to me, that was basically the
4 best way to start thinking about how we're going
5 to be dealing with these products or technologies
6 early -- from now, moving forward. So, the BRS,
7 I mean, we've been close -- really, we don't
8 think much -- we do think about technology, but
9 we really -- we think of the end result, of the
10 product. And the to keep in mind. But we have
11 received several inquiries in the past about how
12 we're dealing with this, with the developing
13 technologies and so on. And we have been -- you
14 know, there's several conferences and different
15 science events that already dealt with this
16 issue, and I think it's important to maintain
17 engagement.

18 And that -- the guidance moving
19 forward on the best way to look at how we can
20 attempt to understand the implication and the
21 advantage and so on when it comes to genome
22 editing. I think the best we have, as I said, we

1 shared with them on how we dealt with the -- all
2 the products that came in front of us. And we
3 have there -- there is strong interest still to
4 learn about how we're going to be dealing and
5 regulating some of these new products.

6 OPERATOR: Are there any other
7 questions in the room?

8 MR. FIRKO: Don't hold back. Is it
9 Miller time or something?

10 MR. GEORGE: Anybody -- is there
11 anybody on the phone that has a question? Might
12 be somebody in the queue. No?

13 MR. FIRKO: Okay. I've got plenty of
14 stuff to do.

15 MR. GEORGE: Okay. Mike, in that
16 case, I'll just wrap it up then --

17 MR. FIRKO: Okay.

18 MR. GEORGE: -- if there's no more
19 questions. Okay. First, I've got to say, I
20 really -- I really want to thank everybody for
21 being here. This is the best attendance we've
22 ever had since I've been here, and we have

1 another 70 people on the phone. And, so, that's
2 a very healthy interest in the subject -- 81 on
3 the phone. See that? It grew.

4 So, thank you very much. We are very
5 interested in putting on a meeting that
6 communicates well and serves your needs as well.
7 So, you will receive a questionnaire in the next
8 day or so, emailed to you. Would you please take
9 a few minutes to fill it out? There's little
10 comment box, if there are things that you'd like
11 us to do better or subjects we didn't cover or
12 didn't cover enough, we really want to know about
13 that for the next time enough. We pull out our
14 lessons-learned document before we start planning
15 every year's meeting -- the lessons learned from
16 the previous year. So, trying to get better
17 every year.

18 I will tell you that all of the
19 PowerPoints today will be on the -- our website.
20 Within a couple of days there will be a complete
21 transcript of the meeting also posted there.
22 That's going to take several weeks before we get

1 that up. It will be a complete transcript of the
2 meeting.

3 And I have one last thing, if you
4 would indulge me for just a moment. We have a
5 group of people that work very hard behind the
6 scenes to make this meeting happen. And I would
7 like to take a moment to recognize them with a
8 nice round of applause. But wait until I've name
9 them all, if you would, please.

10 Starting with Eric Ford who's over
11 here on the headphone. Let's wait. Hold your
12 applause. Let's save it for everybody. So,
13 we've got Eric. We've got Robin Wilcox --
14 amazing up here. We have Miranda Wanex, who
15 should be in that empty chair, but she ducked out
16 for a moment. These people do miraculous things
17 to make this meeting happen. Colleen Wood, where
18 are you? Colleen, who also does a lot of the
19 work, especially having to do with getting all
20 these PowerPoints together and making everything
21 flow as smoothly as possible. Outside at the
22 desk, she's not in the room, is Sarah Lively, who

1 handles all of the registration online and all of
2 the communicating with you before you come to
3 this meeting. And she's helped by Gail Jones,
4 who's also out there and pitching in. So, if you
5 would, please -- Nick?

6 MR. FIRKO: I just wanted to add a
7 heartfelt thanks to everyone who took the trouble
8 to come here today or to call in the webinar. We
9 truly look forward to this meeting every year.
10 We're already looking forward to next year, and I
11 appreciate all the questions. Thank you very
12 much.

13 MR. GEORGE: Let's recognize the team,
14 please. Thank you so much. Thanks for coming.

15 (Applause.)

16 (Whereupon, the above-entitled matter
17 went off the record at 4:33 p.m.)
18
19
20
21
22

A	
abbreviation 13:18	142:10 144:19 145:4
Abel 23:21	145:12 146:3 174:6
ability 131:10 141:10 141:11	added 52:8 69:17,18 141:9,18 159:17
able 10:3 13:8 50:8 51:7 94:18 112:16 121:1,2 121:12 122:7 123:18 128:20 134:19,21 135:20 136:9 141:3 142:10 148:8 149:18 149:18 151:4 152:19	adding 69:11 101:12 145:11
above-entitled 81:3 174:16	addition 145:14
abroad 39:18	additional 15:20 69:12 90:16,18 96:15 145:11 160:7
absolute 108:18	additional 34:8
absolutely 36:7 160:15 163:19	additions 64:8
academics 75:7	Additive 66:12 67:5
Academy 53:2 62:15	address 58:3 71:2 78:2 93:14 97:14 115:10 137:12 155:14 158:3
accepting 77:8	addressed 55:1 145:20
access 119:13 131:10 131:18	addresses 78:4
accessible 131:17	addressing 57:4
accessing 19:1	adequate 122:15
accommodate 102:14	ADJOURN 2:22
accomplished 120:13 121:20 125:9	adjust 134:20
accomplishment 15:14	administered 58:16
accomplishments 13:16 15:22 118:22	Administration 1:17
account 121:2	administrative 35:13 36:6 165:2
accumulate 70:6	administrator 1:14,15 8:8 18:8 23:22 37:9 112:17
accurate 146:8	adopting 44:15
accurately 100:4	advance 43:15
acknowledge 98:6	advanced 64:6
acknowledged 120:16 143:16	advances 14:22
acknowledging 14:22	advantage 41:11 42:8 170:21
acronym 127:19 128:22	adversity 150:1
acrylamide 16:3 69:16	advise 142:15
act 25:21 33:11 35:3 72:14 73:12 133:5 165:3	advising 146:8
Acting 127:3,10	advisory 46:7
actions 21:15 57:4 139:2 140:4 142:7	affect 148:2
active 12:21 29:4 35:6 60:19	afternoon 3:5 29:22 38:2 81:12 118:18
activities 9:13 12:18 13:1 40:11 45:2,8,10 49:2 53:3 68:6 76:18 80:18 94:11 96:1 132:20	afterward 126:15
activity 33:13 66:7	ag 17:5 40:1 43:7 56:21 58:11,16 63:3,4 145:19 152:9 166:1,2 169:3
actual 117:21 132:22 133:1	age 16:15 35:14
add 69:13 93:1 96:15	agencies 38:9 39:22 40:4 46:16 48:9 49:20 50:4,8 53:20 58:10 67:1 73:5 79:16 80:2 80:8
	agency 41:17 47:10 51:4 55:14 71:6 76:7 80:4,9 98:5 100:8 166:1,2
	AGENDA 2:2
	ager 94:4
	ago 11:7 17:6 23:17,21 25:19 27:2 32:18 50:3 50:7 81:7 147:4 149:15 162:11,12 163:21 164:7
	agreement 140:19
	agreements 48:18
	agricultural 18:1 36:1 38:11 46:19 62:15 77:2,14 131:21 147:12,13
	agriculture 1:1 13:2 51:12,16 53:7 55:5,20 62:12 161:17
	agro 85:9,10
	Agrobacterium 71:16
	Aha 67:12
	ahead 26:1 27:18 40:12 92:13 102:18 160:17 164:18
	aiming 97:15 98:9 100:13
	airplane 152:20
	Alan 1:18 10:15 94:15 103:5 113:17
	Alimentarius 54:12
	Allen 159:14
	allergenicity 72:3
	allotted 7:15
	allowed 27:11
	allowing 60:6 147:19
	allows 36:4 101:3 119:18,21 123:17 124:7
	altered 68:22 83:19
	amazing 173:14
	ambiguity 97:7
	ambiguous 41:5
	amended 99:14
	amending 99:20
	amendment 100:3
	amendments 53:13
	America 30:7 52:6
	American 164:10
	Americans 49:9,9
	amount 67:14 87:20,22 142:2
	AMS 63:13
	analyses 14:19 27:17
	analysis 64:21 83:15 89:16 94:22
	analyze 87:15 88:13 89:8 119:15,18 143:9
	analyzing 82:5
	animal 1:1 33:8 53:15 53:18 99:17 147:10
	animals 49:13 100:2
	announce 130:21
	announced 140:20
	announcement 102:2 117:19
	annual 26:22 29:16,18 44:13 112:6
	answer 2:8 32:18 56:5 57:10 61:20 63:21 84:2 115:18 146:11 147:6 154:8 156:7 159:11 160:13
	answered 30:19 32:15 76:9 82:16 85:1,4 113:20 159:15
	answering 84:20 92:6 159:7,8
	answers 24:9 34:19 36:11 116:11
	anticipate 28:1 34:10 136:8
	anticipating 92:18
	anybody 23:2 24:10 163:11 165:4 171:10 171:11
	APHIS 1:2,14,15 8:7 9:10 14:22 17:5,21 18:3,6,10,13,21 20:5 20:6,7 21:15 22:19 26:22 29:21 30:12 34:21 35:1,2,22 37:8 40:3 43:8 46:16 49:21 52:7 55:15 63:1 72:20 73:7 137:21 138:19 139:10,14 140:6,9,19 140:21 144:14 150:19 161:17
	APHIS' 33:7 72:19 73:15 132:7 147:10
	apologize 158:11
	apparently 20:3 162:17
	appeals 123:6
	appear 95:13
	appears 117:5,10
	applaud 150:21
	applause 173:8,12 174:15
	apple 85:9
	apples 85:7
	applicant 113:12 116:13 156:13
	applicants 115:12,14 115:17,20
	application 12:7 31:12 32:10 113:15 115:15 115:18 116:14 156:11
	applications 11:18 55:20 65:14
	Applied 66:11

apply 95:16 96:4
103:13
appreciate 66:16
150:17 151:17 152:14
168:1 174:11
appreciates 168:2
approach 39:6 40:17
42:6 44:15 47:21
52:10 58:2 59:9 72:12
76:14 101:16 127:2
135:3 169:21
approachable 78:12
approaches 32:20
38:19,22 54:17,19
55:10,11 61:1
approaching 153:17
appropriate 18:6
117:17
appropriating 76:21
appropriations 17:11
approval 52:22 99:18
100:8
approvals 100:10
approved 54:9,10,11
116:3
ArborGen 33:21
Arcadia 71:15
area 39:8 45:10 48:13
53:15 54:2 55:13
62:22 106:6,9 130:5
areas 18:13 45:11 52:4
52:16 105:14 136:22
arrange 79:2
arrow 142:20
arrows 143:8
ARS 18:3,8,10,11,12
article 30:17 82:12
83:16,17,22 84:3,7
86:12,14 104:2 114:8
143:20,21,22 144:3
145:15 154:5,7
articles 82:4 86:7
120:22 154:1
as-is 88:11
aside 3:12
asked 21:3 31:9,15 38:3
44:17 58:5 61:6,13
75:4 79:16 94:2
112:13 115:4 146:18
155:22 156:15 157:2
asking 75:20 147:4
155:18,19
asks 135:4 154:2,3
aspect 40:18 88:22
90:15 135:18
aspects 38:10 86:13
129:2 169:1
aspirational 163:2,6

167:19
assessing 125:5
assessment 15:7 16:11
16:19 25:2 26:13
27:20 29:11,21 30:2,9
34:21 54:1 62:13 72:4
122:15
assessments 14:19,21
48:12 53:14
assign 95:6
assistance 128:16
129:6 130:6,9 136:10
137:6
Assistant 23:22
Associate 1:15 18:7
37:8
associated 100:18
Association 161:16
164:10
assume 154:3
assure 112:21
asterisk 113:3
Atlantic 69:19
attempt 170:20
attendance 5:12 171:21
attended 17:17 29:11
29:12
attendees 5:13
attention 51:13
audience 5:16 17:17
19:18 22:22
August 69:5
authority 15:2 17:1
33:10 72:13 73:5,11
79:18 80:5 97:21
100:4,7 155:5,5
158:20 159:9,12,12
authorization 11:4
31:11,13 145:16
156:10
authorizations 9:14,18
10:1 12:12 31:7,9
153:6 155:20
authorized 11:11,13
12:5,7
authorizes 100:16
autoclave 117:4,9,15
117:16
available 14:16 19:11
19:12 32:21 62:5
116:20 127:22 129:12
131:18 138:6,18
141:18,21,22 151:7
average 58:20 108:13
averages 24:4
avoid 55:10
awarding 76:21
aware 19:17 24:19 37:3

78:22 123:3,6,11
148:20 164:21
awesome 150:5

B

back 5:3 7:20 8:16
24:12,13 27:5 30:14
51:4 52:6,7 53:8
55:12 61:4 67:10
79:10,19 80:20,21
84:4 90:12 114:11
122:17 126:19 132:9
138:22 142:3 158:5
171:8
backbone 64:16
background 81:21
95:11 129:22
backlog 150:19
backlogs 151:9
bacterium 85:9,10 94:2
94:5
bad 3:18 107:4
badges 20:13
balance 168:16
ball 163:10
bar 143:13
barred 155:3
barriers 42:14
base 70:22 107:2
base- 154:21
based 26:7 27:20 40:22
41:21 42:11 52:12
75:20 78:11 85:11
105:4 110:21 112:9,9
112:10 157:3 163:20
164:2 168:7
bases 74:21
basic 64:12 74:9 116:12
145:15
basically 38:4,18 40:18
41:14 42:5,20 44:8
58:1 83:14 93:16 99:5
99:19 101:10 115:17
116:5 170:3
basis 40:19 46:22 47:20
74:16
bat 122:16
Bayer 16:13 34:3
beard 5:22
bearer 3:18
beautiful 4:3 19:21 70:9
beauty 133:9 135:2
becoming 120:1 122:9
beginning 21:20
behave 111:20
behaves 108:19 111:7
111:18
beings 35:16

believe 41:2 42:16
59:11 72:17 168:5,12
168:22
benefit 71:5 121:11
benefits 82:2
bentgrass 16:7 b
bentley 59:16,16 60:9
best 30:12 62:5 75:10
77:19 112:18 137:14
137:14 146:7,11
148:17 149:14 169:20
170:4,19,22 171:21
beta 70:3
better 3:11 23:5 24:5
30:22 69:2 81:9 87:21
90:5 91:16 119:13
121:19 150:9 163:11
172:11,16
beyond 38:15 111:19
115:19
big 18:17 20:4 83:13
124:10 131:3,4
biggest 4:21
bilateral 45:12 52:5
53:5
Bill 1:17 81:10 92:14
94:11
bimodal 162:19
binding 47:15
bioengineered 75:16
biohazard 58:21
biolistics 86:5
biological 1:16 25:9,12
25:20 26:4,15 37:11
54:4
biology 54:2 84:13
103:13 104:9 105:4
108:18 109:13 124:16
biosafety 62:17 126:1,2
126:7,8
Biosciences 71:15
biosynthetic 70:4
biotech 15:8 33:3 38:11
42:8 44:7 53:18 66:8
151:2
biotechnology 1:4 2:10
2:14 3:6 18:2 22:16
48:2 53:16 55:13 66:3
66:5,14 67:7,19 68:5
76:19 77:2,3,14 94:21
126:21 127:5,15
131:1,2,22 168:14
bit 12:11,17 22:17 25:7
27:4 28:18,19 30:15
31:6 33:18,19 45:7
49:6 55:22 57:1 59:8
59:19 68:3 70:16
72:17 80:22 84:4

87:16,20 88:9 90:22
116:18 128:13 129:11
129:20,22 130:3
131:6 133:13 149:9
150:15 157:5 164:17
166:13,16
bits 85:9 92:21
blessed 149:15
blight 16:3 69:17
block 127:21 135:16
blocks 64:11 127:21
129:21
blue 143:13 144:8,11
bluegrass 82:19,21
body 50:9 113:9
boils 155:3
bookmark 141:4
bookmarked 141:1
borders 52:22
Borlaug 58:13
borrow 46:11
bottom 25:7 33:5 73:3
82:21 87:11
box 6:19 7:10,20 56:12
139:21 140:7 141:22
172:10
boyfriend 20:2
BPI 92:1
BQMS 22:13 59:12
127:19 128:1,19
129:21 130:1,9,16,22
131:6,7 132:2 133:14
133:16 134:4,17
135:16,21 136:5,11
Bradley 59:17
branch 1:12,14,18,18
1:18,19,19,20,20,21
3:6 10:14 50:10 94:15
94:16,17 118:11,19
127:12 129:15
brand 161:4
BRAP 95:5,5 98:16
129:18
break 5:8 61:19 63:11
80:19
breakdown 10:18
breaks 4:19
bred 75:1
breeder 22:2
breeding 54:7 74:13
83:1 111:8
brief 101:19 130:20
briefly 38:20 140:18
bring 61:2 62:5,16
125:8 147:19 148:9
bringing 49:16
broadly 162:8
brought 68:21 69:9

BRS 1:4,12,14,14,15,16
1:17 2:4 8:8,13 9:10
12:18 17:16 33:9
35:19 37:11,15 38:5,8
41:21 44:12 67:8 81:9
94:12 95:10 118:11
119:9,21 120:9
126:19 127:11 128:1
129:18 130:1 131:11
135:20 137:8 138:4,8
138:13,19 139:5,7,12
150:20 158:8 160:22
162:14 164:12 167:10
168:10 170:6
BRS's 97:10
bud 91:14
budget 23:1
build 40:22
building 40:8 45:11,16
53:22 58:7,9 127:21
127:21 128:17,21
129:21 135:16 136:18
136:19
built 141:13
bunch 85:19 157:13
Burbank 69:19
bureaucracy 161:4
burial 114:6
burn 114:5
bury 114:6
business 2:5 23:10,12
24:11 41:6 71:11
87:10 89:1 90:9,11
136:12 139:4 158:5
165:3
business- 81:17
busy 10:17 31:1,15
37:5
button 98:21
BWMS 133:9

C

C.F.R 13:18,18 30:17
73:2
cabin 15:16
cadre 62:11
cafeteria 5:7 167:22
calendar 27:14
California 14:3
call 85:21 95:19 96:10
103:9 123:3 128:16
174:8
called 20:17 35:19 46:6
88:21
calling 136:19
campus 25:6
Canada 29:18 44:7,20
52:6 65:1
Canadian 63:20
Canadians 44:10
canola 16:13 68:13
capabilities 139:18
140:9 145:12 156:20
capability 141:8
capacities 43:3
capacity 40:8,22 45:11
45:15 53:21 58:6,9
card 24:11
cards 24:13
care 21:1,18 106:10
107:17
carotene 70:3
Carrie 1:16 66:9,13
67:4 80:17
carves 9:14
case 47:11 85:8 93:4
100:14 112:1,1 116:6
121:9 171:16
cases 48:7 86:10 90:21
99:19 154:12
categories 74:16,17,20
74:22 133:15
categorize 133:16
category 10:21 85:21
cause 151:10
causes 89:9
CBI 90:13 136:10,12
cell 5:2
Center 1:11 66:10
central 149:17
ceremony 19:19,20
certain 82:13 116:12
121:22 154:6
certainly 80:11 102:15
cetera 35:8 143:17
CFR 83:17 132:4
chair 173:15
chairs 41:12
challenges 62:8 97:11
chance 48:10 107:6
change 89:11 95:18
112:8,11 139:11
140:20 141:7
changed 126:10,12
138:7 164:3
changes 62:10,10 98:2
99:2 102:5,7,10,14
111:12 139:15,16
163:4
changing 87:7 92:18,22
characterize 12:15
90:17 157:10
Charlotte 17:16
chart 10:2 132:16 145:6
charter 88:10
charts 4:4 145:5,14

chatbox 113:21
check 115:3 128:8
132:17 133:2
check-status 139:19
checklists 91:18
Chessa 1:20 22:18
127:4,9 138:4
Chief 1:12,14,18,18,19
1:20 3:6 94:15 118:11
118:19 127:12
chiefs 10:14
China 29:17 43:22 44:1
53:12,17 165:7
China's 61:14
Chinese 53:6,13,15
62:2,9,15,21 63:6,10
choose 65:8
chose 22:12 65:8
chosen 58:6
chunked 142:3
circumstances 117:3,8
cisgenic 85:7
cite 116:5
citizens 58:20
citrus 26:14,15,17,18
26:19 27:1,7,9 28:4,6
28:8,14,20
City 1:11 14:2
clarify 73:10 100:13
101:13
clarity 103:8
class 64:16
clean 105:17,22 106:19
106:20 107:1
cleaned 106:5
cleaning 105:13 106:3
107:9 124:1
cleans 106:14
clear 13:10 97:6,19
98:8 107:14 158:21
clearance 161:10
clearly 160:6
Clearwell 35:19
Clever 67:13
click 142:13 144:11
clicker's 138:9
clock 29:15
close 34:16 148:19
170:7
closed 74:5 139:15
closely 16:22 18:11
20:21 34:22 35:4
38:12 39:22 40:3 55:2
Closes 34:4
closing 69:8
Cochran 58:13
Codex 54:12
coefficients 4:8

coexistence 51:12,19
coffee 5:2
coin 74:20
cold 149:2
collaborating 39:13
collaboration 1:21
 18:10 53:20
collaborations 18:3
 127:13
collaborative 50:9
 129:16
collaboratively 98:16
colleagues 134:6
 135:20 136:21
collected 11:6 88:17
Colleen 173:17,18
color 22:7
color-coded 4:4
column 86:8
columns 87:3
combination 96:15
combinations 12:14
combine 105:15,16,18
 105:22 106:7,16
 107:9 108:5 144:1
combined 11:1
combines 114:12
come 7:6 8:7 43:5
 45:11,21 48:8 56:2
 63:8 65:15 78:16
 91:11 110:1,2 114:19
 114:21 118:14 123:18
 146:17,19 147:7
 148:18 165:6,6
 167:17 174:2,8
comes 33:11 38:18
 39:12,18 40:8,13 48:1
 50:16 71:15 73:11
 84:1 100:1 110:2
 111:17 170:21
coming 32:9 55:17,17
 60:7 64:21 108:7
 110:16 123:20 125:21
 150:17,19 151:12
 164:19 167:10 174:14
commensurate 97:22
 98:18
comment 5:15 6:18 7:6
 7:10,11,19,21 34:4,6
 34:11 56:12,13 74:5
 76:17 115:5 137:19
 146:20 147:3 164:11
 172:10
commented 14:8
commenters 157:11
comments 2:20 4:12
 7:16 8:12 14:4,13,14
 14:16,21 15:18 30:3

36:14 67:22 73:22
 74:7 76:5,8 77:8 78:6
 146:13,18 147:19
 157:3,7,8 160:6,16
commitment 27:7
commitments 34:18
committee 17:6 62:17
 91:10
committees 46:7,8,13
common 105:21 107:12
 110:19
communicate 6:19
 120:20 162:22
communicates 172:6
communicating 39:15
 41:4 47:5 115:6 174:2
communication 121:3
 124:7 125:11 165:2
communications 1:12
 1:14 3:5 157:17
community 75:8 121:18
companies 37:14
company 69:8 83:12
compared 74:11 112:6
competitive 136:16
complement 42:20
complete 26:9,10 27:17
 68:9 70:12 71:21 72:6
 108:20 113:15 172:20
 173:1
completed 6:11 25:2
 68:11,12,16,19 70:10
 70:14 71:13,22 92:4
completely 97:6
complex 47:5
compliance 1:19 2:12
 47:16 95:8,8 97:1
 112:10 118:12,13,16
 118:19 119:4 123:6
 124:18 125:8 128:16
 129:6 130:4,6,9 132:3
 136:9,11 137:6
complicated 6:7 84:9
 112:15
comply 126:20
component 70:8 85:15
 128:11 134:10 135:15
components 82:13
 83:18 86:5 127:20
 128:14 129:1 130:13
 133:14 168:8
comprised 132:12
concern 15:6,9,13
 41:16,18 43:21 122:1
 125:12 166:6,11,12
concerning 169:17
concerns 48:14 71:2,8
 72:2 121:16

conclude 74:16,21
concluded 69:5 90:5
conclusions 84:8
concrete 107:2
condition 99:4,10,14
 100:13,14,15 101:3,6
 101:12 105:4 107:1
 109:9,10 110:11
 111:18 112:1,5,9,17
 116:4,9,10
conditions 4:8 35:6
 94:13,14,20 95:2,6,9
 95:13,15,20,21 96:4
 96:11,13,16,19,22
 97:3,5,13,17 98:5,9
 98:17,19 100:18,22
 101:2,5,10,14,22
 102:19 103:1,3,6,9,12
 103:13,22 104:5,15
 104:19 108:14,17
 109:17 110:22 111:19
 111:20 112:2 114:16
 115:7,20 117:13,22
conduct 41:6 89:15
 101:20 120:6 122:3
conducted 9:21 14:1
 81:17 101:15 120:8
conducting 13:4,5 39:1
 97:4
Conference 1:11
conferences 170:14
confidential 90:9,11
 136:12
confined 100:6 104:17
confinement 25:9
 101:17 115:11
confirmation 82:10
confusing 91:4
confusion 97:8
Congress 17:2
Congress' 76:21
conjunction 66:3
connection 142:17
consider 73:12 87:8
 134:16 135:12 167:11
consideration 33:12
 75:9 76:13
considerations 29:10
 72:22
considered 94:5
considering 76:8
consist 128:2
consistence 107:12
consistency 88:2,6
 103:7
consistent 55:9 88:4,5
 98:4
constituting 15:11,12

construct 12:14 156:5
constructs 155:21
 156:1,22
consultation 68:12,16
 68:19 69:8 70:14
 71:22
consultations 67:19
 68:9,11 70:19 75:22
consulting 78:14
consumer 1:16 66:10
 77:10
contact 13:3 78:2,4
 80:12 137:7,13
contacted 106:13
contain 91:2 93:3 98:10
 143:1
containment 120:21
content 141:21
context 60:14
continental 145:8
continual 132:14
 133:19
continue 19:7 23:8 31:4
 33:14 34:20 35:8 36:7
 119:6 123:1 135:18
 141:17 168:19 169:3
continued 120:13 168:7
continuing 150:10
control 25:12 26:15
 27:7 87:15 90:1
 103:17 104:21 108:20
 111:3,21 129:2
 133:17,18,18 134:2,4
 135:11
controversial 25:8
convened 1:10
Convention 54:4
conversant 62:13
conveying 38:17 39:13
 41:14,15
cook 114:5
cool 149:9
coordinate 49:21
 120:19
coordinated 38:14
 39:12 40:5 43:6 50:3
 66:4,19,19 79:11,12
coordinates 122:1,2,4
coordinating 68:6
coordination 50:5
 76:22 77:18
core 39:8
corn 9:16,17,22 10:7,8
 111:6 147:9 149:3,4
Cornell 24:21 25:4,6
correct 93:15 153:9
correlate 134:5
Corzine 146:19 147:4,9

147:13,16
Cosmetic 72:14
cost 78:16 122:19
 151:1,2,10
costing 137:21
costs 78:13
cotton 9:16,18,22 10:6
 10:8 34:3
Counsel 35:21
count 157:14
counted 156:16
counterparts 36:9
 42:19 53:7 62:3
counties 28:3
countries 29:5,6 37:14
 40:16,20 41:17 43:3
 43:10,11 45:20 46:6
 47:18 48:15,17 51:15
 53:18 54:15 55:3
 60:20
country 47:20 50:18
 51:18 54:10 148:6,18
country's 63:9
counts 156:6
couple 12:10,14 26:20
 29:2 31:19 79:21
 103:17 104:16 105:7
 117:1 152:20 164:5
 164:16 172:20
course 11:20 29:16
 32:2 38:6 39:19 43:2
 56:8 59:10
court 5:21
courtesy 142:7
cover 45:8 47:8 52:15
 103:16 172:11,12
covered 168:14
covering 123:21
covers 28:2
cow 148:15
create 28:13 36:6 93:5
 93:18 134:22 135:9
created 18:22 19:4 31:7
 70:2 81:7 154:13
creating 86:11 134:16
creeping 16:6
CRISPR 32:2,5,11,14
 84:17 85:4 153:18
 154:1,5,13 158:5,16
 158:18 159:1,16
CRISPR-modified
 158:8
CRISPR-produced
 158:13
CRISPR-type 153:7
CRISPRs 32:7
criteria 140:16 142:11
critical 103:17,20

104:21 127:20 129:1
 129:2 133:18,21
 134:2,4 135:11
 165:21
crop 9:15 69:4 83:12
 103:12 104:10 105:5
 107:12 109:13,16
 124:16
crop-trait 12:14 96:14
crops 9:21 10:5,10
 61:16 73:14 75:16
 103:14 104:6 105:9
 108:9 114:7
cross 42:20 111:9,10
cross-collaboration
 44:5
crystal 163:10
CTV 28:18
cumulative 32:5
current 16:18 27:20
 130:1 158:20
currently 31:2 33:20
 34:4 52:14 99:16
 131:7
curriculum 137:3
Customer 88:21
customers 89:2,4,6
cut 65:19
cycle 133:11
cytokinin 71:17

D

D 2:1
damage 25:7
damaging 24:19
Daria 166:3
data 2:17 11:7 12:8
 18:22 19:2,10 23:14
 28:5 30:18,18 64:13
 64:19 65:9 72:4 88:17
 88:19 91:1,7 93:2,13
 93:19 109:3 110:14
 112:10 113:8 136:20
 138:5,10,18,20,22
 139:3,4,6,9,10,13
 140:1,3,14,15,16
 141:8,11 142:1,3,12
 142:21 143:1,3,4,8,10
 143:11 144:4,7,9,11
 144:13,14,21,22
 145:2,3,9,11,13
database 119:9,13,17
date 13:21 22:21 146:8
 169:22
dating 142:3
Dave 37:12 39:2 40:9
 44:2 45:1
David 1:16 59:18

Davis 14:2
day 7:16 8:11 19:17
 20:19 23:5 35:13
 47:20 65:22 101:1
 139:4 146:16 149:10
 152:16 172:8
day-to- 47:19
day-to-day 46:22 51:16
 62:4
days 11:22 21:3 77:9
 112:15,20 113:3,4,14
 117:1 147:4 152:20
 172:20
deal 23:16 40:7 120:18
 165:21
dealing 14:22 101:16
 161:9 170:1,5,12
 171:4
deals 38:10
dealt 119:2 125:11
 170:15 171:1
dearly 33:22
death 109:18
decade 53:8
December 34:5 70:10
decide 131:11 133:10
 158:12 163:13,15
decided 25:22 104:17
 158:8,14
deciding 42:11
decision 26:5
decisions 158:22
deductive 103:10
deep 22:9 114:6
deeper 129:20
deeply 4:5
defense 28:7
define 87:14 88:9
 113:19
defining 64:19
definitely 118:3 137:11
 166:14
definition 30:16 54:12
 82:11 83:17 84:15
 113:22
definitions 143:3
delay 90:15
delayed 113:11
delays 90:8,20 150:22
 151:1,6,9
deleted 99:5
deletion 86:15 90:22
 91:5 93:7
deletions 86:16 154:22
deliver 28:7
Delivered 4:5
delivery 144:22 145:2
 168:16

demo 23:6
demonstrates 93:2
DEMONSTRATION
 2:18 138:10
denied 11:10 12:4
Department 1:1 38:13
 40:3 58:10 169:3
departmental 51:13
Departments 161:16
dependent 163:19
depending 96:2,13
 103:8 114:7 142:16
depends 7:2
depressed 34:2
depth 65:5
Deputy 1:14,15 8:7 18:8
 23:22 37:9
deregulate 26:6
deregulated 58:22
deregulation 16:1,16
 26:10
derived 77:3,14 86:21
derives 76:20
describe 61:14 83:15
described 90:17 100:17
describing 50:2
descriptions 75:4
design 100:18 101:5
 111:13 115:5,13,16
 116:5,15
designed 119:20
desk 173:22
desperate 27:6 28:3
despite 109:13
destroy 21:5,9
destruction 21:12,16
detail 7:3 37:12 40:10
 45:7 127:12
detailed 45:1 117:20
 118:2 137:8
details 5:1 6:16 10:16
 48:11 53:21 59:22
 75:4 165:4
determinations 123:13
 126:14
determine 75:10 80:3
determined 73:1
determining 130:8
devastating 13:1,1
develop 91:19 119:8
developed 73:14 74:11
 74:12 76:2 88:10
 95:21 119:12 139:15
 141:7
developer 71:3,7
developers 27:8 70:17
 75:7,16,18 90:7
 130:18 153:12

- developing** 48:16 72:11
 73:20 78:20 123:16
 131:21 170:12
development 46:5
 70:21 160:13
devitalization 114:11
 115:11
devitalize 107:3 113:20
 114:2,12
devitalized 99:21,22
dialogues 167:7
diamondback 24:18
 25:1,5
Dick 1:11,14 3:5,13,21
 4:10 8:15,18 34:15
 37:20 138:11 139:12
 147:18
differ 96:2
difference 105:2 131:4
 131:5 154:9
different 7:2 10:11,12
 12:13,15 13:13 15:19
 22:8,14 32:3 45:19
 54:19 74:10,18 80:1
 88:18,20 95:12,22
 96:5,6,10 97:13 98:4
 98:19 100:21 104:6,9
 108:19 111:9,11
 112:2,5 114:4,7 116:1
 116:10,16 117:13
 121:2 122:18,18
 123:4 124:12,13,15
 157:18,21 159:10
 160:9 162:22 170:14
differently 14:5 111:21
 157:19 158:1 160:9
difficult 86:22
dig 48:11 129:20
directed 86:10
directing 139:22
direction 23:4 163:16
Director 127:3,10
Director's 20:10
Diria 56:20
disagreements 100:20
disarmed 94:2
discrepancies 100:20
discuss 123:4 127:14
 128:13
discussed 37:16 54:3
 60:13 72:9 164:22
discussing 78:15
discussion 8:12 43:19
 60:20 63:10 169:4,12
discussions 50:22 52:5
 52:5 53:5,6 55:1,3,12
 61:3 62:2,21 63:4,7
 162:1
- disease** 26:16,18 28:4
dismantle 106:16,22
disparate 160:6
display 141:14 144:9
disposition 124:2
disruption 55:7,10 61:5
disseminate 41:19
dissemination 104:2,22
 105:5,20 107:10
distinctly 132:16
distribution 162:20
diversity 45:21 54:4
divide 80:8
divided 142:1
division 56:21 145:19
DNA 87:8
docket 74:1,2 76:4 77:7
 77:7
document 98:14 99:12
 100:11 133:17 134:15
 135:7 172:14
documentation 16:15
 128:9 135:1 143:2
documents 14:8 135:10
doing 17:8 18:12,15
 24:3 28:13 29:14
 30:12 34:17 60:5
 72:10 79:20 87:21
 88:13 90:2 111:22
 114:20 120:5 122:21
 127:7 147:11 150:4
 165:13
dokie 127:7
Doley 1:17 81:10,11
 92:20 93:11,15 94:4
domain 164:20
domestic 37:6 48:16,20
 108:22 165:5,18
 168:21
domestically 38:5
domesticated 108:9
 109:16 112:7
dominant 64:10
dominate 10:8
Don 157:1
donor 83:20 84:5
door 5:5
doors 128:21
dormancy 108:22
 110:19
dormant 108:16
DOS 38:13
double 71:5
doubled 149:19
Doug 17:16
Dover 92:14,15 93:8,12
Dow 145:19
Dow-DuPont 56:21
- download** 141:11
 142:21 143:14 144:4
downloadable 143:6
Dr 39:2,7 40:9 41:11
 66:9,15 67:4 79:10
 94:8 109:20 138:14
 155:17 158:5
draft 25:20 26:1 168:6,8
dramatic 157:15
dramatically 158:1
drink 5:8
drive 70:3 124:22
drives 33:10
drop-down 143:15
drought 71:18
Drug 1:17 72:13 73:11
dry 109:10 110:12
 149:6
dryland 109:10
Du-Pont 145:19
ducked 173:15
due 90:9,20 132:17
 142:2
dull 3:22 4:1,9,17
dust 152:19,19
duty 127:14
dynamic 47:17
-
- E**
-
- E** 2:1
E-Permit 119:18
EA 16:17
earlier 43:1 51:2 53:19
 67:22 68:21 69:11
 72:9 87:19 107:20
 121:5 134:6 137:5
 155:14 164:11
earliest 27:16 168:11
early 42:3 52:7 61:22
 62:3 70:22 152:10
 170:6
easily 108:10 119:21
 142:22
easy 9:9
eat 5:8 49:9,13,14
ecology 103:14 104:10
 105:4
eDiscovery 35:18
editing 29:9 31:8 55:5
 55:20 59:19 61:7 68:2
 73:14,20 74:11 155:1
 169:15,18 170:22
educate 17:8 77:1
education 16:22 68:5
 76:20
effect 89:16
effective 145:8,16
 167:3,4,17 168:17
- effectively** 124:8
effectiveness 122:21
efficiency 122:20
 139:17
efficient 120:1 122:10
 168:17
effort 17:12 18:17 19:5
 43:6 95:10 123:5
 168:1
efforts 39:12 95:1
 151:18 168:3
eFile 22:19,20
eight 14:6 16:4 67:16
 84:12
EIS 25:20 26:1
either 14:8 21:6 128:8
 134:21
elaborate 38:6 39:2
 42:17 44:2
elevated 156:2,4
elevation 120:17
eliminate 99:7
else's 163:11
email 8:2 78:2 119:21
 137:11,12 147:4
emailed 172:8
emails 35:14 119:22
embarrassed 163:21
employee 12:19 13:7
employees 46:15
empty 173:15
emulate 19:5
encourage 78:5 137:11
 141:4 168:10
Endangered 25:21
ended 140:19
ends 121:21
energy 4:15
enforce 98:11,12
enforceable 97:20
enforcement 1:20 20:9
 97:11 118:12,20
engage 38:16 39:10
 40:15 73:18 75:10,13
 122:7 125:13 126:13
 130:2 157:20 162:7
 168:10
engaged 20:20 46:4
 121:3,17,22 130:14
 131:22 161:3,18,22
engagement 15:21 39:1
 39:12 43:14 44:4,8
 75:20 121:6,14 122:6
 126:1,6,12 158:2
 160:7 164:12,18
 170:17
engagements 28:22
 29:1 38:7,22 39:7

42:9
engages 161:17
engaging 38:9 39:4
 75:15,17 123:8 126:2
 126:8 161:14 162:8
engineered 9:20 17:9
 20:1 22:10 24:22 25:5
 26:14 27:8 28:6,9,10
 28:14 79:19 86:4,6
 93:5
engineering 17:9 83:20
 86:18
enhance 81:18 132:3
 156:20
enhancements 118:13
enhancing 2:12 43:3
 118:16
enjoy 4:17
Enley 157:2
ensure 38:17 39:9,16
 41:4 42:10 98:17
 121:4 128:9 131:14
 132:13
ensuring 39:15 40:18
 41:21 125:5
enter 7:12 142:11
 143:20 144:2,20
entered 119:16 140:16
entering 42:2
entertained 67:17
entities 43:9 119:10,22
 121:4,15 126:14
 128:4 129:8 130:11
entity 129:17
enunciating 166:19
environmental 16:8,10
 16:18 25:2 26:12
 27:19 29:10 52:18
 53:9 55:16,19 69:3
EPA 17:4 38:14 40:6
 46:16 49:21 66:3
 99:19
ePermits 22:20 139:8
epigenetic 87:7,7
equipment 105:13
 124:1 150:3
Eric 173:10,13
Erickson 145:18,18
especially 6:6 48:7 54:3
 59:13 93:4 105:15
 173:19
essentially 28:7 46:11
 54:11 128:17 164:2
establish 137:10
established 128:18
establishing 98:3 105:6
estimate 28:16
et 35:8 143:17

EU 84:11
eucalyptus 25:16,17
 26:6 33:22
evaluate 124:15
evaluated 48:1
evaluation 1:20 25:20
 52:17 71:1 118:12,19
 123:16
event 156:12,12,12,14
 156:15
events 69:11 156:22
 170:15
eventually 142:10
 145:2
everybody 36:3 91:16
 109:19 171:20 173:12
everybody's 162:2,3,3
everyday 127:11
evolution 109:17,18
 131:3
evolve 151:8,8
evolved 84:17 136:5
ex 165:2
exact 92:2 158:6,11
exactly 18:13 64:19
 65:4 103:21 111:12
 112:22 132:11 162:5
example 20:4 44:10
 96:3 99:3,10,13
 100:12 105:9,11,12
 111:6,10 112:4 143:5
 144:12
examples 99:2
Excel 143:7,9
exception 6:9 48:3
 108:18
exclusively 38:9 139:13
excuse 129:17 136:11
 136:17
execute 135:21
executive 50:10
existed 16:16
existing 60:22
exists 131:7
expand 144:12 148:6
expect 19:6 89:2
expectations 61:16
 97:10 98:6
expected 92:17 116:13
expects 89:7
expeditiously 138:16
experience 105:10
experiences 60:2,7
expert 60:16
expertise 52:12 53:9
 80:4
experts 39:16
explain 127:18 136:4

136:14
explained 67:8
export 49:14 165:20
exportation 61:16
extended 149:9
extension 16:4,14
 44:11
extensive 28:22 115:21
extent 55:9
external 89:3,4
extreme 108:17 109:16
 111:20

F

face- 29:16,18
fact 20:17 24:2 27:10
 50:6 117:14 150:14
factor 50:18 69:1
factors 124:19
failure 89:15
fair 87:20
fairly 25:8
fall 73:1,15 106:8
falling 32:1
falls 158:19
false- 116:14
familiar 70:15 74:8
 81:13
family 148:3 149:15
fantastic 38:5 39:15
 43:13
far 10:3 24:6 27:18
 32:15 113:2 138:22
 154:21 159:2 169:22
farm 147:20 148:3,3
 149:4 151:3 152:15
 160:11
farmer 147:9
farmers 105:21 147:12
 168:19
farming 149:19
fashion 50:9 52:2
fashioned 7:19
favor 109:18
favors 109:17
FDA 2:10 16:22 17:2,5
 17:11 38:13 40:6
 46:16 49:21 55:14
 66:3,7,10,14 67:6,22
 68:6 72:10 73:17
 75:14,15 76:22 77:18
 78:10 79:8 80:6 99:18
FDA's 80:17
FDS 38:13
features 141:9
federal 72:13 130:21
 161:12
fee 78:16

feed 49:13 52:16 53:10
 55:15 99:16,17,21
 100:1 104:12,16,18
 106:18 108:1
feedback 3:10 14:13
 23:7 83:9 121:17
 124:4 136:7
feel 10:9
field 10:20 12:21 13:4,5
 25:13 52:15 71:4 97:9
 119:11 122:2 126:11
 163:19
fields 115:14 140:13
 141:10,17,19 143:3
 143:19 144:1,9
fifty-five 85:14
figure 130:2 133:4
 135:5 136:22 157:21
 160:8
figuring 161:11
file 143:1
fill 8:4 30:13 130:5
 172:9
filter 143:10,14,15
filters 143:8
final 91:1,5 93:2 110:18
finally 3:21 42:22 44:3
 89:19 98:15 101:19
find 21:4 39:5 43:12
 77:13 83:6 109:21
 129:13 134:9 162:21
 167:21
finding 20:18 121:16
findings 33:17 133:4,7
fine 146:22
finger 17:7 31:18 32:14
 84:15 85:3
finished 67:19 148:12
Finland 22:1
Firko 1:14 8:8,15 9:2
 23:11 39:8 112:16
 138:14 147:1 152:22
 153:8,15,19,22
 155:13,17 160:1,3,15
 160:22 163:5,8
 164:16 166:9,14,17
 166:21 167:8,14,18
 169:6,9,16 171:8,13
 171:17 174:6
firms 75:13
first 5:6 8:18 13:16
 19:16,17 31:17,21
 33:12 37:8,18 72:3
 74:8 79:13 82:17
 84:15 86:1,20 90:6
 91:11 95:14 97:2,18
 99:3,21,22 106:4
 110:8 127:21 132:2

133:16 135:21 139:5
 141:20 142:6,11
 144:13,20 147:8
 155:15,16,17 158:12
 163:12 171:19
fiscal 13:16 16:1 156:15
Fish 25:21 26:2
fit 18:9 48:20 51:1 54:7
 60:22 134:12,20
 144:10
five 28:16 29:14 33:20
 84:18 120:5 149:15
 161:7
flavor 49:6
flexibility 129:7 133:10
flexible 131:9 134:19
flip 74:19
Florida 28:2,3,3,20
Florida- 26:13
flow 173:21
flow-chart 88:12
flowers 107:18
focus 63:7 67:15 72:1
 98:1 130:8 133:20,21
focused 47:9 52:11
 53:12 63:5 72:4,5
 74:9
focusing 62:20
FOIA 35:12 36:5
folks 8:16 12:17 13:4
 17:6 20:13 21:20
 24:21 33:2,3 116:17
 139:22 145:13 165:5
 167:2
follow 47:7 60:9 77:21
 78:5 80:13 164:11
followed 37:11 94:16
 149:2
following 60:19 65:11
food 1:17 17:9 49:9
 52:16 53:10 54:13
 55:15 66:11,12 67:5
 68:2 70:21 72:2,13
 73:10,11 74:10,21
 75:1,14,18 77:14
 99:16,17,20 100:1
foods 74:17 77:2
fora 54:3
force 50:10
Ford 173:10
foreign 40:1 42:2,18
 43:7 45:12,15 58:6,10
 58:11,16 63:3,4
 165:21 166:1,2
foremost 33:12
foreseen 50:7
Forever 4:21
form 25:11 93:16

formal 18:5 23:11 58:12
 163:3
formalized 59:9
formally 133:11
format 83:8,8 129:16
 134:22 141:12 142:21
formats 93:20 144:5
formed 88:10
forms 93:16
forth 160:12
fortunate 66:6
forty 113:2
forward 2:4 8:14 33:7
 67:11 73:18 119:1,4
 122:22 125:13 137:4
 137:14 146:17,19
 148:9 151:5,12 152:7
 152:12 165:15 170:6
 170:19 174:9,10
found 21:22 97:12
 122:3 130:4
foundation 128:18
 135:17,21
foundational 128:15
four 23:18 29:8 35:21
 68:11 71:21 74:6 76:9
 110:15 113:2 133:15
 156:7
four-year 110:13
Fourteen 54:15
fourth 133:19
fragile 150:12
frame 11:20
frames 140:18
framework 38:14 40:6
 50:3 66:4,19 79:11,12
 168:4 169:2
Francisco 17:15
Free 164:10
freeze 25:16 26:6 33:22
frequent 58:14
frequently 48:5 68:8
Friday 77:9
friends 39:14 40:19
front 37:6 171:2
fruit 69:21
full-scale 25:4
full-time 46:14
fully 142:14 144:11,13
 152:5
function 60:8
fundamental 94:11
fundamentally 164:3,6
funded 19:1
funding 17:2
further 28:11 69:14
 142:9
future 42:4 44:16 51:10

55:21 117:22 125:6
 140:11
FY17 2:4,7 8:13 37:19
FY18 2:4 8:14

G

Gail 174:3
gain 42:1
gamut 47:9
gap 30:13 130:6
gaps 133:5
gasoline 13:9,10
GE 19:14 20:22 21:4
 24:18 28:17 30:10,15
 54:9 114:8
geared 124:6 129:14
 136:10
gene 25:10 28:7 29:9
 69:14,16,18 71:15
 111:2 154:22 169:14
 169:17
general 14:14,20 35:21
 47:6 55:6 84:8 94:13
 98:1 103:7,10,14
 104:4 108:21 109:15
 110:16,17 112:7
 119:21 157:6
generally 98:3
generate 156:10
generated 72:18
generation 64:7
generations 149:15
 151:5
genes 159:17
genetic 12:13 17:8
 83:19 86:17,18
 108:19 110:3 111:4,8
 111:14 155:21 156:1
 156:1,5
genetical 85:15
genetically 9:20 17:9
 20:1 22:10 24:22 25:5
 26:14 27:8 28:5,9,10
 28:13 49:10 79:19
 86:3,6 93:5
genetics 22:6
Geneva 25:6
genome 31:8 55:5,19
 59:19 61:7 63:15,18
 63:20 64:5,9,17 65:13
 65:14 68:2 73:14,20
 74:11 170:21
genotype 111:12
genotypes 111:9
George 1:11,14 3:4,5
 9:1 36:13 56:6 65:18
 80:16 81:6 92:7 93:21
 94:10 116:21 118:9
 125:17 126:16 138:3
 146:14 155:11,16
 159:20 160:2,10
 171:10,15,18 174:13
germane 35:15
germinate 107:7 108:9
germination 149:3
getting 4:18 13:12,13
 18:16 47:1 57:5 92:8
 101:9 150:9 161:9,10
 173:19
give 10:16,18 17:20
 21:7 37:12 38:20
 44:22 45:1 49:6 64:1
 64:2 69:2 76:15 78:2
 81:21 105:1 126:4
 142:15 143:3 154:8
 159:11
given 14:7 18:6 24:10
 51:5 67:14
gives 10:9 12:8 42:3
 71:9 143:2
giving 34:19 153:5
glad 7:21 37:4 94:18
global 37:15 41:10,12
 54:14 169:4,13,14
globe 57:3 166:22
glorious 4:2
gloss 62:18
glyphosate 16:6
GM 61:16
go 4:18 14:18 20:14
 25:22 38:15 40:12
 45:6 51:4,10 52:6,7
 53:21 55:12 59:7
 62:14 74:3 76:3,6
 84:4 89:10,17,18,22
 90:3,12 91:8,18 92:13
 100:11 103:11,18
 104:20 105:11,14
 118:2 119:6 122:13
 124:13,19 129:21
 134:1 146:10 152:7
 152:14 157:7 160:17
 163:16 168:6
goal 13:3 52:19 61:4
 75:11 133:6 139:1
 163:3 167:19
goals 97:18 119:8
 120:3 149:20
goes 79:10 95:7 138:22
 156:12 158:4
going 8:18,19,20,21
 16:20 19:9 23:7 27:15
 28:18 33:17 34:20
 35:16 38:6 45:6 51:10
 52:21 53:8 57:3,7
 61:4,10 65:19,21

71:11 79:14 80:13,19
 81:16 88:8 89:12 90:3
 90:5,6,7,18 91:9,19
 95:3 96:17 97:4,9
 99:1 101:7 103:16
 115:3,10,21 119:4
 122:14,17,22 123:4,9
 123:19 124:17,20,21
 125:6,13 127:8
 136:20 137:16 138:17
 148:18 152:16 157:16
 157:21 161:21 162:5
 163:13,17 165:15
 166:12 168:2 170:4
 171:4 172:22
good 3:4 8:17 13:3
 16:11 18:14 34:17
 37:21 38:1 56:6 63:17
 81:8,11 109:7 118:17
 138:2
gosh 157:11
gotten 51:13 71:4 99:18
 100:8
government 1:17 38:10
 40:1,5 45:12,15 46:2
 46:11 47:3,10 51:22
 54:22 57:6 62:22 73:9
 81:10 161:12
government's 51:15,17
government-to-gove...
 29:7
governments 47:13
 50:13 58:6 67:1
 165:22
GPS 122:2
graciously 140:22
graduate 61:18
graduation 19:19,20
grain 46:18
grains 114:13
granted 16:1,5
graphics 19:9,9
graphs 4:4
grapple 51:17
great 38:8,18 40:7,10
 43:18 44:8,20 48:21
 49:19 50:12 61:8,17
 94:10 125:9 127:17
 147:20 149:21 151:21
 152:18
greater 74:18 122:1
greatly 121:11
green 84:22
greening 26:16,18 27:7
 28:4,15
greetings 147:17
grew 172:3
ground 4:7 27:3 106:8

123:21,22
group 10:15 29:20
 37:10 44:6 55:3,14,15
 60:1,5 63:6 66:1 70:8
 91:10 129:17,18
 157:11 173:5
groups 37:15 45:13
 49:15 61:2 62:22
 66:22 152:9,10
 157:18,22 160:12
 162:16
growers 51:22
grown 99:15
grows 52:1
growth 68:22
guaranteed-to-please
 4:6
guess 152:6 161:4
 163:10
guest 66:9
guidance 64:22 65:1,12
 80:6,13 90:7,19 92:16
 98:13,14 99:12 100:9
 100:11 135:8 137:9
 170:18
guidelines 47:14,22
 51:6 53:14 63:19
guy 5:22 148:5
guys 56:18 104:7
 118:10 145:20

H

hair 152:20
half 15:3,3,3,4 86:2
hall 5:5
hallway 5:6
handing 122:16
handle 66:1 147:2
handles 174:1
handoff 122:11,12
hands 122:18
hands-on 134:19
haphazard 18:4
happen 23:1 28:18 57:7
 109:4,12 163:9
 165:17 173:6,17
happened 149:16 167:1
happens 105:17 108:12
 109:19 163:17
happy 17:18 78:1
hard 106:14 143:7
 160:5 173:5
harm 136:16
harmonization 41:13
 42:7 52:20 55:14
 169:5,11,13,14
harmonized 55:9 61:15
harvest 105:16 106:4

107:16 110:8 148:12
 148:14,19
harvested 124:2
Hawaii 145:10
hazard 103:19,22 104:1
HB4 68:22
head 26:21 27:3
head-scratcher 157:9
heading 23:4
headphone 173:11
headquarters 136:2
heads 37:9 94:17
health 1:1 33:9,9 35:3
 39:10 40:14 55:19
 147:11
healthy 172:2
hear 5:16 8:16 14:4
 26:2 37:21 50:21
 51:19 60:6 61:20,20
 66:22 169:6
heard 91:20 134:6
 169:12
hearing 9:11 16:20
 18:20 26:19 33:17
 72:8 123:8
heart 4:12
heartfelt 174:7
heartland 147:17
heat 149:6
heavily 70:17
HEDGE 103:5 114:1
Hegde 1:18 10:15 94:17
held 53:11 60:4
hello 45:5
help 5:3 9:1,2 30:10
 36:18 40:20,21 41:22
 71:1 75:13 76:18
 78:11 123:11 126:20
 128:3,22 129:11
 132:5 134:4 135:4
 137:2 148:9,9,11
 167:2,11,16
helped 149:11 174:3
helper 148:13
helping 18:9 98:17
helps 71:6 128:6
 148:13 150:8 151:8
herbicide 34:3 68:15
Heron 1:16 37:12 39:2
 40:9 45:5 57:12,14,17
 57:20 58:8 59:3,22
 60:15 61:8,17
Hey 3:13
hi 63:12 92:14
hiatus 130:20
hiccupped 116:17
high 10:3 108:6,14
 114:5

higher 11:22
highest 10:4
highlight 29:2 139:11
highly 109:16 112:6
highly-educated 4:5
history 75:15,17 97:1
 124:18
hit 4:21 7:11 27:4
hold 6:10 8:9 27:9
 91:13 171:8 173:11
holders 98:7 101:13
 102:8
holy 148:15
home 112:8
honor 127:14 138:13
hop 149:16
hope 4:17 39:3,4 58:2
 68:8 76:12 102:2
 116:11 131:4 152:1
 156:2,3 162:8 163:17
hopefully 67:16 70:14
 102:9
horizon 41:20 53:1
horizontally 144:10
horrendous 26:18
host 136:9
hosted 139:13
hosting 36:8
hot 164:15
hours 4:3 122:7
house 23:20 31:3 52:17
 52:18 62:14 128:21
housed 140:2,5
housekeeping 5:1
Houston 164:9,9
How's 127:7
Huff-Woodard 1:20
 22:18 127:4,6,9
 137:22
huge 23:1 105:15
hugely 84:17
human 35:16
humanly 162:9
hundred 14:5
hundreds 4:3
hungry 124:11
Hurricane 27:4
hurricanes 120:18
hybrid 68:14 111:14

I

Ibach 161:5,14,22
Ibrahim 1:15 18:7 29:11
 37:9,18 45:5,6,18
 53:19 56:2
iceberg 61:21
idea 78:18 82:4 91:4
 135:8

ideal 108:14 111:18
ideas 162:3
identify 5:17 6:5 42:13
 91:12 137:14
identifying 89:9
Illinois 147:9 148:5,5
 149:17
imagine 86:22 123:21
Impact 16:8 26:12
 27:19
impactness 64:13
impacts 165:19
implement 91:9 102:6
 102:10 119:8 121:12
implementation 62:4
 63:9 132:8 133:1
implemented 47:19
 71:1 89:21 91:21 92:1
 130:9 139:8
implementing 46:3
 48:16 98:21
implication 170:20
implications 47:14
import 10:19 140:5
importance 148:1
important 41:3,10 42:5
 42:16 43:2 73:12
 88:22 136:13 150:22
 170:16
imported 119:17
importers 46:18
improve 24:7 33:14
 34:20 35:7 83:9 87:15
 89:13 119:9 133:8
 139:16 142:9 144:18
 150:10
improved 88:14 90:3,7
 125:10,10 126:13
 139:17
improvement 2:6 23:10
 23:12 81:18 83:13
 87:11 89:1 119:7
 132:15 133:19
improvements 19:7
 90:4 119:1
improving 35:5 132:18
in-depth 101:21
in-house 139:15 141:7
incidences 104:16
incident 109:4 120:15
 121:12
incidents 104:18 119:3
 121:6 125:11
include 66:16 152:9
 165:15
includes 108:15 119:7
 119:11 138:20
including 95:8 141:10

incomings 24:15
inconsistencies 97:12
inconsistency 153:16
increase 19:9 52:20
 120:4
increased 34:7 71:18
 122:20 123:2 126:1,7
indicate 28:5
individual 14:6,11
 167:2
individuals 14:7 129:7
 162:15
inductive 103:15
indulge 173:4
industry 20:20 21:14,17
 22:12 26:19 27:1
 28:20 54:22
inform 76:18 95:12
 137:2
informally 133:12
information 16:18
 21:12 27:21 41:8,19
 42:1,18 45:2 49:17
 59:10 61:10 62:5,6
 68:1,4 75:6,8,21
 76:10,12,18 77:1,13
 77:17,19 80:12 90:9
 90:11,12,17 92:16,21
 99:9,11 115:15 116:7
 116:12 117:20 118:4
 119:16,19 122:14,17
 136:12,15 137:9
 146:7
informative 39:5 78:7
 80:17
informed 78:22
informs 71:6
infringe 150:12
initial 28:5 77:4
initially 90:10 91:3
initiated 26:11
initiative 54:14 76:20
 77:21
initiatives 45:3
innovation 55:6 168:7
innovative 168:20
input 8:4 137:2 152:11
inquiries 83:4 84:21
 85:5,14 170:1,11
inquiry 92:17
inquiry-based 135:3
insert 64:14 65:17
inserted 86:17 91:2,6
 93:3 154:20
insertions 86:9
inside 105:17
inspect 33:16,16
 124:20,21

inspectability 35:8
inspection 1:1 33:15
 124:4,9,14 126:3,8
inspections 95:7 97:5
 120:4,7,9,11 126:9,10
inspector 97:9
inspectors 97:19
 101:14 122:13
institute 124:4
institutes 62:16
instructions 6:18,20
 7:8 91:16
insurmountable 71:12
intend 93:13 125:13
intended 27:13 68:2
 70:21 158:2
intensity 130:18
intensive 36:8 45:17
 53:22
intent 128:5
intentions 162:22
interacting 48:4 50:15
interaction 40:8 45:17
 47:18 79:1 111:2
interactions 54:1
interactive 145:12
interest 15:20 39:8
 43:18 44:20 46:17
 48:22 49:20 50:12
 51:8,9 65:19,21 171:3
 172:2
interested 33:4 40:16
 43:18,20 44:11 46:8
 47:5 50:19 65:1,11
 80:11 83:7,10 113:6
 144:21 162:9,10,13
 172:5
interesting 13:21 45:21
 46:20 87:5
interestingly 69:21
interface 46:9
interior 107:5
intermediate 70:6
internal 89:3,6 91:15
 109:3 133:17
international 1:21 2:7
 28:22 29:1 36:9 37:8
 37:10,13,19 38:7,22
 39:7,14,21 40:2 41:22
 42:9 43:7 45:9,14
 46:20 48:14,18,20
 53:3 54:3 56:4 57:2
 57:12,13,19,20 58:1
 66:21 127:13 164:12
 164:13 165:5,11,15
 165:20 168:21 169:5
internationally 37:6
 38:17 39:9,11

internet 142:16
interpret 162:6 167:1
interpreted 65:10 160:8
interpreting 157:18
interstate 10:20,22
interviewed 20:14
interviews 88:21
introduce 8:7
introduced 85:8
introducing 70:3
introduction 38:1
investigation 20:6,12
Investigative 20:9
invitation 66:16
invite 79:1 146:19
inviting 43:4 66:15
involve 102:7,10
involved 46:18 48:6
 50:20 79:8 150:18
 160:12
involvement 54:22
Irma 27:4
irradiation 74:13
irrigate 149:13
irrigated 110:10
irrigation 110:7,12
Islands 145:10
isopentenyltransfera...
 71:14
issuance 27:22 99:7
issuances 129:15
issue 27:13 32:3 47:22
 60:18 170:16
issued 9:19 12:12 25:3
 31:9 67:22
issues 13:9,12 35:4
 38:11 42:16 43:16,20
 47:6 55:4 60:7 62:19
 63:5,8 90:9 91:13
 101:17 115:11 123:8
 125:6 129:8 151:20
issuing 28:1 73:21 99:6
it'd 113:21 167:3
item 2:2 93:1
itemizing 116:9
items 122:9 124:1

J

J.R 69:9
January 13:20 27:16
 73:22 81:17 82:1
 102:4,11 104:11
 159:21
Japan 43:17
Japanese 48:8
jargon 33:1
job 34:17 39:15 109:7
 124:7

John 4:14 63:22,22
64:1 153:3
join 95:1
joint 94:21 95:5,9
Jones 174:3
Joshua 155:18 158:5
158:12
jot 36:14
jotting 57:21
journalists 47:2
July 82:18
June 14:2 74:4 102:9
justification 90:13
justify 136:14

K

Kansas 14:2
keen 73:17
keep 13:3 26:21 31:8
48:15 67:17 91:22
150:22 151:4,12
168:16 170:10
keeping 102:7,11,15
keeps 82:2
Kentucky 82:19,21
key 83:18 123:13
keypad 7:1 56:15
125:20
kidding 63:11
killed 114:1,22
kind 3:22 6:15 13:2
28:9 60:11 63:19
64:13 65:6 74:19 84:8
99:11 103:10 117:22
132:15 145:22 146:3
150:13,22
kinds 95:13 116:1
kitchen 148:21
knocked 27:5
know 3:13,17 4:16,16
8:22 13:21 21:6,19
23:17 24:1,18 26:17
27:2 30:5,7,8 32:7,18
33:1 34:12 35:14 37:3
39:4,7,11 40:19 41:22
42:11,19 46:19 51:12
56:18 58:21 59:20
60:10 64:4,21 65:16
66:2 67:9 72:21 77:10
77:12 79:10,14 89:2
95:7 99:5 100:9
102:12 103:9,21
104:4,7,7,13,17,19,20
105:3,10,12,14,18
106:1,11,21 107:6,13
107:20 108:2,10,14
108:17 109:7,8,14,20
109:22 110:13,17,18

110:21 111:3,3,5,6,7
111:11,15,22 112:11
112:18,22 113:6,11
114:3,18 115:17
116:2,19 137:18
139:5 143:9 146:17
147:10 148:22 150:1
150:20 151:9,20
152:6,16 154:3,22
160:16 161:11,20
162:18 163:9,11
164:19 165:1 167:16
169:20 170:14 172:12

knowledge 111:17
112:9

knowledgeable 4:6
knows 92:4 109:20
Korea 44:1

L

labs 28:12
lack 41:5
land 110:12
lands 104:10 105:5
150:13
language 96:1 98:4,10
98:11,13 162:6
laptop 141:15
large 22:7 142:2
largely 93:9
larger 157:14
largest 35:1
Lastly 145:4
late 16:3 69:17 152:16
lately 68:8 87:21
Laughter 94:9 163:7
169:8
laws 26:8 51:5 59:6
79:15,17
lead 1:22 17:11 138:8
138:12 169:3
leader 35:20
leaders 151:13 162:14
leadership 169:19
leading 53:17 54:6
58:11 63:2,3
leads 55:14,14,15
learn 126:20 171:4
learned 3:11 130:15
172:15
learning 40:17 41:14,17
leave 7:21 102:16
led 97:10
left 5:6 29:15 114:3
144:8 154:12
legal 49:22 54:19 71:8
80:5 83:14 99:7
legislators 46:1

lengthy 83:18 101:9
Leon 146:18 147:9
Leon's 160:11
lessons 3:11 172:15
lessons-learned
172:14
let's 8:5 13:15 52:3
84:10 127:17 132:9
173:11,12 174:13
letter 69:7 72:21 73:7
82:12,15 83:16 91:8
92:22 93:17
letters 92:17 153:11
letting 100:9 164:19
level 48:5 51:13,21
52:11 61:18 71:2
levels 54:8 124:12
life 114:3
limiting 50:17
Linda 1:22 18:20 138:8
138:12 146:15
line 63:14 68:16 69:12
80:8 85:3 86:19
134:10
lines 59:14 69:10,18
98:13
link 142:20 143:1
161:10
links 139:21 141:1,5
142:13
list 49:5 84:10,11 92:20
93:1 115:21 134:1
listed 13:19 74:2 77:22
90:3 95:16 137:12
listen 17:20
listened 17:4
listening 37:2
listing 83:3 134:2
lists 82:20 143:16
literally 149:19
literature 30:6 109:2
little 7:1,3 12:11,17
18:4 19:8 22:17 27:4
28:17,18,19 30:14
31:6 33:18,19 34:2
36:16 45:7 49:6,15
55:22 57:1 59:8,19
65:22 68:3 70:16
71:17 80:22 81:21
83:2 84:4 87:16,20
88:9 90:22 91:4
116:18 125:12 128:13
129:11,20,22 130:3
131:6 132:9 133:13
134:18 143:7 149:9
150:15 157:5 159:4
164:5,17 166:13
172:9

live 9:9
lived 12:20
Lively 173:22
lives 12:20
living 34:18
LLC 59:17
LLP 54:14
load 142:14,18
local 51:21
location 52:2 119:19
locations 13:13 156:6
logo 87:12
long 23:20 24:3 52:19
66:12 72:5 87:20
101:9 131:19,20
longer 8:10 45:17 53:22
look 2:4 8:6,14 14:18
29:13 45:18 51:15
55:4 67:10,11 74:3
76:3 81:8 82:19 83:3
83:6 84:10 91:10
107:13 123:22 143:12
156:21 157:8 162:5
170:19 174:9
looked 116:3 166:7,15
166:17
looking 22:5 23:5 33:7
41:20 47:11,12,18
54:5,18,19 75:5 76:14
77:20 84:14 85:17
125:1,3 134:14
142:12 143:21 169:18
174:10
looks 65:17 115:1
143:6 156:10
loop 124:4
loss 120:21
lost 151:10 168:15
lot 9:11 13:11,11 15:5,6
21:20 24:3 33:1 46:17
51:13 53:20 64:22
70:18 112:13 130:13
130:17 131:8 134:5
137:21 153:22 163:12
173:18
lots 51:8 59:10
love 33:22
low 16:3 19:8 54:8 71:2
low-level 55:5
lower 142:20
lumped 10:21
luxury 46:13
lycopene 70:5,7

M

magnificent 5:22
main 11:12 29:3 39:8
45:11 52:16 62:22

maintain 43:13 88:6
 170:16
maintained 19:2
maintenance 68:15
major 10:10 24:20
 48:13 59:21 60:12
making 6:1 19:7 62:9
 72:15 73:17 83:10
 116:7 131:4 139:1
 173:20
Malcolm 109:20
male 16:13 68:13
manage 124:20
managements 2:15
 18:14 22:16 119:9
 126:22 127:3,5,10,15
 128:10,19 129:3,9
 131:1,2,15 132:10,11
 132:13 134:16 135:13
manages 24:1
managing 107:5 109:6
 112:6
mandate 52:1
mandated 21:16
mandatory 130:13
manner 85:2
manpower 122:6
manually 119:17
map 88:12,12 89:19
March 141:4
Margaret 159:14
market 22:11,12 46:20
marketing 36:2 161:6
marketplace 20:22
Maryland 1:11
material 86:17 93:3
 99:15 100:2,5,16
 106:2,7 107:3,6,14
 111:9 154:18,20
materials 124:2
matter 39:16 174:16
matters 123:4
McCaleb 17:16
McCannon 29:3 41:12
McMahon 1:16 66:9,15
 67:5 79:10
mean 35:13 57:22
 117:16 123:22 151:11
 170:7
meaning 20:8 33:2
means 20:8,11 56:7
 73:8 86:3 108:16
 109:12 114:2,2 122:4
 140:10 154:15 161:11
meant 134:12
measure 87:15 88:15
measurement 88:19
measures 48:20

mechanisms 114:11
media 72:19 73:6 159:6
meet 30:16 40:19 66:20
 83:11 137:15 162:13
meeting 1:6,10 3:8,9,14
 3:22 5:10 6:1 7:7 8:1
 8:3 26:22 29:22 36:8
 44:13,14 49:18 53:11
 54:17 66:17 67:8,20
 76:11 78:14 81:3
 145:21 162:11 172:5
 172:15,21 173:2,6,17
 174:3,9
meetings 14:1 17:14,19
 29:7,7,18 37:13 60:4
 77:6 79:2 150:18
 162:15
meets 82:11
meganuclease 32:14
member 17:17 161:15
members 27:1 37:7
Memorial 1:11
mention 12:16 36:17
 42:22 44:3 59:12,18
 70:13 151:15
mentioned 6:12 39:8,22
 40:4,14 41:10 42:7
 43:1 44:22 53:19
 65:21 68:21 77:5
 87:19 95:4 117:17
 121:5,8 139:12
 144:14 157:2
merit 70:18
message 112:7,8
 162:17
messenger 4:11
met 161:13 162:18
 165:7,8
methods 114:4,7
 117:19
Mexico 15:16 29:18
 44:7,20 52:8
microbes 96:6,7
microphone 5:14 6:4
 6:13 56:9 92:8
middle 143:18
mike 1:14 8:8,17 36:13
 36:14 41:9 51:2 56:16
 56:19 57:1,10,18 59:7
 63:12 81:13 87:18
 89:6,7 112:16 121:5,8
 146:17,20 147:18
 153:4 155:11 166:5
 171:15
Mike's 8:9 58:3
Miller 171:9
million 35:14 76:21
millions 108:6

mind 31:8 48:15 97:18
 170:10
minimize 55:6 61:5
ministry 50:14 53:7
 62:12
minor 154:22
minute 6:10 9:17 22:3
 142:15
minutes 8:4 23:14
 25:18 29:14 34:15
 81:1 147:3 172:9
miraculous 173:16
Miranda 173:14
misconception 72:17
 73:7
misinformation 49:11
missed 137:20 166:9
 166:18
mission 18:13 33:8
 122:21 147:10
Missouri 14:2
mistaken 19:22
mitigate 42:15
mix 52:9
model 9:6,6,9
modern 163:20
modernization 169:1
modernize 168:3,12,13
modes 89:16
modification 85:15
modifications 102:16
modified 49:10 101:4
 102:14
modular 127:1
module 128:1,5 132:17
modules 127:22,22
 128:2,3 131:12 134:3
 134:17 135:11
moist 108:8
moisture 108:15
moment 7:4 98:18
 148:1 151:16 173:4,7
 173:16
momentum 168:15
money 17:11 137:21
monitoring 7:13 101:18
 106:9 107:21 110:13
 114:16,21 115:22
 119:15 123:16 124:3
Monsanto 92:15
month 68:17 161:5
months 16:4,9,14 34:13
 68:18 69:6 70:11
 71:21 72:1 112:19
 123:19
morning 34:6 81:14
mosquitoes 79:9 80:6
moth 24:18 25:1

Mother 148:20
moths 25:5
motion 4:15
move 21:7 72:7 73:18
 105:19 106:18,20,21
 106:21 137:3 152:12
moved 22:7 98:12
 150:20
movement 10:20,22
 140:4 142:6
movements 96:5,5
moving 102:18 106:5
 151:4 170:6,18
multi-tasking 127:8
multi-year 96:8
multiple 41:9 42:9 44:1
 51:20 119:19,22
 141:14 144:15 156:5
music 4:13,14,14,15,18
mutagenesis 74:13

N

N 2:1
name 6:6 67:4 80:12
 127:9 138:12 156:12
 173:8
NASDA 161:15,17
Nate 33:18 118:15
 126:17
Nathan 1:19 118:11
national 46:3 53:2 58:1
 62:17 161:16
nations 43:5
natural 18:9 149:12
nature 124:21 148:20
 157:6
near 44:16
necessarily 134:10
necessary 125:15
 129:19
need 6:3 8:22 9:3 15:5
 18:13,15,16 20:11
 27:6 28:4 48:15 50:5
 65:16 79:15,17,22
 82:7 87:4 89:2 97:14
 100:5,10 102:13,16
 102:18 110:20,21
 115:5,17 116:14
 122:15 126:19 128:7
 136:22 150:6,13
 151:7,11,12,22 152:3
 157:20 160:7 162:7
 162:21 168:19
needed 30:11 113:8
needless 25:8
needs 83:11,21 134:20
 137:15 172:6
negative 85:6

Neil 145:18
NEPA 16:15 26:9
Netherlands 85:8
network 116:17
never 95:18
nevertheless 5:11
new 2:17 9:6 11:8 12:3
 15:9,16 16:17 17:16
 18:7,21 19:4 24:20
 25:13 27:6 36:22 48:2
 54:6 69:12 70:13,19
 72:8,12 78:20,21
 79:14,15,17,22 82:10
 82:22 83:5,8 84:11
 87:1 89:20 91:15,17
 93:18 123:7,16
 138:10,17 141:9,13
 141:16,18 143:11
 148:8,11,19 151:11
 151:17,17 158:2
 159:19 161:4 163:14
 163:15,22 171:5
newer 51:1 60:22
news 3:18 56:6
nexus 65:14
nice 64:1 73:3 113:21
 173:8
Nick 174:5
nip 91:14
no-insertion 85:21
non-chemists 70:7
non-pesticidal 70:20
non-regulated 16:5
 33:21 64:8 65:16
 105:19 121:9
non-regulatory 20:5
Nope 153:19
normal 110:22
normally 60:10
North 52:5
not-regulated 159:16
note 32:22 140:2 144:8
Noted 137:22
nother 157:13
notice 9:15 24:11 28:8
 130:21
noticed 130:12
Notices 121:15
notification 11:12
 31:11 104:13,14
 105:2 107:20 109:5
 110:6 112:13 115:16
 143:18
notifications 10:19,22
 11:5,15,21 104:12
 138:21 153:6 164:5
notional 102:17
novel 32:20

November 1:8 17:14
 77:8 120:7
noxious 15:2 34:22
nuclease 31:18 85:4
nucleases 84:10,16,19
 86:10 87:2 93:4
null 87:4,6,8
number 9:18,19 10:6
 11:3,17 12:11 14:6,7
 14:9,10 22:7 49:4
 74:3 120:4,17 123:13
 145:7 155:20,20,21
 156:1,21 157:10
 167:9
numbers 10:12 11:17
 12:10 23:15 145:15
 148:18 156:10
numerous 4:22
nutrient 150:9
Nutrition 66:11

O

objectives 59:21 132:1
obligations 48:14,17,21
 59:5
obviously 12:22 122:10
 165:18
occasions 140:4 142:5
occur 10:12 12:21
 102:17 105:9
occurs 156:17
October 68:17
OECD 29:3,5 41:10
 55:11,18 59:20 60:4
 60:10,16 61:2,6 165:8
 169:13
OECD's 61:4
offer 147:17,22
offered 140:22
office 35:21 66:11 67:5
 79:12 161:2
Officer 1:16 66:10
officers 126:2,8
officials 46:2
oh 89:22 112:12,13
 155:2 157:11 158:19
 166:17
okay 4:10 8:17,17 9:2,3
 9:5 36:11 37:21 39:5
 57:17 58:18 65:18
 80:15 81:6 94:6 108:8
 109:2 110:7,16 112:4
 113:18 114:9 118:10
 126:16 138:1,11,19
 140:12 141:20 146:12
 146:14 147:16 153:9
 153:21 155:10,17
 159:18,20 160:2

169:9 171:13,15,17
 171:19
Okie 127:7
Oklahoma 1:10
old 7:19 23:19 33:21
 34:14 137:20 140:12
 141:2 145:21 148:16
 163:20
once 72:19 152:17
 165:1
one's 84:13
one-on-one 162:15
ones 12:3 29:3 58:12
 72:3 76:8 84:22 85:1
ongoing 23:12 52:4
online 6:15,17 7:5
 56:11 59:10 80:10
 154:10 155:11,13
 159:19,21 174:1
Oops 81:11
open 41:3 42:11 43:19
 56:16 74:4 123:8
 143:6
opened 77:6
operate 130:10 134:11
operating 50:1,1
operationalize 134:7,13
Operations 94:22
Operator 58:5,18 61:6
 61:13 79:6 93:22 94:1
 113:18 114:9,17
 115:1 116:16 117:2,8
 118:5 125:22 126:6
 137:18 160:19 163:2
 169:11 171:6
opinion 26:4
opportunities 50:4
opportunity 43:13
 52:13 71:9 114:14
 118:2 136:4 137:7
 147:20 152:18 162:12
 168:11
opposed 122:16
optimistic 28:16
optimized 144:15
Or-- 166:4
orange 19:21 21:21
 22:3,4,9
order 14:10 102:14
 125:14 128:22 135:9
 137:13 168:22
organism 30:16
organisms 82:2 153:7
 153:18 158:9,13
organization 5:18
 48:19
organizations 53:4
 59:13

originally 21:22 27:13
OSTP 79:21
outdoor 9:20
outgoing 24:17
outlined 82:13
outlines 80:7
outreach 2:7 17:1 37:19
 40:9 41:22 45:9 56:4
 59:13 68:5 76:20
 101:21 165:14,16
outside 9:8 173:21
over-produced 150:15
over-regulation 15:12
overall 15:20 124:22
 126:12
overlaid 132:14
overlap 50:5
overlying 135:10
overseas 40:20 167:2
oversee 79:15,18 80:5
oversees 80:9
oversight 73:16 97:11
 119:5 123:17 125:8
 125:15
overview 37:11 38:4,21
 38:21 103:6

P

P-R-O-C-E-E-D-I-N-G-S
 3:1
p.m 1:11 3:2 81:4,5
 174:17
package 72:4
page 2:2 24:10 30:21
 32:21 72:16 139:20
 140:13,15 141:20
 142:19
pair 154:22
paired 71:19
panels 48:10
papers 30:5
paradigm 132:15,17
parameters 51:5
 129:10 144:20
Pardoe 1:22 18:21
 138:9,11,12 146:5
parent 91:3
parfait 124:10
Paris 61:11,12 165:8
parliamentarians 46:1
parsing 159:4
part 7:7 13:18 35:1,1
 41:9 46:10 51:22 57:4
 60:12,17 66:4 67:6
 69:15 71:17 72:18
 102:8 106:18 108:11
 111:7 116:18 117:5
 117:10 129:5 132:4,4

- 137:5 139:1 142:20
147:8 149:12 150:4
151:19 168:12
parte 165:2
participant 58:19 79:7
94:1 117:7 153:4,9,16
153:21 155:10
participants 136:1
participate 29:6 43:5
participated 23:6 136:2
participates 37:16
participating 43:4
particular 16:16 35:15
35:19 43:16 71:22
103:12 143:20 156:4
156:13,14 158:14
particularly 38:11
partner 41:17 67:2 80:7
partners 36:10 40:15
44:9 120:14 164:14
165:12
partnership 120:13
parts 152:5
pass 161:10
path 16:10 163:15
169:2
pathway 70:4 71:18
148:10
pathway's 163:16
pattern 11:16 12:9
pause 56:1
peaked 31:18,22
Pearson 1:18 10:15
94:15,18 114:15,18
115:8 117:12
pending 11:6,19 12:1,4
143:17 144:2
people 5:10 14:9 20:15
25:11 30:8 31:14 32:8
32:10 36:21 45:19,21
46:4,18 47:2,4 48:5
50:20 51:4 59:5 62:11
78:6 112:13 113:20
114:4 115:2 125:4,17
126:20 147:14 157:13
157:14,18,22 160:9
160:17 162:19 172:1
173:5,16
perceive 108:12
percent 9:21,22 11:5,8
11:10,11,19,19 12:4,4
108:4,5 114:12 120:6
120:7,9,10
percentage 47:3 108:6
perennial 59:4
perennials 112:4
performance 108:13
performed 120:10
period 8:10 74:5 149:10
periodically 46:12
permanent 46:14 62:11
141:8
permanently 12:19
permit 4:8 11:18 21:6,8
25:3,15 26:13 27:14
27:21 28:1 31:12
32:10 35:5 94:13,20
95:2,6,13,15,20,21
96:3,18,22 97:2,5,13
97:17 98:7 99:4,6,7
99:13 100:13,15,17
100:17,19,22 101:2,4
101:9,13,22 102:8,19
103:1,3,6,9,21 104:5
104:13,15,19 105:2
109:6 110:5,6 112:1,5
112:13,17 113:9,9,16
115:9,9,14,18,19
116:13 117:13,21
143:18 154:3 155:8
permit- 96:12
permit-specific 94:14
permits 11:16,21 95:14
95:17 113:1,6 115:6
138:20 140:3 142:5,8
permittee 97:6,8 98:6
106:13 113:5
permittees 97:19
permitting 2:17 10:15
94:12 138:5,10,18,20
139:4,6,13
persist 105:18 107:7,15
107:15
persistence 104:1
124:16
person 3:16 5:19 79:3
80:10 85:6 92:4 111:4
115:4 146:17 162:13
person's 4:10
personal 8:20
personally 161:13
personnel 120:10
persons 78:4
perspective 63:21
pest 24:19,20 26:7,12
27:19 69:17 84:6
85:10,11,15 86:2 94:5
154:16,18 155:2
pests 1:18 34:21 83:21
86:5,21 94:16
petition 25:18 34:7
91:22
petition-tracking 91:21
petitions 33:20 34:10
34:19 64:20 164:4
petunia 19:14 20:20
22:2,4
petunias 19:21 20:22
21:4,21 22:3
phase 77:4 88:9,16
89:8,13 90:2 102:5
phases 87:14 88:9
phenotype 110:18
Philip 4:15
phone 8:20 92:10,11
115:3 125:18 141:15
144:17 171:11 172:1
172:3
phones 5:2
phrase 73:4
pick 143:16,17
picked 73:6
picking 125:3
picture 51:2
pictures 4:4 19:14,16
pieces 85:9 142:4
pilot 130:7
pineapple 69:22 70:1,2
70:9
pink 70:1,1,9
pipeline 52:14
pitching 174:4
place 25:14 45:3 106:22
109:22 128:10 135:6
135:6 149:17
plain 150:5
plan 102:17 121:12,13
132:17,19 165:14
planning 93:17 101:20
117:18 119:11 172:14
plans 124:3 126:2,7
146:3 162:3
plant 1:1,18 26:7 33:8,9
33:11 34:21 35:2,3
39:10 40:13,14 71:3
75:7,16 82:22 83:21
84:6 85:10,11,15 86:2
86:5,21 91:3 93:5,6
94:5 111:18 147:11
154:16,18 155:2
plant-breeding 84:11
planting 124:5 148:22
149:1
plantings 9:20
plants 1:18 30:10 39:17
49:10 65:15 68:2
70:21 74:11,12 75:1
79:19 86:4,7 94:15,17
96:5,7 107:12 109:22
111:20
platform 41:11
play 45:11 62:6 63:8
124:13
plays 47:10
please 5:1,3,17 6:4,10
7:7 8:3,9 36:18 56:9
56:18 76:6 92:10,13
172:8 173:9 174:5,14
plenty 171:13
plus 85:17 144:8,11
podium 36:20
point 25:14 44:14 51:7
85:22 146:9 161:9
162:4 164:15 168:4
points 88:18 103:18,20
104:21 105:8 129:2
131:11 133:19,22
134:2,4 135:11
policies 132:13,20
133:2
policy 1:20 8:19 52:12
72:11 79:13 91:12
127:13
pollination 149:6
popular 144:5
populates 111:4
population 111:15
portion 59:12
portions 168:5
position 29:12 161:20
positive 85:1
possibility 156:8
possible 24:8 27:21
42:15 106:15,21
138:16 156:11 158:17
162:9,9 168:11
173:21
post 68:9 164:14
post-harvest 106:9
posted 6:2 21:13 118:7
118:8 139:9 172:21
potato 16:2 69:9
potatoes 69:20
potential 32:7 91:12
103:19,22 104:1
105:20
powerful 158:16
PowerPoint 4:2
PowerPoints 172:19
173:20
PPQ 34:22 35:4,22
120:14
practical 42:12,13
46:22 54:17,20
106:12
practice 110:19
practices 132:7
praise 14:21
precedence 101:1,3
predictable 87:18
presence 54:8 55:5
71:2

present 1:13 74:18 75:1
144:21
presentation 6:12 7:17
22:17 153:5 160:1
presentations 153:2
presented 19:3 87:1
140:17
presiding 1:12
press 6:22 56:14 92:10
125:19
pressing 62:19
pressure 114:5
pretty 10:17 14:14 22:9
34:16 92:2 125:7
148:19 156:17
prevent 89:12 103:22
104:18,21 105:5
107:9
previous 29:12 60:5
92:1 139:9,19 140:8
172:16
previously 141:18
145:21
prices 150:14
pride 44:9
primarily 51:19 53:13
60:2 147:12
primary 12:6 15:17 33:8
60:8 61:4 132:1
133:15 154:9 160:3
principles 41:1
prior 127:12 139:20,21
prioritize 89:15
prioritized 89:22
private 43:9
proactive 42:6
probably 9:10 26:8
53:17 54:6 58:14 59:8
59:11 61:18 81:15
91:20 107:22 112:19
139:5 156:17
problem 50:13
problems 88:3
procedures 101:14
115:21 132:12,20
133:2 135:6 165:3
proceed 27:11
proceeded 27:12 86:11
process 2:6 23:10,12
23:13,15 24:7 26:9
33:15 44:12,18,19
64:19 81:7,13,15,18
81:19 86:11 87:10
88:12,18 89:1,19,20
90:5 91:13,17 92:5
93:9 102:5 119:1,6
122:8,9 123:6,10,11
123:15,17 124:4

125:1,12 126:15
133:8 146:1 152:7,10
152:12 153:10 154:16
154:19 155:8
processed 12:2
processes 71:11 76:1
120:2 121:19 125:10
133:7 135:6 155:1
produced 83:19 158:18
159:1
producer 147:14
producers 147:13
product 16:2 31:18
35:19 69:14 72:22
82:10 90:18 91:1,5
93:3,18,20 96:2
111:12 154:17 158:17
170:10
production 35:12 51:20
68:14 69:16 70:4
150:13
products 31:7 33:6
35:18 42:2 46:19
52:21 54:9 73:19 76:1
77:15 79:18 80:1,3
95:22 131:22 153:22
154:13 158:14,22
159:16 165:20 170:5
171:2,5
professor 25:3
progeny 86:13 107:15
program 1:21 2:15 9:3
35:6 36:8 58:13,13
59:12 60:11,13,17
70:15,20 71:20 95:1
111:8 126:22 127:4,5
127:13,16 128:11
130:10,10,12,19,22
131:1,2,7,7 132:2
135:16 136:6,17
165:14
programs 18:6 35:22
40:2 58:12,15 94:22
95:10 127:11 161:7
progress 22:19 23:3
145:7 169:14
project 17:1 76:16
81:18,20 82:1 87:11
87:14,17 89:1 94:21
95:5
projects 23:1 58:7,9
130:7
promoter 71:19
proper 71:19 129:17
properties 68:22
prophetic 93:9,10
proportion 12:1 157:14
proposal 160:16,20,21

propose 58:20 155:6,8
proposed 13:17,20
15:7,15,19 155:6
157:19,22 159:22
163:4,14,15 164:18
proposing 102:1 163:1
prosaic 39:4
protect 33:8 136:15
147:10 148:10
Protectants 1:19 94:16
protected 39:17
protecting 33:9 39:10
40:14 147:12,15
Protection 33:11 35:2
protein 70:14,19
proteins 70:20
protocol 115:13 116:6
116:15
protocols 100:18 101:5
115:5,16
proud 135:19
provide 14:13 24:14
37:10 38:4 40:7,10
43:15 49:17 59:10
77:1,19 78:7 80:11
90:18 93:2 95:3 99:11
113:8 115:20 116:13
117:20 118:1 125:14
130:3 139:17 140:8
141:8 148:10 152:11
168:20
provided 17:2 19:6 23:6
30:3 76:10 116:8
164:15
provider 151:2
provides 143:9
providing 39:11
public 14:1,16 17:8,14
34:11 47:2,6 59:13
76:17 77:1,6 164:20
165:16
public-releasable
165:14
publication 30:7 164:18
publish 26:1
published 13:17,20,22
34:6,9,10 65:3 76:5
139:6
Puerto 12:16,18,19,22
13:2,6,7,12 145:10
pull 22:12 172:13
pulled 114:22
Purdue's 9:6
purple 22:9
purpose 25:11 67:9
69:2 79:11 87:17
purposes 128:7
pursuant 35:2 132:6,21

135:13
pursue 123:1
pushed 98:21
put 7:11 8:20 21:11
56:13 65:2 77:10
84:22 96:12 101:11
103:9,21 104:5,15
105:3 113:3 115:15
128:20 129:9 135:7,9
152:1 158:15
putting 98:7 118:3
172:5

Q

Q&A 8:10
QMS 137:10
quality 2:14 22:16 65:7
65:9 122:20 126:22
127:5,15 128:9,18
129:3,9 131:1,2,15
132:10,11,13 134:16
135:12
quantitative 88:19
quarter 80:20
quarterly 29:17
question 2:8 5:15 7:6
49:9,16,19 50:16
51:11 56:5,10,12,22
58:3,19 59:4 61:8,18
63:18 74:14,15 75:12
78:19 79:6 84:5 92:7
92:10,13 93:21 104:8
113:7,19 116:11
117:3 118:6 125:19
125:21,22 126:16
137:19 146:11 147:6
152:6 154:8 155:12
155:22 157:1 158:4,7
159:7,9,10,15 160:11
160:20 166:3 169:7
171:11
questionnaire 8:2
172:7
questions 2:20 6:11
7:16,18 8:10,12 10:13
36:11,14 43:15 49:5,7
52:6 56:1,18 57:6
64:12 65:6 66:1 71:8
73:13 74:7 75:3,14,19
76:9 77:11,12,13
78:15 79:5 84:2 89:4
92:6 102:22 103:4
115:2,18 125:16
129:14 135:4 137:17
138:15 145:17 146:13
146:16,21 147:1
152:4,13 153:1
154:10 155:7,14

164:13 166:20 171:7
171:19 174:11
queue 171:12
quick 38:21 44:22
62:18 115:3
quicker 91:8
quickly 27:11 34:19
64:2 163:17
quite 166:16
quotes 20:7

R

R&D 52:14
Rachel 19:18
radar 70:16
rained 149:8
rainfalls 149:2
raise 121:16 166:6
raised 68:4 71:9 76:19
166:20
range 22:8 52:19 87:21
ranges 45:16
rapidly 64:6
Ray 92:14
reach 79:2 130:17
131:10
reaching 42:4
read 74:8 76:6 158:7
160:17
ready 27:15
real 115:3 148:1
realized 97:1,3
really 17:21 20:1 21:1
24:2,6 30:9,11 31:16
32:17 38:15 43:12
60:16 61:19 66:20
67:2 69:13 73:17 74:9
75:5,10 78:10 92:22
95:15 97:4,15 98:3,13
99:9 100:3 104:21
108:6 111:11,13
112:3 113:5 118:2
124:22 129:14 130:4
130:8 132:4 136:13
137:7 146:6 147:21
148:11,15 150:16,20
150:21 151:17 156:21
165:3 167:3,4,16
168:2 169:20 170:7,9
171:20,20 172:12
rearranged 64:14
reason 11:10,12 12:6
136:19 151:13 165:17
reasoning 103:10,15
reasons 15:16,17 141:6
157:5 159:21 160:4
recapitulate 101:10
receipt 119:14

receive 8:2 157:7,8
172:7
received 11:4,8,18 12:3
14:3,14 15:18 23:7
25:18 31:3 34:8 157:3
170:11
receives 164:12
recessed 81:4
recipient 83:21 84:6
recipients 89:5
recognize 124:12 173:7
174:13
recognized 130:11
recognizing 52:20
54:18
recommend 146:10
reconvened 81:4
record 36:6,22 102:7,11
102:15 148:19 149:1
149:17 174:17
recorded 6:14
recording 102:8
records 35:13 124:1,2
red 70:8 139:21 140:7
141:22 142:19
redirect 71:10 141:1,2
reduce 69:3 87:22
reduced 98:19 122:6,12
122:19
reducing 69:15
reduction 122:11
redundancy 156:8
redundant 134:18
refer 7:7 14:4 85:3
129:16
reference 134:22
referred 82:22 100:22
referring 101:8
REFLECTIONS 2:4
8:13
reflects 100:4
refreshed 139:4
Reg 59:16
regard 57:2 66:7 92:16
134:15 137:9
regarding 82:18
regardless 47:21 165:4
Register 130:21
registrants 136:1
registration 174:1
regular 40:19
regularly 40:15 161:18
regulate 10:10 40:21,22
66:2 159:10,13
regulated 2:5 4:9 9:21
23:9,13,15 24:12,14
28:13 30:14,16 31:10
31:15 32:9,12,16,19

44:18,19 51:3 59:2,8
72:20 73:4,8 81:7,13
81:19,22 82:6,7,8,12
83:16,17,22 84:3,7,21
85:2,7,11,18,20 86:7
86:11,13 88:16 89:5
94:3 100:2,5,16 104:2
106:1,6,7,9 107:3,6
107:14 114:8 119:10
119:22 120:22 121:4
121:15,18 126:13
128:4 129:8 153:10
153:13 154:1,2,5,7,14
155:4 158:9,13,15
159:6,8,16 170:2
regulating 157:16
171:5
regulation 66:5 94:6
107:13 132:8 153:17
157:12 158:20 163:18
164:6 169:18
regulations 15:10 46:9
47:14,15,22 51:6 59:6
95:16 99:9 126:21
129:4 132:3,6 133:22
134:7,11 135:13
137:10 163:22 165:18
168:13,18 169:15
regulations.gov 14:17
76:3
regulator 59:4
regulators 43:4 57:7
122:21 136:15 167:12
regulatory 1:4 3:6 9:13
10:8 15:13 18:2 21:15
33:13 36:9 38:19
40:18 41:7,16 42:1,2
42:8 46:2 47:12,21
48:9 54:8 61:14 73:13
75:18 76:1 78:15,19
82:3,3 87:1 94:22
97:21 139:2 158:19
161:7 164:2 168:3
169:2
reinsert 133:7
reinvigorate 18:9
reiterate 135:18
relate 49:22 77:12
82:22 134:7
related 55:2,4 56:3
57:17 75:14 84:21
102:22 129:3,8
131:19,20,21 135:12
137:10
relates 119:4 120:15
123:6 126:11 132:7
relations 1:17 47:2
81:10

relationship 17:22
relative 133:22
relatively 9:6 45:16
relayed 165:9
release 9:15,19 10:6,20
11:1,2 12:11 18:22
26:14 28:2 96:7,8
101:15 120:21 138:5
140:1,3,14 142:5
145:7,15,15 155:20
released 162:4 165:10
releases 12:9 25:4,14
96:6 143:12 165:16
relief 15:13 28:4
rely 35:16
remainder 120:12
remained 19:12 86:15
127:19
remember 5:10 104:11
162:10 165:22
remind 92:9 95:12
125:17
reminder 78:10
reminding 51:3
removed 117:5,10
repeatedly 113:7
replaced 22:15
replacement 22:20
64:10
replanted 149:3,4
report 2:6 9:12 17:20
23:10 53:2 118:13
119:11,12
reported 30:17
reporter 5:21
reporting 102:11,15
reports 13:5 72:18
119:10,11,14,15
represent 5:18
representative 66:6
request 14:12 21:11,14
23:19 67:21 73:22
74:7
requested 90:16 156:13
requests 11:4,9 16:2
30:20 32:13 35:12
36:5 165:11
require 50:9
required 117:4,9
requirements 47:15,17
115:6 130:14 131:16
research 18:1,12 46:5
53:15,18 62:16
131:22 140:1
researchers 48:9 59:14
resistance 16:3 28:14
69:2,17
resistant 16:6,13 34:3

resolvable 71:10
resolve 71:9
resolved 4:13
resource 127:3,10
 130:18 131:14
resources 50:17,17
respect 10:18 15:10,11
 33:15 34:19 72:12
respond 33:16 82:14
 88:1
responded 24:16 85:14
response 64:1 69:7
 82:18 85:6 87:18
 120:15 121:13
responses 24:17 32:21
 83:4 86:2 87:19 88:3
 89:5 113:12
responsibilities 99:8
 132:5 134:14
responsible 46:3
responsive 36:4
rest 167:11
restate 168:2
result 86:9 122:5
 126:21 170:9
resulting 140:15 154:17
results 143:22 144:3
rethink 79:22
retire 34:1
retransformations
 69:10
review 39:18 46:7,12
 48:10 96:21 119:15
 122:9,17 124:3
 140:18 146:2,9
reviewed 116:8 121:18
reviewers 46:15
reviews 62:7
revise 95:1 97:16
revisions 13:17 101:22
 102:6,10
rewrite 151:19
Rico 12:16,18,19,22
 13:2,6,7,12 145:11
rid 106:15,17 114:2
right 5:6 6:7,16 8:21
 19:8 23:2 31:17 39:18
 57:21 73:18 75:21,21
 76:7 79:20 80:4,4,5
 85:19 87:12 90:1 93:8
 93:11 96:9 108:11
 109:19,21 114:18
 118:5 122:15 126:17
 127:7 136:20 138:9
 142:13 143:2 148:16
 148:22 149:5,16
 155:9 156:2,9 168:16
 169:2,7

righty 127:17 138:1
rigorous 130:12
risk 15:7 26:12 27:19
 29:10,21 30:1,9 34:21
 40:21 48:11 54:1
 62:13 75:2 94:21
 97:22 98:18 103:8,20
 124:16 125:5
risk-based 125:1
risk-proportionate
 168:17
risks 74:10,18
risky 112:3
River 1:11
Riverdale 1:11
RNAI 69:14 70:2
road 1:11 28:11
roads 13:10
Robin 173:13
robustness 130:3
role 47:10,11 51:16,17
 91:17 127:11
roll 166:12
rolled 22:22
room 6:13 7:20 12:17
 14:3 37:1 56:8 171:7
 173:22
root 89:9
ROP 95:5,6 98:16
 129:18
ROPs 97:3
round 173:8
row 85:19 86:1,8 87:5
 144:8,13
rows 87:3
Rpi-vnt1 69:18
rule 13:17,20 15:15,19
 155:6,9 157:3,19,22
 159:22 163:4,14,15
 164:19
ruled 168:9
run 7:17 8:22 47:9
 132:22 133:1 141:13
 144:15
Russet 69:19

S

safety 1:16 47:11 48:1
 52:16 53:10,14 54:13
 55:16,19 58:21 61:14
 66:10,11,12 67:6 71:8
 72:2 73:13 74:10 75:2
 75:14,18,22 78:18
Sal 41:12
Sally 29:3
Sally's 60:16
sample 20:2 145:6
San 17:15

Sarah 173:22
save 173:12
saved 122:8
saw 17:6 22:3 126:19
 151:20
saying 27:15 30:8 32:9
 32:11 93:17 100:15
 101:8 103:19 106:13
 159:11 161:21
says 65:6 72:21 73:4
 84:15 99:5 137:19
scale 92:3
scanning 41:20 53:1
scenarios 87:1
scenes 173:6
schedule 65:20 80:21
scheme 54:8
Schmidt 56:20,21 57:19
 166:5,11,15,19,22
 167:9,15,20
science 15:1 27:11 30:6
 40:21 42:12 75:20
 78:11 79:13,14
 104:12 151:8,17
 163:20,21 170:15
Science- 168:6
science-based 168:18
Sciences 62:15
scientific 30:6 46:15
 62:6 74:16,21 91:12
scientist 1:16 22:2
 37:11
scientists 4:6 46:4,6,12
 58:21 62:14
scope 15:9 18:6 129:10
scoping 53:1
Scotts 82:18
Scotts/Monsanto 16:6
screen 141:14 144:10
 144:15
screenshot 144:7
scroll 83:6
SDN-1 32:22 154:15
search 2:17 18:21
 138:10,18 140:9,14
 140:16 141:10,13,16
 141:17 142:11 143:10
 143:14,19,21 144:1,1
 144:20 145:3 146:3
 156:9,20
search-data 140:13
searchable 83:7,11
searching 139:17
 141:19
season 25:13 124:5
second 58:18 74:15
 84:5 85:18 86:8,8
 97:20 106:19 107:11

111:7 128:11 132:4
 133:17 135:15 140:7
 148:17
secondly 163:14
Secretary 9:5 161:3,6
 161:19,22
Secretary's 161:1
section 9:16 28:21
 115:9 143:19
sections 85:16 143:13
sector 27:1 59:14
sectors 43:8
security 161:10
see 9:17 10:4,4,7 11:3
 11:12 19:20 20:10
 23:15 24:9,15 25:17
 29:15 32:5 34:1 42:19
 45:16,22 49:1 50:19
 56:15 75:12 76:4 78:1
 78:5 80:22 85:18
 87:12,14 108:12
 109:12,22 117:14
 120:2 121:22 122:14
 123:9,18 124:6,9,15
 125:20,20 127:17
 133:14 134:4 135:17
 136:21 139:20 140:8
 142:1,19 143:7,13
 144:3,9,12 145:9,9,13
 153:16 158:17 165:17
 172:3
seed 68:14 108:5,16,22
 110:6,19 150:2
seedlings 108:7
seeds 105:19 106:1,15
 106:17 114:13
seeing 52:14 102:4
 122:5
seeking 76:17
seen 31:19 119:3
 120:16 154:21 159:2
 159:6
sees 9:8 36:3
segment 8:9
segregant 87:4,9
segregants 87:6
segregated 86:14
select 144:2
selected 144:4
selection 58:8 124:9,14
selections 141:12
 143:15
self-produced 86:12
seminar 59:20
Senate 17:5
send 7:12 78:3 82:12
 91:7 119:22
sending 69:7

- sends** 72:20
sense 130:13 131:9
 132:12 150:14 160:5
sent 25:19
separate 50:2 85:16
 98:14 99:12 142:2,6
separately 115:13
September 135:22
 138:7 139:12,20
 140:20,21 141:22
 149:8
sequence 87:8
sequences 91:2
sequencing 63:15,18
 63:20 64:5,9,17 65:5
 65:13,15
serious 76:15
serve 46:7,12 48:10
serves 172:6
service 1:1 18:1 25:22
 26:3 36:2 40:1 43:7
 58:11,16 63:3,4 166:1
 166:2
services 1:4 3:7 18:2
 19:5 20:9 36:1 43:8
session 2:8,20 33:19
 56:5 57:15 58:4 80:17
 146:13 147:6
set 5:2 47:19 54:15
 58:14,15 60:10 95:19
 96:3,5 102:2,18
 115:19
sets 96:6,10 97:13 98:5
seven 60:21
shape 137:2 169:4
Shaqir 1:15 18:7 37:9
 37:20 57:10,13,16,22
 59:1,15 61:12 63:17
 169:17
share 41:3,18 57:8 60:2
 75:8 78:21 169:21
shared 42:10 44:12,18
 63:19 169:22 171:1
sharing 41:8,14 42:18
 44:9 52:12 53:9
shattering 108:3,4
 109:1
shed 106:22
shelf 152:1
shoot 4:11
shores 42:4
short 7:17 30:15 67:14
short-term 45:17
shortened 49:5
show 21:19 23:13 31:16
 32:4 91:1,7 99:1
 103:20 109:14 110:4
 110:15 112:21 113:14
 117:12 140:11 143:22
 145:22
showed 30:1 116:4
 155:19
showing 12:9 30:5
 109:11 145:10
shown 142:12 144:13
shows 25:7 32:6 33:5
 132:16 142:20 144:7
 145:7
shut 8:22
shy 49:16
Sid 23:21
side 38:12 39:14 42:10
 52:17,18 53:10 62:13
 62:20 63:1,2 74:19
 85:20 162:19,21
Sigma 87:12,13 88:11
 88:22
sign 32:6 107:4 144:8
 144:11
signed 14:9
significant 168:5
signing 14:8
similar 11:16 153:13
simple 45:16 74:14
 114:1
Simplot 16:2 69:9
simply 101:5 104:14
single 154:21
single-year 96:7
sink 148:21
sir 92:13 118:17
sister 39:22 40:4
sit 79:17 152:2
site 13:8 19:1,12 24:12
 24:14 123:19 141:2,2
 141:5 145:21
site- 86:9
site-directed 84:19
sites 9:15,19,22 10:6
 12:13 63:15 145:8
 155:21
sitting 20:10
situation 15:9
situations 31:14
six 24:16 31:2 34:13
 81:6 87:12,13 88:11
 88:22 149:15
sizes 141:14 144:16
slide 9:3,14 31:15 32:5
 101:19 155:19
slides 4:3 67:12,16,17
 78:3 116:19,21 118:6
 118:7 140:11
slightly 22:14
slow 27:10
slowing 32:6
small 91:10 130:17
 131:3 156:17
smaller 11:17,21 92:2
smart 141:15 144:17
Smith 94:8
smoothly 173:21
snapshot 11:9
snow 123:21
Society 30:7
software 142:22 144:6
soil 107:7 108:8
soils 149:14 150:4,11
solution 20:5 121:10
solutions 35:12 42:13
 89:15,21 168:20
solve 89:18
somebody 3:12 21:22
 22:2 31:9 114:9 155:7
 169:12 171:12
somewhat 150:18
son 148:4,13
soon 13:13 28:19 34:11
 158:17 167:5
sooner 28:19
SOP 91:15 115:13
 116:6,15
SOPs 100:19 101:6,11
sorry 120:5 166:18
sort 24:1 27:5 51:7 59:3
 60:3,6,21 64:19 80:21
 91:14 95:14 98:20
 102:3,4
sorting 76:8
sorts 153:13
source 146:7
sources 119:19
Sousa 4:15
South 44:1
southern 64:11
soy 9:16,17,22 10:8
soybean 34:8 68:20,21
space 66:19
spare 69:15
speak 5:19 6:5,14 10:14
 98:2
speaker 6:11
speakers 36:18
speaking 114:10
 121:14 169:11
speaks 66:20
special 103:21 147:18
specialist 1:17,22
 81:10 138:8,13
species 25:21 80:5
specific 14:12 20:8
 45:2 65:4,12 74:6
 92:16 93:13 96:13
 103:2,11,12 104:5,15
 105:3 110:17 124:18
 128:1,19 129:8
 142:12 144:3 157:4
 169:1
specifically 96:14
 102:22 115:10 121:8
 131:20
specifications 124:17
specifics 39:3
speed 24:4 142:16
 144:22 145:1
spell 6:5
spend 82:5,6
spent 157:6 160:4
spice 4:13
spinach 28:7
spits 93:6
spoke 28:12,15 137:5
spoken 66:21
spreadsheet 141:12
 142:22 143:6 144:5
staff 17:17 29:3,4
 135:19 137:8 139:16
stage 70:22
stages 61:22 62:3
stakeholder 1:6 3:8
 15:20 29:22 67:8,20
 76:11 101:21 102:1
 117:18 152:9 158:2
 162:11
stakeholder-meeting
 165:1
stakeholders 57:3
 73:19 75:6 78:12
 106:12 117:21 128:4
 130:2,15 131:5 136:7
 137:1 140:21 152:4
 157:20 160:7 162:7
 162:10 164:13 168:11
stand 68:1 76:13
standard 95:1,14,17,20
 96:1,4,10,18,22 97:17
 115:7
standards 61:15
standby 33:21
standing 138:14
standpoint 88:3
stars 84:22 85:3
start 8:21 9:5,12 72:15
 133:8 147:21 170:4
 172:14
started 8:5 22:5 24:3
 82:1 89:9 109:11
 148:15 149:1,19
 150:17 161:14,19
starting 27:3 31:17 51:7
 64:8,17 81:17 82:16
 96:20 173:10

Starts 4:20
state 38:13 40:4 58:10
 120:14 146:2 148:5
 161:16
stated 118:18
statement 16:8 26:12
 27:19 103:15 104:4
 108:21 109:15 147:5
 147:8
states 1:1 22:11 24:21
 46:14 146:6,10
 168:18
stationed 12:19
status 16:5 33:21 64:9
 65:16 143:16 144:2
statuses 145:22
statutes 50:2
staying 65:20
stays 100:5
step 52:1 73:21 92:3,5
 102:3 132:9
step's 102:18
steps 75:13 88:20
 98:19 101:20 160:21
 167:5
sterile 68:16
sterile/glufosinate
 16:13
sterility 25:10 68:13
Steve 20:10,11,11
stewardship 150:11
stock 60:3
stop 70:5 152:17
storage 106:22
stores 124:1
story 149:21
stovepiping 50:14
strange 137:20
streamline 98:9
streamlined 98:8
streamlining 117:6,11
street 22:1
strengthened 17:22
stress 108:15
stresses 69:3
stretched 32:17
Stripes 4:20
strives 78:10
strong 18:4 40:2 135:17
 171:3
strongly 168:10
structural 62:10
structure 49:22
struggled 86:20
struggles 66:22
struggling 26:20
strung 67:12
study 111:14

stuff 171:14
subject 26:8 39:16 94:6
 160:20 172:2
subjects 4:7 37:14,16
 67:16 172:11
submission 69:7
submissions 14:6,11
submit 115:12 148:6
submitted 68:18 71:14
 100:19 101:6 115:16
 119:10 138:21 153:12
 155:7
submitting 78:6
subpoenas 20:15
Subray 1:18 10:15
 94:16 102:21
Subray's 116:18
successfully 130:11
succinct 131:15 134:3
 135:10
sugars 69:15
suggest 167:3
summary 12:8 19:10
 85:13 145:5
summer 25:15 48:8
sunflower 69:1
supplement 96:21
supplemental 4:8 94:13
 94:14,19 95:2,6,20
 96:4,11,13,16,18,22
 97:16,17 99:4 100:12
 101:22 102:19 103:1
 103:3 115:7
support 2:15 18:12
 22:15,16 25:3 26:13
 39:21 45:13 110:14
 127:5,16 131:2
 147:22 166:2
supportive 168:7
supposed 110:1
suppress 69:4,14
sure 16:17 17:18 18:11
 18:14 27:18 28:20
 37:2 41:13 49:15,16
 61:9 72:16 73:17 75:9
 75:19 88:5 91:6 100:5
 116:21 120:19,20
 123:5,10 125:4 149:8
 150:6 158:6 160:11
 160:15 164:21
surprised 51:19
surprising 49:8
survival 109:17 110:4
survive 109:21
suspect 71:16
Sussman 63:12,12
sustainability 150:11
sweep 107:2

switch 52:3
synchronize 119:20
synthase 70:3
synthetic 54:2 84:13
system 22:15 23:4
 41:21 42:3,8 44:15
 46:4,21 62:9 63:6,9
 82:3 91:19,21 126:22
 128:10 131:15 133:9
 134:16 135:13 137:20
 139:8,9 168:4
system's 56:7
systematizing 35:11
systems 48:17 51:20
 61:1 102:13 132:11
systemwide 63:5

T

table 5:3 19:20 24:13
 85:13 86:1 141:11
 142:4,14 143:13
 145:3
tables 141:13,16 142:2
 143:11 144:14
tablet 141:16 144:17
take 7:18 8:3,6 20:2
 21:18 24:6 25:14
 41:11 42:8 58:1 67:10
 72:5 75:9,13 79:4
 80:19 101:1,2 103:4
 103:11 106:10,18
 107:17 112:8 113:16
 122:4 125:2 132:9
 133:6 137:2 142:17
 142:17 146:21 172:8
 172:22 173:7
taken 21:15 32:6,19
 81:8 168:5
takes 44:8 76:14 112:15
TALEN 32:15 84:16
 85:4 86:20
TALENS 31:21 86:21
talk 13:15 17:18 29:9,9
 31:6 33:3 37:15 52:13
 54:16 66:7 67:18,21
 72:10 78:17 81:16
 85:22 87:16 94:19
 96:17 102:21 118:20
 132:10 133:13 148:1
 150:7 151:16 165:3
talked 35:10 44:4 52:22
 53:1,2 81:14 103:1
 162:20 168:9
talking 9:7 49:3 50:15
 51:2 62:4 153:5 157:6
 160:4 161:1,2 164:15
 165:19
talks 65:6
targeted 16:10 86:16
 90:22 91:5 93:6 129:5
 137:6
team 37:8 38:8 41:12
 42:15 67:7 88:10,10
 174:13
teams 147:22
tease 156:20
Tech 19:2,6,12 138:5
 139:7,14,22 140:2,13
 140:19,22
technical 6:16 7:3
 29:19 41:7 44:6 52:11
 53:6 62:2,20 63:1,6,8
 88:3
technique 64:6 74:12
 78:21
techniques 32:12 51:1
 54:7 60:22 65:5,8
 73:20 83:1 84:11,20
 84:21 87:13 154:6
technologies 72:8,12
 150:3 170:5,13
technology 36:2 48:2
 78:22 79:13 84:17
 148:8 150:2 151:12
 153:14 154:1,13
 158:18 159:1 170:8
telephone 7:1 56:15
 125:19
tell 3:17 19:15 37:7 59:5
 81:9 90:19 127:2
 138:7,17 149:22
 153:19 172:18
telling 153:10
temperature 108:15
template 134:22
templates 91:18 128:2
 131:13
ten 49:4 62:1
tend 8:22
tens 14:10
term 18:5 20:7 53:22
 148:21
termination 123:7
terms 9:18 35:7 38:16
 53:5 72:10 83:11 97:9
 165:10,11,12
Terry 59:15,16
Terse 155:18,18 158:6
test 119:11 132:22
 133:1
tested 156:5
testifying 17:5
testing 52:15
text 51:6
text-box 143:19
thank 3:4 8:15 30:2

- 36:12,13 37:20,22
45:4 56:20 64:4 65:20
66:13,15 67:13 79:4
80:15,16 81:2 94:10
113:17 118:10,17
126:17,17 137:22
138:1,3,11 146:12,14
147:16,18 152:17,21
152:22 153:4 160:17
166:5 169:6,10
171:20 172:4 174:11
174:14
thanks 23:5 45:5 65:18
147:18 155:10 174:7
174:14
theme 55:8
therapy 28:10
They'd 23:19
thing 8:1 22:4 32:11
39:20 92:2 94:7 144:4
151:22 157:10 173:3
things 10:12 14:5 17:10
18:16 19:10 21:8
23:18 41:16,18 42:17
43:2,18 51:9 57:17
60:3 64:7,15,15 78:5
82:5,7 83:22 84:12
85:20 89:10,11,12,17
90:2,13 91:8,11 97:2
100:21 103:18 104:20
105:11,14 111:10
112:11 115:22 116:2
118:21 121:10,20
122:22 123:2,14,20
124:13,16,21 125:2,9
130:16 132:21 134:5
148:2,7 150:19 151:4
151:8 152:3 158:10
164:5,17 172:10
173:16
think 19:22 21:20 22:1
25:9,11 28:9 34:16,17
35:10 36:22 41:2,8
44:15 50:6 55:21
61:10 65:18 66:20
70:17 71:5 84:1 88:4
101:12 103:5 109:3
111:13 145:19 146:6
149:7,10,22 150:16
151:21 152:2,2,3
155:18 156:16,18
159:18 161:3,8 163:8
170:8,8,9,16,22
thinking 41:15 76:7
86:19 89:16 92:1 98:2
148:15 162:2 169:20
170:4
thinks 22:22
third 48:13 64:7 87:5
97:21 111:16 133:18
142:7
thirsty 36:19
thorough 96:21
thoroughly 125:14
thought 21:20 76:15
105:14 113:21 146:5
151:16
thoughts 77:10
thousands 14:10
threads 49:1
three 14:1 16:1 17:7
23:18 29:8 35:21
45:10 49:20 60:11
67:16 77:11 79:16
85:2,5 88:17 95:12
97:18 103:16 108:5
110:21 113:2 127:20
127:20 142:2,4
143:13 156:7
throw 148:20
tied 88:11
till 77:8 88:6
time 7:15,17,18 8:5,11
11:9,20,22 12:3 16:9
16:10,11 19:11 23:1
23:20 27:21 29:13
36:16 56:1 63:11
65:22 67:14 68:10,18
76:15 82:5,7 87:18,22
88:1 91:22 102:16
111:5,17 113:10,13
113:16 118:1 120:1
122:8 138:1 140:18
145:4,13 146:15
147:19 151:2 152:14
155:7 157:6 160:4
161:8 163:22 168:13
171:9 172:13
timely 24:7 31:4 36:5
timer 8:21 29:14,15
times 29:8 122:18
146:9 156:7,7
timing 122:11
tip 61:20
title 13:19 22:14 66:12
To-Be 89:19
to-face 29:17,19
Toby 5:22
today 5:13,21 38:2 49:3
50:22 51:2 66:6,17
67:10 72:9 81:16
88:13 94:4,19 96:18
116:22 118:21 127:15
127:18 133:20 134:18
172:19 174:8
told 78:13 94:20
tolerance 68:15 71:18
tolerant 25:16 26:6
33:22
tomatoes 70:8
tomorrow 163:6 167:19
167:20
tool 2:18 18:21 19:4
30:2 134:22 138:10
146:3 158:16
tools 30:8 47:12 129:11
136:4 138:18 148:11
151:7,17 156:9
top 49:4 85:3 96:11
top-most 139:21
top-ten 145:14
topic 35:15 47:8 48:13
48:21 50:21 63:22
topics 45:8 54:5,6
77:12 103:16
total 11:3,17 12:5 45:19
87:22
totally 32:2
touch 131:10
touch-tone 92:11
tough 13:9
toxicity 72:2
trace 154:17
track 92:3 119:13,18
tracking 91:19 119:9,13
trade 38:12 39:21 42:14
45:14 46:19 48:19
55:7,10 61:5 63:2
164:10 165:20 166:1
166:1
traded 52:21
trading 36:9 44:9
165:11
traditional 74:13
traditionally 75:1
train 149:16
training 35:20 36:1 40:9
137:3
trait 68:13 69:22 108:13
110:21
traits 42:1 69:12
transcript 6:1,8 172:21
173:1
transcription 69:1
158:7
transferase 71:17
transformed 69:11
transgenic 74:14 79:9
transitioning 130:22
transmission 19:13
transparency 35:7
123:2,12
transparent 41:4 139:2
travel 13:11
treated 100:2
treatment 4:7
tree 28:9,14
trees 28:8,10
trends 136:21
triage 91:10
trial 110:6 122:2 124:16
124:18
trials 10:21 12:21 13:4
13:6 121:2
tries 42:15
trigger 164:3
trilateral 29:19 44:6
45:12 52:4
tristeza 26:15 27:9 28:6
trouble 174:7
true 87:6 108:3
truly 174:9
try 66:18 80:3 88:18
127:8 138:15 156:19
157:20 160:8 167:2
trying 24:6 51:16 55:4,6
60:21 61:2 167:21
172:16
TTWG 44:5
tumefaciens 71:16
turn 92:5,12 94:7
102:20
turned 19:22 22:6 110:5
Turner 63:22 64:4
tweaks 164:1
twice 156:6,16
two 14:5 15:17 23:18,21
24:5 34:8 37:7 52:15
54:6 55:13 58:11,15
62:22 69:9 77:5,9
83:18 84:2 85:16 87:6
93:16,20 95:10
103:20 107:21 108:5
109:9,11 110:20
112:19 113:20 116:16
128:14 132:1 136:9
142:15 152:13 158:10
160:3 162:10,12
two- 102:4
two-and-a-half 25:19
72:1
two-phase 106:3
two-step 107:8
two-year 109:6
type 65:7 75:21 76:13
79:1 96:2 103:1
143:17
type-A 159:5
typed 114:9
types 47:8 49:7 95:22
121:6
typical 15:8,18

typically 29:6 48:4
71:21
typing 115:2

U

U.S. 1:16 39:17 43:5,9
46:21 49:12 51:20
61:15,16 73:8 169:18
ultimate 75:11
ultimately 11:13
unannounced 120:11
unauthorized 20:22
120:21
uncertainty 97:7
under-regulation 15:11
underregulation
157:15
understand 40:20
60:15 71:7 110:22
111:1 128:3,6,22
129:11 132:5,7
134:13 136:13 152:5
167:12,21 170:20
understanding 41:5
42:3,6 46:8,21 108:11
109:13 121:20 123:12
152:11
undertook 96:20
undue 151:9
Unfortunately 85:5
unhappy 24:2
unique 131:16 156:22
156:22
United 1:1 22:11 46:14
168:18
universities 130:17
University 24:21 25:6
unmute 92:12
unusual 6:6 109:9
unworkable 168:9
up-front 15:6
upcoming 59:19
update 44:22 90:8 95:3
updated 22:13 127:1
140:10 141:5,21
updates 2:10 66:14
68:9 94:12
uploaded 140:10
URL 24:12,14
USA 61:7
usable 142:22
USDA 1:1 9:6,7 58:17
58:20 63:13 76:22
77:19 148:18 161:4
USDA's 58:11 63:2
66:16
use 35:11 36:2 37:21
64:17 68:2 70:22

84:13 91:15 96:1
99:15,17,20 100:7,16
105:15,16,16,18,21
107:9 108:4 114:4
128:5,8 129:12
131:14 133:15 134:21
136:20 156:9
useful 77:13
user-friendly 127:2
users 140:15 141:17
142:10 144:19
USTR 38:13 40:3
usual 5:9
utilization 150:9
utilize 128:7 131:12

V

Valentin 13:8
validation 117:4,9,15
117:16
valuable 136:7
value 36:3 70:18
variance 88:1
variation 108:20 110:3
111:4,14,16
variations 116:1,10
varieties 22:8
variety 10:11 153:6
various 13:15 95:22
100:21 102:13
vector 83:20 84:5 85:12
94:2
venue 118:1
venues 167:10
Verdeca 34:7 68:20
verify 47:16
version 30:1,4,15
versus 93:19 96:7,8
115:6 122:5
vibrate 5:2 8:20
Victor 13:7
view 83:5
viewed 157:22
viewpoints 15:19
violate 8:19
Virgin 145:10
Virginia 19:2,6,12 138:4
139:6,14,22 140:2,12
140:19,22 164:9
virtual 79:3
virtually 48:2 50:18
virus 26:15 27:9 28:6
visible 5:11
visit 13:8 68:8
visited 43:16
visitors 43:1,11,12,14
43:16,22 44:1 45:18
46:18 47:1 48:7,8

49:7 165:6
visits 20:14
Voice 88:21
voluntary 131:8
volunteer 4:7 101:17
107:16,17,18,21
108:1 109:6 110:13
112:5 114:16,20
115:22 119:12,15
124:3
volunteers 108:7,10
109:8,11 110:9,14
114:19

W

wag 17:6
wait 5:14 6:4,13 22:3
56:9 173:8,11
waiting 26:2,3
walking 22:1
walls 128:20
Walter 5:22
Wanex 173:14
want 3:17 9:5,12 21:9
27:17,18 31:11,12
32:9 36:17 37:2,14
42:22 57:14 61:20
63:21 64:15,20 67:18
70:13 72:9,11,15
73:10 75:19 78:1,21
87:22 88:5 91:6 92:21
104:3 109:18 112:14
112:21 118:20 123:9
125:2,4 127:18 129:9
129:21 131:12,13
134:18 135:18 139:11
140:2 144:19 145:2
145:12 146:21,21
147:3,17,21 150:17
151:15 158:21 160:10
169:9,16 171:20
172:12
wanted 10:18 20:1
31:16 105:1 109:14
112:12 113:14,19
164:10,20 174:6
waste 100:1
water 5:3 26:21 36:18
149:12
way 4:21 21:21 22:8
27:15 39:1,6 41:4
42:5 49:20 52:10
56:11 73:18 76:16
82:9 85:16 95:11
103:11 104:7,18
109:21 118:3 122:10
135:4 137:14,15,20
140:8 144:16,19

146:1 162:22 170:4
170:19
ways 12:15 27:7 28:17
41:9 42:21 47:6
114:22 143:9 145:1
we'll 4:18 6:19 8:11
21:7 35:8 36:11,15
55:17 56:13,15,19
58:3 76:12 80:21,22
82:14 92:12 99:11
101:15 102:1 103:3
125:20 133:13 136:18
137:1 145:11 154:8
we're 6:15 7:3,21 16:20
18:16 19:9 23:3,7
24:6 26:2 30:12 31:4
32:17 34:17,20 35:18
37:3,4 38:3,6 39:9
47:12 48:6 49:17 50:1
50:1 52:12,14 61:22
62:3,20 63:7 64:7,8
64:16,18 65:11,19,21
68:6 72:16 75:20 76:6
76:7 78:12,22 80:19
89:14 90:1,6,7,18
91:19 92:8,22 97:15
98:7,9,16,22 99:6,19
100:9,13,15 101:8,8
101:20 102:1,4 116:7
119:3 124:11,20,20
124:22 125:3,3
128:21 134:14 136:19
136:20 145:1,9
147:11,14 148:7
149:18 150:4,9 159:7
159:8,11 160:19
161:21 165:19 169:18
170:1,4,12 171:4
174:10
we've 6:21 9:19 11:8
12:3 18:17 24:10,15
26:19 27:10 30:21
31:17 32:13,17,19
34:12,13,18 35:5,6,10
35:11,20 36:1 43:14
43:22 46:13 53:6 59:9
62:1 67:19 68:10,12
68:19,20 70:14 72:8
73:1 81:8,22 82:16
84:20 85:1,4 87:21
88:6 97:11 98:8,18
99:2 100:14,21 116:2
116:8 119:1,2,3
120:16,17 121:1,1,3,6
121:22 122:8 123:7
125:8,9,10,11,12
132:15 141:18 142:1
149:4 150:14 154:21

159:2 163:12 165:7,7
 165:8,8 170:7 171:21
 173:13,13
weather 109:9,10 149:2
 149:7
web 5:20 24:10 30:21
 32:21 92:18
webcast 7:11
webcasting 5:9
webinar 5:16 6:19 7:7
 36:21 56:12 58:19
 79:7 94:1 113:18,21
 115:2 116:17 117:19
 125:21 136:3 174:8
webinars 102:2
website 6:2 19:3 21:13
 67:9 68:7 77:22 80:12
 82:14,20 83:3 90:8,10
 116:22 128:1 131:11
 138:6,19 139:3,7,10
 139:14,14,22 140:6,9
 140:21 141:9 144:19
 172:19
websites 19:4
wedged 116:15
WEDNESDAY 1:8
weed 15:2 29:21 30:1,6
 30:9
weeds 34:22
week 9:11 15:15 17:15
 34:1
weeks 6:3 11:7 27:2
 161:7 172:22
welcome 2:3 3:3,7 8:4
 36:22
well-intended 168:6
went 17:19 19:19 20:8
 20:11 21:1 64:14 74:1
 87:13 88:16 174:17
whatsoever 21:15
 154:20
wheat 94:14 104:12
 105:8,10 106:1
 107:19,20 108:1
 110:6 111:10 114:12
 114:13,14
wide 26:14
widespread 49:11
wife 148:4,13
Wilcox 173:13
Wildlife 25:21 26:3
 35:22
win-win 82:5
windows 128:20
Windsberg 19:18
withdrawal 15:17
 164:14 165:12
withdrawn 11:6,14,19

12:7 155:9 157:3
 159:22 160:21
withdrew 15:15 20:21
wonderful 57:9 66:18
 71:20 72:20 127:6
wondering 124:10
Wood 173:17
word 20:7 22:14 103:7
 150:6
wording 131:3 158:11
words 6:14 159:4
work 7:2 10:9 17:3
 18:15 24:4 28:13
 34:22 35:3 38:5,12,18
 39:22 40:3 46:9,10
 60:11,13,17 76:22
 80:2,7 94:19 95:3
 97:16 129:7,15
 135:20 137:13 144:5
 144:16 145:7 151:18
 161:11 163:12 169:4
 173:5,19
worked 20:20 51:21
 107:22 121:10 138:4
working 6:16 7:3 16:21
 18:11,18,19 23:8
 24:22 29:5,19 39:16
 44:6 45:13 56:8 60:1
 60:1 63:6 66:19 67:1
 71:3 78:17 96:9 98:15
 142:9 144:18 145:1,4
 146:1
works 35:2 38:9 41:9
 46:21 82:9
workshop 55:18,18
 59:20 61:7 128:12,14
 128:15,16 135:19,21
 136:18
workshops 48:6 136:10
world 48:19 49:12
 148:7 149:12,14
 167:12
worries 35:3
worst 149:3
wouldn't 10:3 20:2
 93:13 98:11 165:17
wrap 68:3 78:9 171:16
wrapping 89:14
write 93:17
writes 9:8
written 7:21 102:5
 164:7
wrong 3:13 89:10,12,17
 89:18 103:18 104:20
 105:11,15
www.regulations.gov
 74:2

X
X 2:1
Y
y'all 167:17
Y17 69:13
Y9 69:12
Yates 1:19 33:18
 118:11,17 126:4,9
yeah 57:22
year 3:9,12,12 4:13 8:6
 8:6 9:13 13:16 16:1
 17:21 18:18 22:13
 24:5 25:1,22 26:11
 27:14 28:15 29:2,8,22
 30:17,19 32:4 37:5
 40:11 44:19 45:20
 49:5 52:8 53:12 55:17
 67:22 68:10 69:22
 70:11 71:13 76:11
 81:16 94:20 95:2
 102:9,12 110:20
 118:14,14,22 119:2,8
 119:16 120:8 121:11
 121:15 125:9 128:12
 135:19,22 136:8
 145:16 156:15,19
 164:22 172:16,17
 174:9,10
year's 172:15
years 12:10,20 17:6
 18:4,22 23:17,19,21
 24:16 25:1,19 26:20
 28:16 31:20 32:18
 47:4 49:4 50:3,7
 51:14 52:8 55:12 60:5
 60:12,21 62:1,10 64:5
 66:18 67:7 79:21 81:6
 84:18 88:17 107:22
 108:16 109:9,12
 110:15,20,21 126:19
 138:4 161:15 162:11
 162:12 163:20,21
 164:1,7
yep 23:2,2
yeses 85:19
yesterday 17:14,15
yield 34:7 149:20
yields 69:4 148:17
 149:11,18 150:2
York 24:20 25:13
young 148:15
Z
zero 78:15
zinc 31:18 32:14 84:15
 85:3

0
0 6:22 56:14 92:11
 125:19
1
1 6:22 56:14 92:10
 125:19 141:22
1:00 1:11
1:04 3:2
10 32:18 51:14 120:10
100-year 75:17
107 43:11 45:19
11 16:14 98:20 112:22
118 2:12
12 31:19 80:22,22
120 11:21 112:15,20
127 2:15
13 11:5 30:18,18,19
 31:19
138 2:18
14 30:20 31:22 68:17
 69:6
141 113:4
146 2:20
15 1:8 16:8 30:18 67:7
15th 140:20
16 32:15,16
162 10:6
17 11:18 30:19 43:10,11
 45:19
174 2:22
17th 77:8
18 30:22,22 33:7
19 27:16 32:13
1980s 79:19 142:3
1985 138:22 139:1
1990s 139:7
19th 13:20
1st 120:8 140:22 149:8
2
2 11:6,7 12:4 16:10 75:3
2:33 81:4
2:48 81:4
20 162:14
20-year 75:15
2000 52:8
2000-plus 10:7
2006 130:1
2007 130:10 139:7
2008 31:18
2011 24:10 25:19 31:22
 34:13 54:15 82:16,18
2015 96:20 130:15
2016 30:19 44:13,13
 104:11 112:16,22
 145:8
2017 1:8 3:7 13:16,20

67:10 73:22 113:1
130:20
2018 27:14 67:11 124:5
208 14:4,11
22 96:10 98:19
23 2:6
25 52:7 55:12 70:11
26th 34:5

3

3 2:3 11:10 75:4 76:21
3,724 12:12
30 34:15 50:3,7 162:15
163:20,21 164:7
30-minute 8:21
30-year-old 168:4
33 108:4
340 13:18,19 30:17 57:4
57:12,13,17 73:2
83:17 128:19 129:4
131:16 132:4,6,21
134:1,8,13 135:14
137:11 151:19 157:2
164:14 168:12
356 12:12
37 2:7

4

4 75:12
4.0 30:1
4:33 174:17
40 29:6 113:14 136:1
408 11:18
44th 148:14
45,000-plus 12:13
4700 1:11

5

5 30:4
50 10:5 113:1 120:6
55 82:16 120:9
56 2:8
583 76:4

6

60 113:1
60-day 34:4
66 2:10

7

7 13:17,18 30:17 73:1
83:17 132:3
70 36:21 172:1
71 9:22 12:4
725 120:5
755 120:8
7th 17:14

8

8 2:4 51:14
801 11:5
81 172:2
82 11:11

9

9 11:19 12:3 35:14
90s 52:7
94 9:21
97 114:12

C E R T I F I C A T E

This is to certify that the foregoing transcript

In the matter of: Stakeholder Meeting

Before: USDA APHIS Biotechnology Regulatory Services

Date: 11-15-17

Place: Riverdale, Maryland

was duly recorded and accurately transcribed under
my direction; further, that said transcript is a
true and accurate record of the proceedings.



Court Reporter

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701