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

BRS STAKEHOLDERS MEETING

Date: November 17, 2009
Time: 8:40 a.m. – 4:20 p.m.
Location: USDA/APHIS
4700 River Road
Riverdale, Maryland

P R O C E E D I N G S

MR. GREGOIRE: Good morning, everybody. I'm Michael Gregoire, the Deputy Administrator of Biotechnology Regulatory Services in APHIS, and I want to thank you for joining us today and welcome you to our stakeholder meeting. We have a very full agenda for you today and we very much look forward to today's meetings and discussions.

I just want to begin by saying that I believe that public engagement really enhances the government's effectiveness and improves the quality of the decisions that we make. I believe that the knowledge is widely dispersed in society and, as public officials, we benefit from having access to that dispersed knowledge.

The President has encouraged departments and agencies to offer Americans increased opportunities to participate in policymaking and provide their government officials with the benefits of their collective expertise and information. So it's with that guidance and in that spirit that we've undertaken this meeting today.

Today's meeting is going to consist of presentations by staff from Biotechnology Regulatory Services Unit and we're going to have interactive plenary discussions and small table group discussions amongst the participants on the agenda topics that we have today.

The presentations and the discussions are going to focus on four key areas today. The first area is program delivery initiatives. The second area is the petition process, what concerns people have, what improvements we might make in that process. The third topic area deals with our implementation of the National Environmental Policy Act, and we're going to talk about a pilot project we plan to undertake and get some of your input and ideas on how we undertake that. Then, finally, we're going to be talking about the Biotechnology Quality Management System.

We plan to use your thoughts, ideas and suggestions that we gather here today to inform our decisions and programs as we move forward in these areas over the next several months.

There are several other issues that stakeholders have expressed an interest in including in today's agenda, including such things as our proposed regulations, appending regulatory decisions that are before us, and litigation that we're involved in. I will be providing a brief update on issues like these and taking questions from the audience before we break for lunch today.

However, because there have been other venues for public input on those issues and those issues are currently in the decision-making process within the department or are still in the courts, we don't plan to engage in more substantive discussions on those topics today. But I will cover updates on where we are with those and be taking questions.

So at this point, I'm going to turn the mic over to one of our facilitators, Jerry Coursey, who works with the Policy and Program Development Unit in APHIS. Jerry facilitated the public meeting that we had in April on the proposed rule and did a fantastic job. So we're very happy to have him helping us out today.

Jerry?

MR. COURSEY: Thank you, Mike.

Good morning, everyone. I'm going to be joined as facilitator today by Anne Dunigan and Anne is going to be speaking after me. Again, we're both part of APHIS. We're in the Planning and Evaluation Division.

The first thing I'd like to ask you to do is look at your packets, the light blue folders there. I just want to go over the four pieces there quickly. Mike has just walked you through the agenda. That's the first piece there, a one-page agenda.

The second piece is a list of ground rules and norms for the meeting. Anne is going to go over those in a second. The third piece is the questions that were posted on the BRS website, I think, last week, and we thought it was important to have those in the packets, also. These are questions that we're asking the table groups to discuss and address after the presentations today and we'll talk a little more about that.

The fourth piece is a short evaluation of the meeting, which is very important to us. So we ask you, if you can, to fill this out before you leave this evening and we will be collecting those. That will give us important feedback for next meetings and, also, other information that's important to us. So that's the packet.

Let me talk a little bit about our roles as facilitators, Anne and I. Now, one thing we're going to be doing today is a lot of work at the tables. You are sitting at tables of 10 right now. Most tables don't have 10 people.

So at the end of our little presentation here

from myself and Anne, I'm going to ask those folks who are just three or four to move over to another table. We still have people coming in and they may people the other tables. But if we can consolidate some of the tables, particularly up front here, before the presentations, that would be great.

Our role as facilitators today is pretty simple. We're here to help you folks, the stakeholders and BRS and the staff of BRS, have a good dialogue and discussion about key issues that are important to you.

To do that, we will be keeping track of time. As Mike said, there is a full day of work here. We want to make sure we use our time as effectively as we can. We will be managing how long the groups talk together, how long the groups then report out to all of us. Breaks are during the morning, afternoon, and a lunch break. I think most of you know we are selling lunches to kind of streamline the lunch break. If you haven't bought yours, you can still buy them out front, I think.

Now, let me say a little bit about the process we're going to be using with the groups. We've got four areas of discussion, as Mike told you, if you look back at your agenda. The first area of discussion is petition process improvements. We're going to be taking questions from the full floor, the large group. There will be no discussion at the small group tables. That's going to be reserved for session numbers 2, 3 and 4.

What we will do with those sessions is there will be presenters walking you through their PowerPoints and presentations. Immediately after their presentations, you can ask clarifying questions from the floor. Anne and I will be circulating with microphones to get your questions.

Once all the clarifying questions have been answered, you will focus on your group work together. You'll go back to your table for about 30 minutes and discuss the two, three or four questions that BRS has laid out for you.

In the report-out, what we'd like, because we have so many tables here -- we have nine at this point, maybe 10 -- are key highlights from each table around the issues that were discussed. This means a report-out of maybe one or two important things that would take one or two minutes. So Anne and I will be managing that with all of you and we'll take questions as we get into that. That's the process we will be working with you on.

That's our role, again, to help you folks have a good discussion with BRS staff, to manage the time, and, also, to manage the group process, where BRS gets a chance to understand your perspective on a number of these issues. You get the chance to talk with your colleagues, other stakeholders at your table.

Anne is now going to talk about the ground rules we have for the meeting. Thanks.

MS. DUNIGAN: Good morning. If you would just open your packet, if you don't have it open already. Inside, we included just a really brief description of

some meeting norms that we'd like to follow and, also, just a little bit on how the meeting will be run, just to follow-up on what Jerry said.

The ground rules are very simple. We'd like for everyone to share their ideas, be respectful of everyone's opinion, just speak one at a time to allow everyone to share their thoughts and opinions. Please express your interests around the key issues; this is most important. Please express your key issues and why they're important to you.

We will have some scheduled breaks, but if there's anything you need during any other time, please just step out of the room. The restrooms are just outside. If you go out of the room, turn to the right and walk down the hall just a little ways, you'll see a small cafeteria where you can buy coffee, snacks, and if you decided not to purchase your lunch, they will be serving lunch around noon.

Just in terms of another logistic, if you would like to step out of the building during the day, please just make sure you have a badge on. We have a guard's desk and if you wouldn't just mind keeping that on during the day.

In terms of the process guidance for our small groups and our larger groups, when we have a panel or a presentation and you have a question from the audience, if you would just identify yourself. We have somebody recording the meeting and it makes it easier for her to identify differences in people.

Just, again, we do not need to reach consensus during this meeting. It's just free to share your ideas, your thoughts and what's important to you.

During our smaller groups, we will have a BRS staff person at each table. They will be there to record some of your thoughts, answer any clarifying questions, but really just to listen and not join your group so much as just to listen in and make sure they are able to capture your thoughts.

During our small groups, we would ask if someone would be willing to -- we have some flipcharts

on the side -- if somebody would be willing to write down the key points during that. After the meeting, we will ask for each group to report out a few key highlights and that will make it easier for that person to share those with the larger group. We will have different BRS staff during the day joining each table. So just be aware that you might have a different person joining your table throughout the day.

Are there any questions about how the day will run or anything we can help answer? Thank you.

MR. GREGOIRE: Thanks, Anne. Let's just take a couple minutes now at your tables to introduce yourselves to each other. What I'd like you to do, you may know everybody at your table, you may not, but take turns, say who you are, what organization you're with, and what is your role in that organization.

That would be very helpful, because you're going to be together for a number of hours today. So this is a quick introduction, who you are, what organization you're with, and what's your role in that organization.

[Individual table introductions.]

MR. GREGOIRE: Folks, if you could finish up your introductions, we're getting ready to start the first presentation. This first presentation will be looking at program delivery initiatives.

Let me say a little bit about the process here. I'll just go back and repeat myself a bit. But during this session, we'll have three presenters. I'll introduce them. We will be taking questions from the floor after each presentation. This is not one of the sessions where the group is working together. We will take time after each presentation.

Let me introduce our three presenters. First, we've got Lee Handley, who is going to talk about the ePermits update. Lee is a senior biotechnologist in the Environmental Risk Assessment Programs in BRS.

John Cordts will be doing process modifications. John is also a senior biotechnologist in the Environmental Risk Assessment Programs. Thomas Sim will be reporting on the planting reports. Thomas is director of Regulatory Operations in BRS.

So we will start with Lee.

MR. HANDLEY: Good morning. I think we'll start off this morning in the exciting world of ePermits. As most of you guys know, we're using permitting for notifications and permit submissions.

ePermits was launched in 2006 as a part of the eGov initiative and it has been amazingly successful for BRS; 98 percent of our applications come in electronically now and are processed electronically. It includes permitting and notifications, acknowledgement of notifications.

About a year ago, we launched the compliance workflow as a part of ePermits. A lot of that you guys don't see because it's internal to BRS, but you'll get notices of compliance or warning letters and that kind of thing will come to you electronically.

The program is used by four different programs in APHIS and there is a very high level of support from APHIS senior management for the ePermitting and the whole eGov initiative.

Last year, we had a couple of major releases in ePermits. One of these was what we call the permit conditions handshake. Those of you who are getting permits have seen that new step that we have in the process. We actually have to read the conditions and agree to each of them before we will issue the permit.

As I mentioned earlier, we have the compliance workflow that was implemented about this time last year, where all the inspections and communication with the permittees about these inspections takes place electronically.

As part of the supplemental permit conditions handshake, basically, we have about 20 different templates within the system that we select from when we're starting to develop the conditions of the permit. Then the biotech can tailor those depending on the permit by adding other conditions, depending on the nature of the permit. Then it goes to the applicant to read the conditions and agree to them, and then it

comes back to us to process.
Particular future enhancements may include crop-specific supplemental conditions. Right now, they're fairly generic and we have to tailor them by the crop, and we're talking about developing particular permit conditions, say, for corn, for soybean, trees and other things like that.

The inspection process is now incorporated into ePermits. The work flow is routed from BRS to PPQ. PPQ actually conducts the inspections for us. Then after PPQ inspectors do their work, they're routed back to the compliance group in BRS.
As I mentioned earlier, notices of compliance, notices of noncompliance, warning letters are generated and sent to the permittees through the system. In some cases, BRS may require a reply from the permittee and that's all done electronically. I think some of you guys have actually been a part of that process.
The other thing we did was we launched what we call the Location Unique ID, and that was about, I guess, a couple of months ago. This is where we use a unique alphanumeric code to identify each release site. We did this because in the future, people will be able to submit planting reports, field data reports, those kinds of reports that are required by the permit conditions or in the regulations electronically.
So that the system would recognize a particular planting site, we have to use this unique ID. This is primarily for people who are going to be

uploading through XML.
That unique ID can only be used once within the application and it must be different for each location. As I mentioned, it's going to allow the system to identify where your planting reports are coming in, so it knows under what permit to put those, in what location.
The other thing we did at the same time was we changed the formatting for GPS coordinates so that those were required to be in decimal format. Before, as you know, it was an open text field and people were using many different formats. There was a lot of text in there and it makes it very difficult for us to do any kind of mapping. So what we did was to impose the condition where we have six pairs of coordinates. One is required and five are optional. And, as I mentioned, they have to be in decimal format.
One of the things that we did recently was clarify what is CBI and PII on the application to facilitate the approval and responses to FOIA requests. In the future, the use of CBI brackets will not be allowed on certain fields.

Those of you who this affected, you got a memo from Cindy Eck. There's only a couple of you in the room, I think, that were affected by this. But if you have any questions about this, just contact Cindy and she can give you additional information.
For the next upcoming release, this is going to be a major release, hopefully, about this time next year, where you'll be able to submit your planting reports, annual reports, final field test data reports,

monitoring reports, pre-plant notices for pharmaceuticals, pre-harvest notices for pharmaceuticals and industrials, return equipment to general use notice, and compliance incident reports, or the self-reporting function.

Those of you that have been involved in this very lengthy, complicated process of trying to come to consensus on what the data fields need to be or where, we determined what those data elements would be and everyone agreed to those basic elements in March of 2008.

The final data tables were sent out to all users of ePermits that are planning to submit via XML upload. I sent that out in May of 2009. The plans were to implement this in October of this year, but this was delayed.

We now have just finished the data requirements documents. The design documents, we're working with the contractor and these are targeted to be completed by the end of December of this year. Depending on funding, the launch for online reporting is anticipated to be October of 2010.

The important thing to understand is that you will have to have used the Unique Location ID for this to work if you're going to do this by XML upload. So the sooner you can start using that unique ID, you'll be able to upload. If you haven't used the ID, you can't upload. So if you want more information about that, I'll be glad to talk to you separately.

The other thing that we're talking about doing is -- for those of you who have looked at the Virginia Tech website lately, you'll notice that we've got some data integrity issues. The regulated article can be spelled in a number of different ways and common names are all over the map.

So what we're going to do is we're going to lookup tables for things like institution, regulated article, for example, the scientific name, the county within the state, and the country so that you'll have to pick from a dropdown. Those of you using XML will be affected by this because you'll have to use the correct naming standard for whatever the regulated article is.

Your institution, for example, county within state, really, the reason we're doing that is that there are a couple of counties in the U.S. that have commas in them or have apostrophes, and this creates all kinds of problems in ePermits, so we're going to eliminate the apostrophe.

Those of you who have very large permits and notifications are aware that we've had a major problem with large PDFs not being able to generate. ITS just recently made some changes to help solve the problem and, knock on wood, I think the problem has been fixed.

We just had a permit that was uploaded last week that's over 1,500 pages and it will generate within less than two minutes, which is a record for ePermits, because sometimes it's taken up to 30 minutes to generate the PDF.

So having said that, it looks like we may be

able to increase the number of sites on a notification. Right now, we've had to impose a limit. Those of you who have the very large permits and notifications that would like to increase the number of sites, give me a call or e-mail me and let me know what you think your anticipated site limit will be so that we can get a handle on just how big we think these things could come.

The other thing we're looking at longer term is being able to do various requests via ePermits. This would be a separate workflow in the ePermits. So various numbers would be assigned automatically. Those variances will link to all permits where the variance has been used. Since they are not very common, we don't anticipate doing this through XML.

The other thing that we are looking seriously at is having an institutional applicant. This would allow individuals to submit applications as an institution, as an applicant within ePermits. This

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would allow employees to work on and view all applications within their institution. It would also avoid the problems that are associated with having to reassign existing notifications and permits to different individuals when a person leaves an institution.

I know a number of you have asked for this. We're looking into the logistics of it. PPQ has the same issue. They would like to be able to do the same thing. So we're looking at trying to do this globally within the ePermits.

Now, a question that we have is how is the permit conditions handshake working for you guys? Do you have any thoughts on how we could do it better? The compliance workflow has been implemented and it seems to be working well for us. Are there any issues, from your perspective? Location information, how is it working? Do you have any suggestions for improvement?

That's it.

MR. COURSEY: Thank you, Lee.

We're going to do a little housekeeping right now. I was alerted that we've got a table in the back

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with about five people, right over here.

How about folks, at the break, you folks will then move up to the front over here? It would be better so you can -- we'll make sure you have additional company. So at the break, which will be in about 45 minutes, we'll move you up.

Another quick housekeeping point is that the PowerPoints were developed to help facilitate discussion here in the hall and in the table groups. As Anne said, the transcript from the court reporter and BRS staff will be posted on the website after this session. So you will have, at that point, Lee's commentary and the PowerPoints and everybody else's commentary and their PowerPoints.

So let's open it up for questions, some of these questions or other questions you have for Lee. Let us get to you with microphones.

Questions, anybody? And would you please tell us your name and the organization you're with?

MR. GONZALES: My name is Bob Gonzales. I'm

with the Noble Foundation. With regard to the institutional permits, how soon do you think that might

be implemented and will that involve, also, the central movement permits?

MR. HANDLEY: It would involve all permits. Actually, we have to build like a separate gateway for an institution. It's fairly complicated. I'd like to say we'd have it within a year, but it depends on how complicated the process is going to be. They're looking into the level of effort that it would take to develop something like this.

MR. GONZALES: So this is not a policy issue. It's just an implementation issue.

MR. HANDLEY: It's an implementation issue, yes. You would still be e-authenticated like you are now as an individual and you would be the responsible party, but it would just let everyone in an institution share and look at all of their applications.

Right now, the head of the regulatory group in some institutions actually can't see any of the permits or notifications that their whole group is in charge of.

MR. GONZALES: Actually, where we have a problem is on the low end of it, though, not so much

the environmental release, but just simple movement. We have principal investigators who might submit one permit every two years and. And, actually, the e-process is a bit cumbersome for them, and we're looking at probably staying with the paper system. But if I could do it for them -- plus the fact that it would allow the institution to know what's going on within the institution.

MR. HANDLEY: That would make a lot of sense, yes.

MR. COURSEY: Thank you.

Other questions?

MR. GUYER: Dave Guyer with Syngenta.

Lee, what are BRS' expectations when reporting release happens, if it's in October? Will there be a transition period for the permittees?

MR. HANDLEY: The way we've done this in the past is we always give people six months to get up and running, particularly with XML upload, because it takes time for you guys to get your systems compatible with the ePermit system. So every time we launch a new schema, we always give you at least six months.

It's also going to depend on timing in this situation, because you'll want to be submitting reports for things that you planted that year. So I'm guessing it really won't be until the 2011 planting season, permitting planting, that this would actually start working for real.

MS. DEATHERAGE: Claudette Deatherage, Monsanto.

Lee, what about an XML upload for permitted vendors. Is that off the table or what?

MR. HANDLEY: We really haven't considered it. We can look at that. I mean, there's really not that many. You have to think about the cost-effectiveness of implementing something like that. That would be a

fairly major design change. But we could look at it just to get an idea of how much it might cost and how much time it would take.
MS. DEATHERAGE: If we have a large number of constructs to add to a permit, the manual process for doing that is very time-consuming.
MR. HANDLEY: Yes, I understand. Yes, I know. Yes.

MS. DEATHERAGE: Thank you.
MS. BUEHNER: Gina Buehner with Dow AgroSciences.
With regard to the Unique Location ID, does that differ from the site ID?
MR. HANDLEY: We have Location Unique ID, which is just a code, which is meaningful just to you. It doesn't mean anything to us. This location name, that's a different field, and that's where the name of the farm or the name of -- where the planting is going to take place.
MS. BUEHNER: Thank you.
MS. FITZPATRICK: Sharie Fitzpatrick with Forage Genetics.
Within ePermits currently, there is a field where you can ask us a question and we can reply. It would be very helpful if there was a field where we could ask you a question and you could reply. Right now, it's just one-way communication.
Then the other question is there's a note on it that says no CBI information can be entered in the response. So it feels like you have to go around that

useful tool every time to convey information.
MR. HANDLEY: Yes, I know. That is a good idea to have the message coming from you to us. That's something we can certainly look at. The problem with putting CBI in those fields is that it's not protected. There's a separate area within ePermits where CBI information is held and that message function is outside of that. So we're really constrained in that situation. And, honestly, if you want to discuss CBI information, we should really do it over the phone anyway, because, technically, it's not really a good idea even to e-mail CBI information.
But the one thing you can do is that you could put an attachment in the file that's got CBI information in it. I've done that before by communicating with people for a long message or something, stick an attachment in there and say there is a message in this attachment for you to read that has CBI in it.
MR. COURSEY: Other questions? Okay. Thank you.
Thank you, Lee.

MR. HANDLEY: Sure.
MR. COURSEY: Now, we'll hear from John Cordts.
MR. CORDTS: Good morning. As a result of our stakeholders meeting last year, there were a lot of recommendations that came from stakeholders, as well as we had a lot of internal discussion from that meeting. Some of the recommendations that came out of that

meeting were made available, obviously, and we addressed some of those over the course of the last year. And I'm just going to go over a few of those in terms of delivery improvements that we were able to accomplish over the last year.

One of the recommendations was related to our evaluation of design protocols that come in with notifications and permits and could we accomplish that in a quicker fashion so that permits and notifications could be approved in a more timely manner.

So we took it upon ourselves to ask people if they wanted to go down this road, they could send us their design protocols in December or January that they were proposing to use over the course of the next year,

and we would look at those and then we could make some determinations about the adequacy of those prior, in many cases, to even notification submission or permit submission.

So for those of you who anticipate this again, we'll be doing the same program this year. If you want to submit design protocols ahead of time, send it to us in December or January and we'll be able to take a look at those and get back to you about those.

One of the questions which still seems to come up relates to specific guidance about what's considered a release, and it just relates to acreage and number of releases. We have provided information within ePermits that talks about both number of releases and then what constitutes a release. So there is guidance within ePermits now that answers that question. If people continue to have that question, it's within ePermits. We can certainly talk about it again, if somebody wants to.

For those who work on microbial permits sometimes or plant pathogens, particularly, there were issues with our coordination with plant protection and

quarantine and whether the permit requirements and specific issues were coordinated well between PPQ and BRS.

We worked with PPQ over the course of the last year and have worked that out now such that any permit conditions that we put on a microbial permit for interstate movement or importation are consistent with PPQ and, therefore, somebody doesn't have to go to PPQ separately. So they can come just to us and our conditions are adequate for PPQ.

There were other questions about GPS coordinates for each release site and I think we've clarified that now. I think our current requests relate to either one GPS coordinate approximately in the middle of a release site or up to six GPS coordinates that would bound a release site. So those are kind of the current guidance that we provide for people in providing GPS coordinates to us to locate release sites.

There are always questions about NEPA and Dangerous Species Act checklists. Although we don't make those directly available to applicants, we have

talked about these extensively internally and we can provide specific guidance if you have questions about

information that you need to submit to us in order that we can complete our work efficiently.
There continues to be questions about the need for our writing of environmental assessments or environmental impact statements. We will be putting into place a team of NEPA -- a NEPA team, specifically, that will be providing, in the future, specific guidance to stakeholders, to applicants, when we will be needing to complete an environmental assessment or an EIS. I think somebody this afternoon will talk more specifically about this. So I think we'll have that covered today.
Finally, if there are any questions, the primary one in this regard is how can APHIS continue to improve our efficiencies and effectiveness in our processes.
So I can take questions from the field, if we have any.
MR. COURSEY: Any questions?
MS. NYGAARD: Linda Nygaard with Dow

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AgroSciences. In regard to coordination of BRS, either notifications or permits and PPQ, I'm assuming, though, that PPQ permits for the release of microbials on transgenic field trials are still needed. It's just that the permit conditions coordinate now.
Is that what you were saying --
MR. CORDTS: Yes. The permit conditions are coordinated. We do work with PPQ. So if we get a request for a release, our permit conditions are typically adequate, but we still do talk to PPQ, if we need to, for a release for plant pathogens.
MS. NYGAARD: So the two permits are still required.
MR. CORDTS: I'm not sure.
MR. COURSEY: John, if you could speak closer to the mic.
MR. CORDTS: Yes, sorry. The question is about the need for both PPQ and BRS permits for release of genetically-engineered pathogens. I believe our permit requirements will still be adequate. If we feel a need to talk to PPQ, we will do that internally. But I think right now our permit conditions will be

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adequate. So there wouldn't be a need for new permits.
MS. NYGAARD: Then, again, if the release of microbials, if the microbials are non-genetically modified, to remain in plant pathogens, let's say, then I would assume -- am I correct to understand that you would still need the PPQ permit?
MR. CORDTS: Yes. You would have to deal with PPQ in that regard.
MR. COURSEY: Other questions? Please put this close to your mouth.
MR. PEARSON: Hi, John. This is Les Pearson with ArborGen. I guess I want to put a question back to you.
In those cases where you're not meeting the timeframes for approvals of permits or notifications, can you talk a little bit about what are some of the the high level -- what are some of the delays that you're seeing there and things that you think we can help you with?

MR. CORDTS: Well, for the most part, I would say that in well over 95 percent of the cases, we're meeting our timeframes for notifications and permit

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approvals. I know Steve Bennett was in the room and he can certainly answer that.

If we're not meeting those timeframes, it's going to relate to preparation of an environmental assessment or something like that, which goes outside of the timeframe.

Steve?

MR. BENNETT: When looking at the trends of the data and stuff, when looking at the trends of the data, we track all our times and process for all the different types of permits, releases, movements, releases, importations, interstate movements, as well as the notifications. And I would say we're probably more up to around the 97 percent range of having everything processed within the timeframe.

The one area we seem to hit the most is on the notification of interstate movement, which is a very narrow window of time that you're operating under, which is 10 days. So to have an application received, reviewed for completeness, do your assessment and allow for review and comment with the state, you have 10 days to expedite that whole process.

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That's the one area that I wouldn't say we're comfortably 100 percent, but it's very small. And for the most part, some of the challenges we see are a few states have recently gone to where they're doing furloughs. There's a lot of cutbacks.

BRS has taken a proactive approach and working and trying to get things with the applicants that we know might have -- the case in some of these states that are being furloughed, to be proactive in working through some of these challenges that the economy has kind of brought forward.

But for the most part, I think that the program is really -- through the ability of the utility that ePermits offers us and to really expedite that state process a lot better, we've done remarkable in those areas. I would say that there's less than probably 2 to 3 percent and a lot of those have unique circumstances around them.

MR. COURSEY: Was there another question over here? Anyone else?

MR. CORDTS: I'll pass you along to Tom.

MR. COURSEY: Okay.

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Now, Tom Sim will talk about planting reports.

MR. SIM: Good morning. I'm glad you're here. I just wanted to visit with you a little bit this morning about some modifications or improvements -- we hope they're improvements -- relating to the notification and planting report process.

One of the things we try to do in our program is to do a continual improvement process, and this particular issue had not been visited for a while. Some of the discoveries we made in looking at this particular process was the last direct communication with the regulated community was in January of 2005. So we were coming up on almost five years now since

that last communication.
This particular issue was also identified in the 2005 audit performed by the Office of the Inspector General. They made several recommendations to us about this particular issue and we've tried to address all those and reach a management decision with the OIG.
Another factor, Lee talked to you about the ePermits deployment and that's been something that we've tried to take into consideration. And last but

not least, the submission of these reports is actually a regulatory requirement, as stated in the biotechnology regulations.
This is found in 7 CFR 340.3. We don't need to cite all the language right now, but the three items that are required through that part of the regulations are the location, date and the area of the planting.
Now, this information supports three functions that BRS performs. One is the risk assessment. The second one is that we use that to verify compliance. And the third one that we don't often have to deal with, fortunately, is that of incident response. If there is a weather event or some other thing that's happened to that plot or near that plot, we really need to know that so we can perform any mitigation actions that may be necessary.
Now, in the notification process, there's two phases of the information submission. One is when you submit your notification. This is the first phase, and this one defines the outer boundaries, which contain the actual planting. Also, with that, define the maximum area that will be contained with that planting

and then the estimated release period. Then subsequent to the acknowledgement, more specific site data is needed for the actual planting. And this gives us the specific location, which must be within that acknowledged boundary, the size of the planting, and the actual planting date.
Again, some of the things to fulfill the requirements of the regs that define that, we need to know where it is and there are various ways that people have done that, usually through GPS coordinates. Over the years, people have used a wide range of methods to report that to us, including a legal description in a township or any section numbers, and those are always difficult to deal with if you don't have the right plant maps to use when we're looking for those; and, the size of the planting in acres and the actual date.
These have trickled in. Most of the reports have come in in fairly good order. Some people get a little slow. So what we like to do is revisit the "when" part of this and have the report to be due no later than the end of the month following the month in which the planting occurred.

For example, if these were due at the end of the month -- let's say in April you make a planting on April 29th and you don't have the information to send to us at that time, then that planting should be reported on the May report at the end of May.
The next slide here describes a little bit about what Lee talked about. The ePermits reporting

module is something that we've tried to take into account in this review so that this information is consistent with the module.

The elements that are listed here are kind of a hybrid based on information from current planting reports that people include, what the ePermits module looks like, and some discussions we've had with internal staff and external customers as well.

So quickly, the notification number is obvious and then the state/county is obvious. The unique ID that Lee talked about is mentioned. The plot name or ID, this is one that you can use if it applies to your situation. We have planting reports come in from some folks in industry that have a name associated with a particular planting. We don't want to cut that off if

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people are still using that, but I don't believe this is included in the reporting module of ePermits. So in this transition year, we will still accept that if people would like to send that in.

This listing completes the list of latitude and longitude coordinates that Lee mentioned and then whether or not the planting occurred. This is one that the Office of the Inspector General was concerned about.

To reach a management decision with them on this particular point, we need to know -- if you've told us you're going to plant something and you actually don't, we need to know that. Then, of course, the planting date, the acreage. Then something else that's up to the discretion of the submitter is some folks like to put down the actual contact information for the cooperator at the site. If your institution would rather have another contact person within the company, that would be certainly fine.

Over the years, we have received these reports in any number of ways. Some people send them in electronically. Some people send them in with quite

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large stacks of paper. Others send them in via e-mail. It's been very difficult for us to manage all these different types of information formats and submissions.

So I think what we'd like to do this year in this transition year to ePermits is to try to get these in electronic format. If we could work with you on that, we would greatly appreciate it. We prefer some type of spreadsheet format and we could talk about the details if we have time. If we don't have time, I'd be glad to visit with you offline about that.

If you could submit those either through e-mail or on a compact disk, it would be greatly appreciated. This will assist our staff in processing the information and getting assignments out through ePermits to the PPQ inspectors in a more timely manner.

We sent out a memo late last week that has some more additional details on this. And since this is a regulatory requirement, I guess I'd be a little remiss if I didn't mention the final two points on the slide here, that failure to provide these reports is going to be considered an alleged violation, and then enforcement action will be initiated upon discovery.

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That concludes the slides and I'll try to

answer your questions.
MR. COURSEY: Questions, folks?
MR. MUNDELL: Scott Mundell with Pioneer Hi-Bred at DuPont.
Tom, you mentioned submitting the reports electronically. We don't currently do that and I know others are doing it.
A couple of points that I think immediately come to my mind and may come to the minds of others who aren't currently doing that. One is confidential business information. You say, also, about a spreadsheet and the editability potentially of a spreadsheet.
Can you speak to how you might suggest handling those two issues and/or how they might have already handle them?
MR. SIM: Sure. A couple ideas we've had is that on that editability, I guess what we would like to do, or suggest anyway, is that if you want to send in a paper copy or even a PDF file, those can't be easily changed, as the official record and then submit a

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companion document in a spreadsheet format or some type of table that we can extract the information as part of our processing. That would expedite that process quite a bit. If you want to submit a CBI-deleted version, that would be entirely fine, too.
There may be other ideas that we haven't even thought about, but those are the two that we've considered. If you have others, we'd certainly be willing to talk to you about that.
MS. ECK: I'm Cindy Eck and I'm a document control officer with BRS. What I've been doing lately is asking folks who are submitting their planning reports to send me a CBI-deleted -- or CBI version, CBI deleted version, and then in a separate FedEx, send me their password where they protected the document, so then I can go in and open the document and resave it. So if that helps, have two separate mailings.
MR. COURSEY: Other questions?
MS. FITZPATRICK: Cindy, this is Sharie Fitzpatrick, Forage Genetics. When you talk about saving a document as a CBI, are you comfortable with all fields in the document being CBI? Because,

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generally speaking, we kind of alternate between CBI and non-CBI within the information provided.
Are you comfortable just going all CBI for a document?
MS. ECK: Just realize that the county and the state, of course, have to be released, but anything else, exact locations, we would consider that CBI. We would agree with that.
MR. COURSEY: Steve, did you want to respond?
MR. BENNETT: Yes. I wanted to clarify something. I just want to make sure we're all on the same page as far as when we talk about submitting the reports via e-mail, people are uncomfortable with that because of the CBI and the sensitivity around that.
When we say we would like it electronically, most people traditionally send in hard copy formats of their planting reports. Our preferred method would be to have that on a CD or some form of removable media as

opposed to the hard copy.
So I just wanted to make sure we clarify that, because when we get the hard copies in, we have to convert them to electronic formats to get them

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associated with the appropriate files within the ePermit system. When we receive them electronically, it makes the process a lot easier internally and I would think that might be easier for you all, also, so you're not going through the expense of having to print out hundreds and hundreds of pages of reports and, also, the mailing that's associated with those. There might be a cost savings on your end as well.
MR. LEE: David Lee from Edenspace. Just a quick clarification about the information requirement.
You mentioned that you'd like to get a yes/no answer on whether or not a certain rotation was planted. Do you mean by that the level of detail as to each construct that was included in the notification? Because quite often, we list all the potential constructs that might be present, and when the season comes around, we might not actually plant --
MR. SIM: Yes, that's a good question. I don't know if we've talked about, on our staff anyway, the individual constructs. Maybe we could kick that around.
MR. HANDLEY: No. Just the site.

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MR. SIM: Just the site would be fine.
MR. REDENBAUGH: I'm Keith Redenbaugh from Arcadia Biosciences.
Upon receipt of the reports, what is the process that BRS uses in reviewing or evaluating reports? Are you looking for completeness? Are you doing sort of an analysis or data mining of the reports? What happens to them?
MR. SIM: Well, the completeness is checked and then it's mostly used in part of our inspection selection process. So we're trying to revise that process as well. We have a system that's been around for a while, an internal system called BIDS, which was kind of a precursor to ePermits. Well, that system can't be supported any longer. So now we're transitioning to ePermits. But mostly the information is used to help us in the selection of sites for inspection.
MS. BUEHNER: Gina Buehner with Dow AgroSciences.
Would you require a site or a location to be reported only once? So if you have multiple plantings

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at a single release site --
MR. SIM: One of the issues that we had to deal with with the inspector general was knowing where all the plantings were. So each time you make a new planting, even if it's in a previously reported site, we'd like to have that information.
MS. BUEHNER: Okay. Is that going to interfere with the Unique Location ID then?
MR. SIM: That's a good question. No.
MR. HANDLEY: When ePermits gets implemented, that won't be an issue, because you'll be able to submit local planting reports for each unique location.

Often, people plant five, six, seven times, particularly the people planting perennials in an individual location, so there won't be a limit
So I guess you're asking prior to that, you're asking Tom if he wants multiple planting reports and I think the answer is yes. You would just send in another CD.
MR. SIM: Correct, yes.
MS. BUEHNER: Okay. I'm trying to get this straight as far as you would have to then -- on your

notification application, you would have to record each individual intended planting at that site?
MR. SIM: I don't think so. You put in the dates that you are going to have this activity occurring and that's going to be a date span, and then each planting within that would be separate.
MS. BUEHNER: I know, Lee, you were shaking your head no.
MR. HANDLEY: You're asking on the application?
MS. BUEHNER: Correct.
MR. HANDLEY: You need to indicate you're going to have multiple plantings.
MS. BUEHNER: That's correct, but you wouldn't have to identify each individual location ID.
MR. HANDLEY: No, within the ID.
MR. COURSEY: Lee, the microphone is working up there.
Tom, if you could step a little closer to the mic, that would be great.
MR. HANDLEY: So within the ID, you only need to indicate how many times you are planting.

Does that answer your question?
MS. BUEHNER: Well, I'm just trying to understand how it's going to link when we actually submit the electronic planting report, because it's going off that Unique Location ID and we have several locations within that report, at that site. We may plant it and have the planting dates throughout the season.
MR. HANDLEY: Right, that's fine. It'll work. Once you see the design, I think it'll become a lot clearer.
MS. BUEHNER: Okay. Thank you.
MR. COURSEY: There's a question right here.
MR. PEARSON: Les Pearson with ArborGen. To your point, Gina, we do have perennial permits. So for a particular site, we would plant multiple times over several years and each time we do that, we submit a planting report. We use the same site ID. Internally, we have different experiment IDs, and then every time we plant at that site, we submit a planting report with respect to that planting location or ID.
But I just wanted to question as well -- so

because we do have perennial permits that lasts four or three years, the yes/no planting question can still raise some issues because we may not plant the first two years, and that's something I think we still need to work with you guys on, getting information to the inspectors so we're not having to explain that we

haven't planted that site yet; we may plant it two years from now. So that's just a little quirk around the yes/no question with respect to multiyear permits.

MR. SIM: That's a good point, Les. I think, if I remember the OIG concerns, it was with notifications. So you may be okay, but we'll look into that. Thank you.

MR. COURSEY: Just to remind the speakers, please identify yourself. This helps the court reporter. Thank you.

MR. GUYER: Dave Guyer with Syngenta. I'm sorry, but just to follow-up on this planting issue.

I know you do, but just take into account when you're requesting of us this information that at some of our sites, we could plant for weeks, many events every day for weeks, and providing that information on

a daily basis, so to speak, could get pretty burdensome.

Just one other question. I've seen a document recently, Tom, I believe that is kind of requesting of the permittees some additional report information for these monthly reports as we transition or prior to ePermits being rolled out.

What is the status of that document and what opportunity will the permittees and the stakeholders have to comment on that?

MR. SIM: Well, the document itself that you may be referring to went out last week. It contained the very elements I went through just a moment ago. So we had input from external customers, internal staff.

So if there are some things that need adjustment after you look at that memo, now is the time to interact with us because we may be able to make some more adjustments as needed before the planting season gets going and harvest. So we'd be more than willing to visit with you about that.

MR. GUYER: Okay. Thanks, Tom.

MR. COURSEY: Question over here?

MR. MUNDELL: Scott Mundell with DuPont. I just want to kind of reiterate what I think the other table over here is saying around these planting dates. I think you, as the agency, really want to think about what you're asking because I would say the same thing that Dave said.

We've got multiple sites where we're planting every day for a month. I don't think that's the data that you're asking for. But if I translate what you're saying into reality, that's how I would translate it. We would be reporting every day that something went in the ground at a given site because it's a different planting date; it's a different planting. Just knowing you guys, I have trouble believing that's really what you want to see, because that's a whole lot of data.

MR. SIM: That's a lot of data, but that's what we told the OIG we're going to implement.

MS. DEATHERAGE: Claudette Deatherage, Monsanto.

Tom, another question that comes up in my mind is you're asking for no plant information. So plants change. You're in the season and what may be a no

plant and intended, and, really, thought to be a no plant early on gets planted later. And so, in our mind, we want to tell you when we're sure.

So what is the timing on that that you're requiring or how does that work? Can we then change it? Is it in flux or not?

MR. SIM: The data that would come in on the monthly report is what you know at that time, and it's always subject to change. So if you have decided you're not going to plant at a site and you tell us no, and then the next month or at some point in the future, you decide that you do, just include that in that month's report and that would be fine.

MS. DEATHERAGE: I guess I just have to ask for this clarification. Are you saying that it is a compliance infraction or a compliance incident, whatever you want to call it, for not reporting a planting or are you saying that it's an incident for not reporting within that timeline that you designated on that letter?

MR. SIM: Well, kind of both. If we don't get a report and there's activity going on that we don't

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know about, then that's a violation. The letter details the timelines in there and that's going to be our yardstick.

MS. DEATHERAGE: You know that's a challenge. It's very difficult. Of course, we tell you those as soon as we have them and we process them through, but that's a very difficult timeline.

MR. SIM: That's why we built in some flexibility in that submission.

MS. ARIAS: Diana Arias from BASF Plant Science.

Coming back to the last question, what is the position for planting? Because within a month, my understanding was that when you plant within that month, it is the same notation; that is a planting.

So are you supposed to report in every single day activity or is it within that month?

MR. SIM: You can wait until the end of the month to give us all the activity for a particular month. That would be the activity that you know about. Like I said in my example, if you have a planting on April 29th and you turn the report in on April 30th,

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you may not have time to get that information in the report, and it's perfectly fine to submit that information before the end of May.

Okay. Did that help?

MR. COURSEY: We've got a clarification back here.

MR. GRANT: Tom, I'm Doug Grant with BRS Plants, Inspection Branch. On the sites that are not planted, I'm just trying to get clarification that I think might help our applicants and myself as well.

When we're talking about whether or not a planting has occurred, that information comes to us from some applicants, because when they submit the planting report, they're including all of the sites that were listed underneath that permit application or notification, and they are telling us, okay, these locations were planted on these dates, but these other

locations have not occurred.
But if no planting occurs under a given notification, there is no reason for them to give us a planting report, right? So we're not expecting them to tell us when nothing has occurred under a notification.

We're just saying tell us when you have planted under that notification.
MR. SIM: Well, again, I need to go back and see what the OIG said, but they wanted us to know when things were not planted. So it could be after you've told us you are and you change your mind. So we'll have to follow-up on that.
MR. COURSEY: One more question here.
MR. MUNDELL: Scott Mundell, DuPont. I don't want to try to beat this to death, but I want to be clear on something.
So what I heard is that you want and have told OIG that you want every planting date at a given site reported, and I understand the timeframe.
Would you say that failure to report every single planting date and instead rolling that up into one planting date, the first planting date of a month -- so you've got two options. You've got the concept I think that's being put forth here of I'm reporting every planting date, April 4th, April 5th, April 6th separately on my monthly report, and I've got the concept of my first planting date was April 4th and

I report that date as the planting date, and then all of the acreage for the entire month, and that's one entry at that site.
Is the second version, where I have one entry, would you see that as a compliance violation?
MR. SIM: That's not how I understand what the OIG expected, so I guess that would be a yes.
MR. HANDLEY: Scott, the way it's going to work at ePermits is there will be a planting start date and a planting end date. So in that case, you could roll up all the plantings that occurred within those days at that site, because that's the way it's going to work in ePermits.
MR. SIM: Right. If that's what's designed for ePermits, then that will work for this interim as well.
MR. COURSEY: Quick question back here.
MS. FITZPATRICK: Sharie Fitzpatrick with Forage Genetics. I do work with a number of perennial permits for three years and I understand the need to know about the plantings. I've also been using the planting monthly packing report to tell you when I

terminated studies, so that the acreage count comes down to the actual in the ground as of that date.
Is that appropriate?
Then is OGC also concerned about sort of trying to tally up actual acres? If all you get is planting and you never get terminations, you can never really pull those targets off your GPS map.
So how can we deal with terminations effectively?
MR. SIM: Well, again, you're dealing with permits and I think that's fine. This only deals with

notifications. So the way you're doing the permits is fine.
MR. COURSEY: Anyone else? Other questions?
MR. GREGOIRE: Thank you, Jerry.
I just want to emphasize the key principle here is that we have a responsibility and an affirmative duty, because we're providing regulatory oversight, to know what is planted out there.
In other words, the shortcomings that were identified by the IG, that is a principle that is not up for negotiation. Now, how we execute and implement

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that and deal with it in a way that's practical and doable, we're open to suggestions. But the bottom line is because things are under our regulatory oversight, we need to know what's out there and what is planted. I just wanted to emphasize that. Thank you.
MR. COURSEY: All right. Any other questions? If not, folks, why don't we take a break and be back here at 10:15? The cafeteria is out the door to your right. We'll all come back at 10:15. Thanks.
(Whereupon, a recess was taken.)
MR. COURSEY: Okay. Thanks for coming back.
Let me give you a little preview of the group process for this session and the next two after lunch. Now, there will be presentations for about the first 15 minutes, and then we will take clarifying questions from the floor about the presentation.
Then we will get you into groups, where you are now, your table groups, and for 30 minutes you will work with your groups on answering the questions that you have in your packets, BRS questions.
I think for this petition process improvement case, there are basically four questions, and you can

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manage that as you want. What we're asking for is after your 30 minutes of discussion, that you report out to the whole group one to two key points or issues that your table feels strongly about.
Again, as Anne said earlier today, you don't have to reach consensus. They can be totally different issues. If you can't come to some agreement on a couple, just share three or four. But we have to get reporting done in about two to three minutes, because we have so many tables, and we want to hear from everybody.
Let me introduce the folks who are doing the petition process improvements. First, we have Michael Watson, who is the director of Environmental Risk Analysis Programs, and, also, Sid Abel, who is the assistant deputy administrator of BRS.
So, Michael and Sid?
MR. WATSON: Good morning, everyone. One thing I'd like to point out on this slide is, as you can see probably from our titles, Sid is my boss. So just keep in mind that if there are any tough questions at the end, you can direct them to him.

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[Laughter.]
MR. WATSON: What I want to do here is -- there are three different areas -- I want to give you a really brief overview of the petition process, which will start with this slide; then talk a little bit

about some of the issues that affect the efficiency of the review process; and, then, finally, give you a little idea of some of the steps we're taking to try to improve the efficiency of the process. Then, finally, we'll, as Jerry said, turn over the floor to you-all to discuss the three questions at the tables.

This is just a general overview of the petition process. It doesn't include very step and I don't plan on going into detail about every step. I just want to give you an idea of how the process looks overall.

Essentially, when a petition is received, we have a number of administrative steps, ensuring completeness, that all the information is there, those kinds of things. Then we put together a petition review team. This team can be anywhere between two and five people, depending on the complexity of the

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product, workload, those kinds of things.

The first task for this petition review team is to assess whether or not the data submitted in the petition is sufficient. Generally, we don't get petitions that are 100 percent sufficient initially. So we do develop what's called a deficiency letter or a letter of completeness.

This step right here can be an iterative process. It could take a very short time or take a long time, depending on what kind of data or information is missing. Sometimes it's just clarification of some of the information presented in the petition. Sometimes it's additional data that's necessary. So, again, the length of time that this process would take can vary depending on the submission and the complexity of the project.

Once we have received a completed petition, the next step for the petition review team is to develop a plant pest risk assessment. This is under our regulations at 7 CFR 340.6.

Here, we're looking to see if the organism is potentially a plant pest. After that determination has

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been made, assuming it's not a plant pest, the review team moves on to develop a draft environmental assessment. The idea here is to fulfill our obligations under NEPA. This looks at any potential impacts on the human environment.

Once these two documents are completed, the petition that's submitted by the applicant, along with the risk assessment and the draft environmental assessment, are put out for a 60-day comment period. This is an opportunity for the public to comment on the analysis that we have done and also the completeness or the information presented in the petition.

Once the comment period closes, we develop what's called a response to comments. In this document, we respond to each unique comment that's provided by the public.

I should say this. When we get comments from the public, we may revise our EA, depending on comments we receive. If there's something that we should amend or change or no information is provided, we will develop a final EA that contains information provided by the public.

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Assuming that we can reach a finding of no significant impact in the EA and there's no plant pest risk, this is when we can make a decision to deregulate the product. If we cannot reach a finding of no significant impact, we may have to move to an environmental impact statement. Again, that would then feed into our decision of whether or not to deregulate.

So we've heard concerns from our stakeholders about the efficiency of our process and we've also been looking at our process ourselves. So looking at the process, we've identified both internal and external factors that have affected this efficiency of the review process.

So when we look at the internal factors, we've had a significant increase of pending petitions over the last few years. If you look at the last year or so, it's been pretty steady about 17 to 18 petitions that are pending at one time. As we get one or two done, we get a few more in. So it's been pretty constant at that number, about 18.

This is in contrast to, say, three or four years ago, we might have had five or six pending at one

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time. So it's been a significant increase in the number of petitions that are pending.

We have also seen an increase in the complexity of our review process. One of the things that we've done -- in the previous slide, I showed you that we do a risk assessment separate from a NEPA document.

Up until a year ago, these two steps were combined into one document, so the NEPA document contained risk assessment. Now, we're breaking these two review analyses apart. So with any new process, of course, it takes time to make sure that your process is as efficient as possible. So, again, this has only been going on for about a year now and you've seen a couple of these documents out for public comment, but we haven't finalized any of these petitions yet. We have separated the risk assessment from the NEPA document, but you should be seeing those soon. But we are looking to improve that process and make it more streamlined.

Another thing is competing demands for our staff time. We have lawsuits, we have rural banking,

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we have other program delivery issues to deal with, you have notifications and permits. So staff's time is very -- the number of staff is limited and there's a lot of different things competing for the time. So that also affects our internal efficiency in terms of getting these petitions done. And staff shortages; we are in the process of increasing our staff, but we haven't kept up with the increase in workload. So it's coming, but it just hasn't happened yet.

When you look at external factors, of course, the first bullet, increased number of submissions is related to the previous line, where it says "pending submissions". So we have seen an increased number of submissions over the last few years and, as I said, with the competing interests, it's been difficult to keep up with them, but hopefully we're getting a better

handle on that as we move on.
We are seeing an increased complexity of submissions, whether it be stock trades, new or novel trades, new crops. Those all affect the ability for us to move through quickly. It's not just for risk high tolerant corn or herbicide tolerant soybean anymore.

It's a bunch of new things that are coming along. So that, of course, increases our review time.
We've also seen a very large increase in the number and content of public comments. Again, if you go back a few years, we may have received tens of comments. Now we receive thousands of comments for each petition. So, again, we have to respond to each unique comment that is received from the public. So it takes some amount of time to do that. That increases the overall time.
We also do see variable data package quality. I mentioned at the beginning the iterative process going back and forth with the applicant in terms of getting a completed petition. It could take a week, it could take a year in some cases. So that affects our pending petitions and the amount of time and, if need be, the effort to get through these documents.
So what are we doing to try to improve the process, our efficiency internally? I mentioned that we are increasing our staff numbers. So we have five new biotechnologists who we're bringing on staff. They should all be on staff by hopefully the first week in

January. So that will help us in terms of the risk assessment and the environmental assessment side. We're also bringing on two policy analysts in a policy position. That will also help us with our efficiency.
One of the things that's happening, also, is the creation of a NEPA team. We're going to have a team of folks who focus on NEPA analyses also housed in our risk analysis division, and their job will be, again, to focus on people to be trained and, theoretically, that's a person in NEPA. That will take the NEPA part of the analysis away from the risk assessors. So the risk assessors can then focus on the risk analysis. The NEPA team can focus on NEPA. That will, again, help streamline our process a little bit.
I did mention that we were now separating the risk assessments from the NEPA documents. So, again, it's only been a year since we've done that. We've only done a few of those. We're trying to make that process more streamlined and more efficient.
One of the things we're doing both internally and also to help our stakeholders is to develop models for our risk assessments and for our NEPA documents.

We figure if we can develop these models that we can put out so everybody can see, it will help us internally, so we're all doing things consistently internally. But, also, it helps you in terms of what you submit to us in your petition. So that when we get the information from you, it's not too little, it's not too much. It's basically what we really need to perform our assessments internally.
Neil Hoffman is going to talk after lunch about a pilot project to examine third-party

contracting. Again, this is to help with the NEPA side of things, to see if the third-party contracting might help reduce the timeframe, improve efficiency and those kinds of things in terms of reviewing our petitions.

We're also, we have been for a while, encouraging more pre-meetings with our applicants to, again, ensure that the information we're receiving from the stakeholders or from our applicants is really what we need, because, again, we do get -- in some cases, we get much more information than we actually need to do the assessment. But whatever we get, we review and we have to do that.

So if we actually get information that's more relevant to what we really need for our assessments, that will really help streamline the process a little bit also.

So I'm going to stop there in terms of the presentation and see if there are any questions you might have about that. Then the next step will be for you all to address the questions there on the screen at each table.

MR. COURSEY: Questions?

MR. ZEPH: Larry Zeph, Syngenta.

Are those models far enough along that you could share those in pre-submission meetings with us, give us some guidance, or is that still to be determined?

MR. WATSON: It's to be determined. We need some more time. What we're trying to do is get our NEPA team in place so the NEPA team can actually work on that side of things and our risk assessment team -- we are working on the risk assessment model and we're pretty far along, but I don't think we're to the point yet where we can say this is exactly where we want to go. But I would say it won't be too long in the future until we reach that point, hopefully sooner rather than later, for sure.

MR. COURSEY: Other questions?

All right. We are going to start then the group process. Let me remind you of a couple things and then see if you have questions.

Each group has a flipchart. They're probably on the side of the wall. You've got a packet of markers on your table in the middle. What I'm going to suggest, because the tables are big and it's hard to hear in here, is that you move the flipchart toward the back of the table, right in the middle.

Let me give you an example. For this table here, it would go right here in the middle, facing this way, so people could see. Most people can see and hear a little better in the middle.

We're looking for a volunteer at the table to keep notes on the flipcharts as you go through the questions. That's important. We're also looking for someone to report out after 25 to 30 minutes.

One more quick thing. Remember you have a BRS staff person at the table. They're not involved in the discussion, but they can help answer technical questions and they may make some suggestions about process. Again, it's important that everybody get an

opportunity to weigh in on certain things.
Let me see if you have any questions about the next step here. Some of the BRS people can help move the flipcharts around for you over here.
Now, the report-out, folks, real quick, we are looking, as I said earlier, for two important things that your group came up with, and what we don't want to see is a lot of redundancy. If another group said it, you can say, yes, we agree with that group and move on. These are new things. So that's important.
So Anne and I will be around and the BRS folks will be around, also, if you have questions. Thank you.
(Whereupon, a breakout session occurred from 10:32: a.m. to 11:04 a.m.)
MR. COURSEY: All right, folks. I'm going to move into the sharing of the highlights. Now, if you can help me out, as this group has done over here, if

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you could move your flipchart back towards the wall, out of the aisle there. Thank you.
You all have your presenters and everything? You might want to volunteer some people right now. Thanks for the work you're doing. Two quick things I want to remind you of. There's a BRS staff person at the table with you who is taking notes, that's going to be documentation. We're also going to take these flipchart notes; that is going to be documentation. Just to let you know, if you don't get to all your issues, we're going to have full discussion.
So why don't we do this? We go one, two, and we'll go back and forth here. We've got seven groups.
So group number 1 here, you have your spokesperson? Again, the highlights, things that were important to you as a group.
MR. RUCKERT: I'm the spokesperson for group one. In any event, these are issues that we talked about -- Ed Ruckert with McDermott, Will & Emery.
The first issue was -- and I think this is sort of a common theme we had expressed throughout the discussion, is the need for greater clarity from the

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agency regarding the information the agency needs to make any sort of decision. That seemed to be, again, a central theme.
More information, greater clarity from the agency helps the petitioner do whatever they need to do, so they put things into format, because everybody wants to get their issue addressed quickly and efficiently. So the more the agency can do on that, the better.
Then that leads into -- we were talking, in order to try and achieve that, one of the things that's not within the regulations as expressly or as boldly as it should be is communication. So you want to be communicating more with the staff.
What we're finding out or what was being observed is there aren't enough staff to handle the increased activity. So to the extent you're trying to accomplish something, you need to get on the agency's task guard (ph), whoever the agency representative is. And there's a lot of people trying to get on that same task guard.

So that is a timing problem. It delays
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activity or action on whatever the request is that's being made to the agency. So it was sort of a plea for increasing staff. I understand that is something that's underway and also is done or addressed at some higher levels inside the agency, but it's a common theme.

What was also being noted was we needed sort of an increased efficiency in the involvement of other agencies. Fish and Wildlife Service, for example, is becoming much more involved in this process. How do they become involved? What are the standards they're going to use in that involvement? What kind of information needs to be put together? What are the timelines that are going to be involved? And then, what does the agency do with the information once it gets it? All that needs, we think, some greater clarity.

Again, better communication, another common theme, as early as possible in the system, knowing who those people are. One of the things we talked about was would it make sense for the agency, for example, to have on its website, for different particular areas,
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specific individuals identified. Then it was pointed out that perhaps the better system than the one that they use now is typing your question and then it's routed to whoever. Maybe that's a better approach; I don't know, but at least this was teed up.

Again, as part of the issue about the efficiency, the agency must articulate to the EA and EIS decision process. People do want greater clarity about that because, again, it's a hurdle. It's something that people have to get over, and when you have to get over something, it takes time. And the more you become efficient in the process of meeting the agency's needs, the quicker you can get whatever request you want accomplished.

This last one, this was an interesting one. We spent a fair amount of time on this at the end. The question was, on a going-forward basis, there are certain traits, for example, in the pipeline, and is the current statutory authority sufficient to allow a full examination of those traits.

One of the questions was should that be a role for BRS, is that something they should even be involved
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in.

So, Jim, I think on this one, I will turn it over to the person who was making the point, if you want to explain it a little further.

MR. BAIR: Jim Bair, North American Millers' Association.

I think you did fine, Ed. I know this was discussed last spring at the last stakeholder meeting and I put it on there because I think it's an ongoing question.

There are a lot of new traits coming out. What I've heard from BRS staff in the past is the current system, which is sort of cobbled together, those are my words, has worked pretty well over the last 10 or 12 years. The question is, is it going to

be sufficient going forward.
The traits that have come to market so far have been first generation traits. They've been fairly straightforward. So maybe the current policy has worked well so far. So I put that on there, saying, oh, by the way, we discussed this in the spring. It's a continuing issue, and in another 10 years, will we be
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looking back at this and saying that, yes, in fact, the old policies, the old authorities have worked well or maybe they won't. Maybe we won't be saying that.
I think that given the pig through the python that's coming toward the agency, I think it would be a much easier -- not easy -- easier task to address that question now than to wait even a couple of years when you're confronted by lots of new and novel traits. I think that would be a really hard time to address that. It would be better to do it now.
MR. COURSEY: Great, thanks. Thank you, Group 1. Let's go over to Group 2 here, please.
MR. WACH: Michael Wach, Bio.
I don't think too many of these are brand new. So speed was a major concern. Particularly, the timelines, that you know reasonably certain when you provide your materials to the agency, that you're going to get seen at a certain relatively reasonable period of time.
The other group talked about communications. We specifically were interested in clarity and guidance as to data required for the environmental risk
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assessment and the NEPA, those concerns.
For crops improvement, viable planting, clearly separate the plant pest risk assessment from NEPA. I think that was already talked about by Mike. But in addition to that, it must be adequately staffed to work.
Then development of models for datasets provide guidance for those who don't know how to handle this. So there was a discussion for improving the process for people who don't have a lot of experience with the process, and one was to provide some clear models or datasets that a lot of people can structure their data on. That would be non-prescriptive; if you already have a successful way of preparing the data for a petition, that the model does not conflict with those.
Then for the last question, we didn't actually rank them. We just sort of put down some ideas. The first two are sort of a scoping approach to public comment. That is, put it out for public comment when the product is still in the field trial stage, later when the petition is first filed, and then the purpose
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of that and why we called that scoping was it gives the developer some clear ideas of the challenges that they are going to face as they move through the process further.
Then currently, we noted that when the petition is being completed is when it goes out. Then there was another suggestion or an idea, and that is to decouple comments on the plant pest risk assessment from those that are coming in on the NEPA documents.

So either set them as separate comment periods. In some way clearly differentiate for the public that their comments are addressed in two separate documents. But we didn't rank these. We just put them up as ideas.

MR. COURSEY: Okay. Thanks.

Any quick questions for clarification on Group 2's list?

All right. Thank you.

How about table three here?

MR. HOWIE: My name is William Howie with BASF. Our table, we didn't really have anybody involved in the petition process. Well, that's not

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true. We had one individual. So we were kind of in limbo here, but we were just kind of gathering ideas from maybe people we talked to in our programs. And we also spent quite a bit of discussion on the first question and not too much on two and three; we didn't get a chance to list.

But what I will say, for the updated petition, it's already kind of been mentioned that it comes through in the theme of communication, of not being aware as regs may change by the time you start your program until the time you make your actual filing, and then it's too late.

But in maybe a pre-meeting time, whichever company has that option to do with BRS, but if someone does have a pre-meeting or something like that, to establish a contact person within BRS to go back to and maybe ask -- requirements could change over the course of the two or three years you're doing field trials. Then either the company or the person can have communication exchange and letting you know what needs to be improved in your application.

The other concern we had was, sort of in

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quotations, bulletproof the NEPA assessment. This sits outside BRS, obviously, and I think it comes back to what was already mentioned, again, communication, the clarity that people need and then making the application, what sort of things could be considered in this whole process that it's going to go through.

I could just comment on the last point, and it's not listed here, but we were going back and forth on the time period when the public should be aware for comment. And we were sort of in discussion of, well, on one hand, it's good to have it all together, one big data package and you do it all at once, but then there were advantages in splitting it up or decoupling, as the other table mentioned. So we didn't really reach a conclusion on what's the best way of doing that.

MR. COURSEY: Okay. Thank you.

Any questions from the other groups, of Group 3? Does anybody have an additional comment over here?

Let's go over here and then we'll come back.

MR. GONZALES: Bob Gonzales from the Noble Foundation. We kind of looked at the three questions kind of in a rough discussion. The primary thing we

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were concerned about was the time the whole process took from the submission until some kind of decision was made.

The key thing that came out, which I thought was kind of interesting, was that the submission part of the process seems to be okay. A lot of that has to do with the pre-submission meeting. They felt as though there was enough guidance and enough information to get everything in and, basically, any roadblock was not because of missing information, which I thought was pretty interesting.

The key is really in knowing what's going on once you've submitted the process, not really good information. There are contact people, but there is not consistent information coming from them. So there appears not to be any guidance from BRS to the individuals as to what kind of information they can give out or even whether or not they know what they can say. So there's a consistency of information that's missing.

We are looking at solutions to that. The submission process is basically a linear process and

once it's divided into the individual themes, each is a case-by-case basis. So each face their own individual roadblocks, and so the time can vary depending on the content of your submission.

The question is what are these roadblocks and is there any kind of predictability based on your submission content as to how long it might take, and that kind of information would be really nice to be able to receive during the process.

A lot of times, they understand that it's going to take a while to get something done, but we'd like to know why it's taking that long. Is it just because of staffing needs? New genes that haven't been seen before, they're going to take a little longer to review. We just need that information so we can relay that to the principal investigators or the project managers. Right now, it's basically, "It's under review, it's under review, it's under review." That's the only information we're getting back.

So these roadblocks in predictability, can this information be documented and provided at the pre-submission meeting so you have some kind of knowledge

in advance that this is going to be a long submission or it could go through really quickly?

Then, again, what is the actual process of review? Are there milestones that are reached during the stages of the review and can those milestones be documented? So if we call in, what's the status of the project, they can give us the milestone. And knowing the milestone, is there any information that we could provide back that would help get through these milestones?

So it goes back to communication. But a lot of it is once it goes into the submission process, where is it, what's happening to it, and this information we need to be able to relay back to the people back home.

MR. COURSEY: Thank you, Group 4.

Any clarifying questions to kind of focus out on their presentation? Anything else on the table from before, anything that needs to be shared? All right.

MR. PEARSON: I'm Les Pearson of ArborGen,

again. We actually found ourselves jumping around trying to answer question 2 at the same time. So as we came up with a concern, we kind of immediately began jumping into some of the steps that could be taken for an improvement process. But a lot of things we've already gone over. So I'll just kind of start on the things we wanted to get back to.

So unpredictability, one of the major concerns. So whether the process takes a year or two years or two and a half years or three years, having some predictability helps develop this plan on how they're bringing that process forward. I guess the group over there mentioned milestones. So we've got the completeness review milestone, but maybe there are other milestones that could be put into the process to allow an applicant to know where they are in the process and how things are moving along there.

Consistency is one of the other concerns that was raised. Are the standards clear? Are the standards changing? So as we talked about how people worked on a petition together, we got lots of examples that BRS had improved in the past. So we have examples out there that we can look at which guide people on what needs to go into a petition. But it seems that as things have changed over the past couple years, perhaps even with the plant pest risk assessment or NEPA assessment, those previous petitions no longer give us good guidance on what needs to be in a petition submission. So one of the things we talked about involving this and the next element was getting some more clear guidance on BRS, and I'll get to that as we get to the next thing.

So I guess all this feeds into reducing the overall process, the time it takes to go through the ePermits. Again, we identified, to help with all of these areas, some better guidance from BRS on what needs to go into a NEPA analysis or a plant pest risk assessment analysis so that the applicant can help to gather that information upfront and submit that.

There was one other thing, but I forgot what it was.

Anybody from the table? Okay. I lost my train of thought, so I guess we'll wrap it up there.

Just one point, but it's important to me. As we're going through looking at how BRS operates, BRS really is the standard for what the rest of the world looks at in terms of bringing things forward through the approval process. It's got a great track record, but all the things that we're seeing in terms of concerns we're raising here and, again, you guys have to be aware that this is something that the rest of the world looks at. And how you resolve these things, I think, will help on the global scale.

MR. COURSEY: All right. Thank you.

Again, checking for questions for clarification. Anyone?

MR. DOLEY: I'm Bill Doley with Bio Development. Our group, there is a timeline thing I'll get to in a little bit, but the main concern is the lack of clear guidelines, where there's examples you

can look at, but there isn't a bullet list of these are the things that are required or these are the questions you need to ask yourself to move ahead. So some kind of template would be helpful, I think, for these kinds of petitions.

There's a lot of discussion about the timelines and the decision being too long. Then we had a solution there that we need to increase the resources

in the agency to make the timelines stay on track.

There is the issue of dependence on other agencies, where other agencies submit some of the information or comments, and they're not bound to timelines, and could it be some way to bind them to the same timeline, that would be helpful. Another concern is that due to the long timelines, some of the documents become obsolete during the process, so that they're not really saying what you want them to say.

Another step that was suggested to improve the process was to have clear outcomes from the pre-petition meeting, so that when you go into a meeting, you have something to go home with that's real clear guidance as far as what to expect, what you need to do, and what to expect with regard to your petition.

The third thing was about when to post, and the suggestion was not to post these petitions for public comment until BRS has exhausted all of their scientific questions, as opposed to posting more of a draft document. So something more of a finished product that gets posed for comments. And I think that's it.

MR. COURSEY: Okay. Thank you.

Again, anything else at the table? Other comments people want to make at the table? Questions for clarification? All right.

Last table?

MR. LEE: David Lee, Edenspace. Unfortunately, no one at our table has gone through the petition process, but we came up with a couple thoughts on what we've observed from outside that might be useful.

One, as everyone mentioned, the timeframe seems to be slowing down and that we want to improve the efficiency of it. So one point that we've noticed was that in a number of cases, the public comment periods for petitions seemed to get reopened and extend the review period.

One way to possibly avoid that is to either announce pre-notice of a petition availability so that the public and interested parties can have a little more preparation time; they schedule their review process before they see the final APHIS documents, or, alternatively, to pre-release somewhat draft petition

documents, possibly once they completed the data requirements stage or at some later stage that could be agreed on.

We were just concerned that there needs to be some established position where the public could at least get an idea of what is going on in the pipeline.

Alternatively, we felt that there was no need for the agency to limit itself to the 60-day time

period, which might not then need to be reopened for a further comment period. So possibly divide the petition process into more of a trait-based system in which more familiar sorts of traits would go under a 60-day comment period and have more of a streamlined public comment period as opposed to newer traits, which aren't as familiar to both the agency and the public, which might have a 90 or a 120-day comment period, with the goal being to avoid having to reopen the comment period later.

Everything else that we've discussed was previously mentioned. It would be nice for new developers to have a clear pathway and to understand what the new requirements are, what the petition

document would be, and to just have an idea of at least the timelines and timeframes.

So if there's anything else that our group wanted to add.

MR. COURSEY: Okay. Thank you. Again, thanks for your work on this. Everybody got right to the point. I think going through the questions was helpful in getting out other points as you went along.

Just a reminder, again, that we're going to take the flipchart notes. We're suggesting, and the BRS staff don't know this yet, but that the BRS staff person at your table type up the flipchart notes.

[Laughter.]

MR. COURSEY: Number one, they've heard the discussion and they're familiar with it; number two, because they have been taking notes, and we thought that would be the best approach. And I think it would be a most accurate approach.

Okay. Mike and Sid, anymore comments?

MR. WATSON: Nothing. We just want to say thanks for all the input. I think it's very helpful for us to hear your thoughts. So thank you very much

for your help with this.

MR. COURSEY: All right. Thank you.

Now, we're going into our next section, which is Mike Gregoire talking with the group about some key BRS updates. Then Michael Watson will do updates, and then we'll take some questions from the floor.

Just a reminder, also, if you haven't registered outside with the registration table, please do that. That's great information for us to have. So just a reminder.

MR. GREGOIRE: Thank you, Jerry. With me up on the stage here is Bev Simmons. Bev is the associate deputy administrator of Biotechnology Regulatory Services, and John Turner is the director of the Policy Coordination Division in BRS.

So what I wanted to do at this part of the agenda is just to provide you with an update on some issues and areas that we've been working on where I know there's a lot of interest. We had some comments in advance of this meeting. Folks asked for updates on these things. I get a lot of questions on the status of these issues.

So I'm going to provide you with updates on some of these things and then we'll open the floor for

questions you might have on these items or other items, and then we'll be breaking for lunch.

The first thing I want to talk about is proposed regulations that would revise the 7 CFR Part 340. We published a proposed rule last October 2008. We extended the comment period a couple of different times. We had five public meetings, I think, in all on the issue. So by the end of June of this last summer, when the comment period closed, we had received 66,000 comments on the proposed rule.

At this point in time, we are working with the new administration policy officials in the new administration to lay out for them the issues that were raised by commenters during the comment period that require some sort of policy decision or some sort of direction to be determined by the Secretary on where he wants to go on these particular issues.

So that process is underway. We don't have a particular timeline to give you on what might happen next. There are a number of rather complex issues.

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Many of these issues were discussed at a public meeting that we had in April of this year and comments we got at that meeting, and that we got subsequent to that meeting in April really reinforced the issues that were highlighted at that April public meeting. And those were around the scope of the regulations; that is, what should be subject to the regulations; the incorporation of the noxious weed authority in the agency's regulatory decisions; the elimination of the notification procedure; and, the regulation of organisms designed to produce pharmaceutical and industrial compounds. So those were some of the key issues that were discussed at the April public meeting for which we got a lot of comments during the public comment period.

So moving from that particular item to the draft environmental impact statement for Roundup Ready alfalfa, we expect that to be published next month, before the end of the calendar year. This is an environmental impact statement that we have prepared following a lawsuit brought against the agency in 2007 that brought Roundup Ready alfalfa back under APHIS

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regulation; had been deregulated in 2005.

The court ordered the agency to prepare an environmental impact statement. We've done that. It will be published in December. We're planning to have a 60-day public comment period on the draft EIS. We're also planning to have one or more public meetings on the draft EIS.

When that is published, we will be letting folks know in a variety of different ways. The Environmental Protection Agency actually will be publishing a Federal Register notice. You will be able to access the document on their website. APHIS will also be putting out an e-mail and a press release to let folks know when this is coming out.

Then the agency will be doing a separate Federal Register notice to let folks know about public meeting dates, locations and times, and so on. So look for that in December.

Moving on to the sugar beet lawsuit, Roundup

Ready sugar beets was deregulated by APHIS in 2005 and there was a suit brought against the agency in that particular case. On September 21st of this year, the court granted the plaintiffs' motion for summary judgment, finding that APHIS is required to prepare an environmental impact statement before approving its deregulation of GE sugar beets.

When the court issued that judgment, at that point in time, they had scheduled a case management conference for the end of October. That has been postponed by the court until early December, and that is a conference during which the judge will discuss with the agency and the plaintiffs the process by which the remedies will be determined in this particular case.

So it's really just a procedural sort of discussion that will take place in early December with the judge in that particular case. I would expect the remedies phase of the case to take several months. At this point in time, the agency is working to prepare for that case management hearing. And there's really not a lot more I can say about the case, other than that is the next key event.

The next item that I just wanted to touch on was the petition for deregulation for amylase corn. We had two comment periods on that. I think we had over 13,000 comments in the first comment period and 50-some additional comments in the second comment period.

We are still working on drafting the response to those comments and we'll be discussing the issues that were raised by the commenters, the agency's proposed response to those comments, and the final decision with senior policy officials within USDA, but there's no particular timeline for that to take place. So that is still a stage where it's undergoing agency review for a decision at this time.

So those are four things that we get a lot of questions on I wanted to bring you up to date on. At this point, I'd be happy to take questions or the panel will be happy to take your questions.

MR. PEARSON: Les Pearson with ArborGen. Your comment about the EIS for alfalfa, you mentioned EPA. I wasn't quite sure I understood where EPA is involved with that.

MR. GREGOIRE: Okay. All federal environmental impact statements are published by the Environmental Protection Agency. They have a centralized website where all federal agency environmental impact statements are published. It's sort of the central clearinghouse. So we work with them and through them to get those documents published.

MR. PEARSON: Okay. Thank you.

MS. SIMMONS: I don't know if this is on. Tell them they're only published on Fridays.

MR. GREGOIRE: Yes. Bev reminded me that EPA only publishes those notices weekly on Fridays. It will be a Friday in December.

It won't be Christmas, whoever said that.

[Laughter.]

MS. FITZPATRICK: The question on that is that

would make it only two Fridays in December. Is there an alternative date chosen when there's two consecutive holidays that follow Fridays?
MR. GREGOIRE: They do it on Thursday.
MS. SIMMONS: Before the Friday. Before the Friday.
MR. GREGOIRE: What is the question?
[Laughter.]
MR. GREGOIRE: You're trying to pin me down to a specific day, aren't you?
MS. FITZPATRICK: No. Let's say there's three Fridays in December that the document could publish on and -- Sharie Fitzpatrick with Forage Genetics. I failed to identify myself.
So I'm just curious that at least into the beginning of December, it's the 25th, and then the next Friday would be the 1st. Does EPA have an alternative day that's allotted to them if the Friday came --
MR. GREGOIRE: I see; if Friday is a holiday. I'm not sure.
MS. SIMMONS: It's Thursday.
MR. GREGOIRE: It's Thursday, I'm told.
MS. FITZPATRICK: It would be Thursday. Great.
MR. GREGOIRE: If Friday is a holiday, they publish on Thursday.
MS. FITZPATRICK: Great.
MR. COURSEY: Other questions?
MR. SCORZA: Ralph Scorza, ARS. I'm curious how the original petitioners in this alfalfa or sugar beet, how are they involved in all these court-related negotiations or suits? Is it just between APHIS or are they involved also in this and require more information, et cetera, et cetera?
MR. GREGOIRE: I think that interveners can have a role in the remedies phase of the case, but the original suit, as I understand it, just deals with the plaintiffs and the government.
MR. COURSEY: Mike, could you speak closer to the microphone, please?
MR. GREGOIRE: Yes.
MR. WENZEL: Bill Wenzel, Farmer to Farmer Campaign. Originally, there were some provisions enacted in the Farm bill that were rolled into the proposed rules we got from administration and oversight of field trials.
Since there's no timeline for the proposed rules, how are you going to deal with those provisions?
MR. GREGOIRE: Well, not all the provisions of the Farm bill require regulatory changes and a number of the Farm bill recommendations reinforced some things that were part of the IG study that was done a few years ago, and we've actually implemented a number of those things already. There are, however, a few things that require regulation changes and the Farm bill doesn't trump, if you will, the need for us to go through the regulatory process, which is prescribed in law.
I expect that the Ag Committee will be asking for some sort of accounting from us over the next few

months on where we stand on all those things. There was an oversight hearing recently, but I think it focused more on other provisions in the Farm bill and not so much on the biotech provisions. But we've done a number of things, to the extent we can, under the existing regulations and authorities that we have.

MR. COURSEY: Other questions? Okay. If not, we will adjourn for lunch. We'll get back together at 1:00. Lunch should be arriving soon. It will be set up in the back of the room and there will be sodas and water in the back. So it should be here momentarily. Thank you.

(Whereupon, a lunch recess was taken at 11:43 a.m.)

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MR. COURSEY: We're ready to start this afternoon's session. Let me invite the new BRS staff people to their tables. We have a new group of BRS staff sitting at the tables this afternoon.

Can the BRS staff people raise their hands?

Let me introduce Neil Hoffman, who is going to do the NEPA implementation presentation. Neil is the special assistant to the deputy administrator.

MR. HOFFMAN: Can you hear me? I can shout real loud.

Well, I hope everybody had a nice lunch and is now nice and sated. I'd like to talk to you about a pilot program that we're implementing for the preparation of EA and EIS.

This is something that's very different, but it's something that we feel gives us an opportunity to address some of the problems that we've been discussing this morning, like timeliness of determinations for petitions and that sort of thing.

So why do we need a pilot program? Well, we've heard numerous times this morning about a

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shortage of resources in our program and we think this is a way of more efficiently using our resources. We've gotten a large increase in the number of petition submissions and we're also now getting permits which require an EA. Actually, we're getting increased numbers of permits which require an EA.

So this slide shows the situation with the petitions. So the open boxes show the pending petitions that we have since 2004. You see for the first five years or so, the numbers are 10 or less. Then from 2008 to 2009, we had a huge increase. So we're up to about 18 pending petitions. If we look at 2010, we're expecting to get another six to eight.

If you look at how many petitions we've completed each year, it fluctuates from about two to four. Even in 2010, if we expect to do about five, which would be better than what we've done in the past five or six years, you see we're still going to see an increase in the number of pending petitions. So what options do we have to address this, to bring that number down a bit, and how can we use our resources more efficiently?

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Well, if one looks at the CEQ regulations for

NEPA implementation -- and CEQ is the Council for Environmental Quality -- there are three opportunities for applicants to contribute to a NEPA analysis.

The first one is one that we do already, and the language says the applicant may provide information for possible use by the agency in preparing an EA or an EIS, and that is done. The applicants submit to us information that we may or may not use.

But there are two other options that we have not utilized and that's what we'd like to try in this pilot. One is to use third-party contracting for the preparation of EAs or EISs. The applicant may hire a contractor to prepare an EA or an EIS using third-party contracting, is what the regulation says. It also has a third clause which says at the discretion of the agency, the applicant may prepare and submit an EA.

There are many other agencies in the government that do these. So this table just lists some of the agents that have NEPA implementing procedures which allow applicants to submit EAs. So the FDA, the FCC, there's another agency in the USDA

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that does this, Department of Energy, Department of Homeland Security. And there are a number of agencies that use third-party contracting, and this table lists those. The FDA, also, USDA Rural Development does that, Department of Energy, the Federal Aviation agency, EPA, DOT, DOI and Army Corps of Engineers. I don't assume this is even exhaustive. This is just what we found with a simple Google search.

So let me just make sure we all understand what third-party contracting is. Third-party contracting is the practice where contactors are paid by the applicant or sponsor, but are selected by the agency. So really the applicant is only contributing money. The contractor is actually working for the agency.

So the contractor is responsible to the Federal Government for preparing the environmental analysis and documentation and meeting all agency requirements. The agency is responsible for the scope and contents of the document and independently reviews and approves the work of the contractor. Really, the only thing the applicant does is pay the cost of the

0107

contractor.

One of the big concerns in this process is ensuring objectivity. With EISs, there are higher standards, and third-party contracting is one where there are more safeguards in place to assure objectivity.

In EAs, there are less requirements. The applicant can use internal staff to prepare the EA or they can directly hire contractors. It's not third-party contracting. It could be done -- an EA could be done by third-party contracting, but they could also do it -- they could hire a contractor directly and, in that case, the contractor is working for the applicant or sponsor.

So the safeguards to ensure objectivity. So regardless of whether it's an applicant-submitted EA or the use of third-party contracting, the document is the property of the agency and that has certain

implications. So one of the things that we want to make sure that you're aware of and to kind of gauge your interest in this pilot, if you're going to hire that contractor and pay for that contractor, you don't

really have any say about what's in that document and that document is really owned by the government.

So just like we post our EAs and make them publicly available, that would still happen. If there are other products that can utilize information in the EA so that we could tier to that EA, that will still happen. So even though you're paying for that document, there's someone else that could potentially profit from it. So that's just something to be aware of. There would still be a public comment period, just like there is now.

I just want to stress the agency responsibilities that help to ensure the objectivity. The agency is responsible for the scope and content of the document. So the document comes in to us. We don't just stamp it and let it go through. It needs to be reviewed and we need to define what the issues are within that document.

The agency is responsible for the accuracy of the contents and independently evaluates the submitted information and the environmental issues. So if the EA does not cover issues deemed by the agency to be

necessary, either the preparer will need to make the necessary revisions or the agency will need to take over.

So this gets to a very important point that there needs to be effective cooperation and communication between all the parties to make it worthwhile. You can imagine if a document just comes to the agency and is not covering the right issues and there is some reluctance on the part of the preparer to make those changes, it could take longer and it really won't be of benefit to either party.

So there's an even higher bar for third-party contracting. I just want to emphasize, I may have said this, that applicants are allowed to submit EAs but they're not allowed to submit EISs. So third-party contracting is the only option for doing an EIS.

In this case, the agency selects the contractor. The agency closely monitors the work of the contractor throughout the review process. There is no direct contact between the applicant and the contractor. Public disclosure of the third-party contracting arrangement is part of the process and the

contractor may not have a financial interest in the outcome of the project.

So what do we anticipate from this pilot? Well, we're going to be evaluating the following to make sure that this happens. This is what we consider essential for a successful pilot; that there will be improved quality of the analysis; that there will be more timely document preparation; and, there will be more efficient use of agency resources. But we're also very interested in hearing what some of your concerns are and what some of the criteria that you think will be important are.

We're still in the phase of looking about how to best implement this and, again, we solicit your input. This pilot would be voluntary. We're considering opening it up to any permit which requires a NEPA document and any petition that's deemed complete.

So you heard this morning from Mike about some reorganization in the environmental risk analysis programs and I'll just kind of show to you visually what we think is going to be happening.

Right now, we have two existing branches, called the Plants Branch and the Plant Protection Branch, and this group will continue to work on the permit and petition review, with the primary focus on the plant pest risk assessment.

A separate group is being formed, and Mike referred to them as this NEPA team, which would be responsible for the NEPA analysis. We envision them to act -- well, if need be, they would write EAs, to act like project managers for the NEPA process. These would be people who have advanced training in NEPA. And we think that acting as project managers, if there's a lot of interest in applicants preparing EAs or using contractors to prepare EAs, that this group will be able to process these documents more rapidly acting as project managers than having to prepare the documents themselves.

Okay. So questions for you to discuss. What advice do you have for the USDA as we move forward with this pilot? Now, some of the things I hope you'll talk about are if you could share with us your interest in participating. If you were to participate, what are your expectations? If you have concerns, what are they and how can we address them?

There are some little even smaller questions, such as should applicants be allowed to see the EA or the EIS before they're made public. Another question is how do you envision creating a system that works for a wide range of stakeholders. We imagine that the companies that have the most money are going to be able to do this with universities, with the ARS. Would others, would smaller companies, feel that they could participate? So we want to know are there certain things that we can do to make this pilot widely accessible?

What criteria should we use to evaluate requests to participate in the pilot? We'd certainly like to make it open to every petition that's deemed complete, for example. We don't really know how many of these we can handle. If we get more than we can handle, how should we prioritize them?

Lastly, what criteria should we use to evaluate the pilot? I mentioned that we're interested in improving the timeliness, improving the quality, improving the efficiency of our resources. What metrics are important to you in evaluating this pilot?

Thank you. I'm happy to take any questions, if there are any.

MS. ROOD: This is Tracy Rood from Pioneer DuPont.

Neil, you didn't mention what the estimated cost might be for an applicant to use a third party contractor.

MR. HOFFMAN: I don't think I know. I think from EAs, we've heard 50 to $100,000, and EISs could be $750,000 and on up, depending on how complex they are. But that's just not having actually dealt with that. And I don't know if there's somebody in the audience who has a better sense of what those costs are.

MS. RISSLER: Jane Rissler, Union of Concerned Scientists. I have two questions.

One, what do you mean by improving the quality of the EAs? And second, for stakeholders who are not submitting petitions or permits, that is, NGOs, for example, do you see any advantages or benefits for them, us?

MR. HOFFMAN: Well, I would hope that the second question, you could give us input about whether you see advantages or disadvantages for yourself. In terms of quality, what we think about, what that means to us is, one, that we improve the scholarship of the documents; that conclusory statements are not made, but that there is more rigor in defending the conclusions that are made. That's one thing.

The other quality, we've had two lawsuits over our EAs and we're 0 for two. So what we're thinking is that maybe we want to see that these documents withstand those legal tests.

MR. COURSEY: Other questions?

MR. SCORZA: Ralph Scorza, ARS.

Neil, having the system work for a wide range of stakeholders and you mentioned universities and government, I'm wondering what are your thoughts -- because, obviously, you all have thought about this. How do you make that system work for these groups, especially if they're working on problems or crops that are really a public concern, let's say, resistance to the base of species or something of that nature?

Have you all thought -- I'm sure you have, but how do you all see that working for these stakeholders that are really working, in many cases, to the public good?

MR. HOFFMAN: Well, I'm hoping that I address that question, though it doesn't stop people from making some other good ideas. We know that there are a number of campuses that have faculty that do this kind of analysis, and to what extent there could be collaboration, that graduate students can do kind of -- if you're in an environmental program, do that kind of an analysis as a project. So that might be a way of increasing -- for companies, for small companies or for universities that don't have a lot of resources, that might be an opportunity.

But hopefully, some other people might -- I'll just throw that one out and maybe there will be some other good ideas, because we really would like to hear from you all about that.

MR. COURSEY: Additional questions before we get into groups?

MR. WENZEL: Bill Wenzel from the Farmer to

Farmer Campaign.
I was wondering. Are you contemplating that you will develop a pool of qualified contractors that will be available for EAs and EISs or when you talked about, on the EAs, that the applicant could just go out and hire a contractor, are you contemplating that that could be anybody?
MR. HOFFMAN: Well, the way other agencies have done it -- so we haven't decided how we'll do it, but other agencies, the applicant or sponsor would do a request for proposals and would solicit contractors for that project, and then the company would come to us with three applicants that they considered their three favorite and we would pick from one of those three.
They can't have any financial -- they have to sign a disclosure that they have no financial conflicts of interest, actually, any conflict of interest with that company. So that's how other agencies have done it.
MR. WENZEL: Will that same process be applied both to EAs and to EISs?
MR. HOFFMAN: Well, for EAs, coming up, that's
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an open question. For EAs, according to the CPQ, they don't need to do third-party contracting. They could write an EA themselves or they could hire a contractor without even using the third-party contracting. We're considering to adopt that, and, in that case, no, they wouldn't need to do that process and the safeguard would be that the agency would be responsible for the scope and the content and would need to independently evaluate all the information.
MR. COURSEY: Any other questions?
Okay. We're going to get ready to go into groups again. Let me remind you about a couple things. You can certainly have the same note-taker, flipchart-taker, and report-out person or you can change it. That's up to the group.
The BRS person is going to listen to the discussion and, as I said earlier, that same BRS person will transcribe the flipcharts, because they're in a group for the discussion and we think they're the best ones to transcribe it.
We're going to have 30 minutes again. We've got the form questions up front. Those are a good
0118
guide.
Any questions before we begin?
Okay. Anne and I and other people will be wandering around. So if you need assistance, let us know.
(Whereupon, a breakout session occurred from 1:25 p.m. to 1:59 p.m.)
MR. COURSEY: Okay, folks. I think we're ready to go. You can move your flipcharts, the back towards the wall.
Anne, let's start over in this corner.
Folks, could we give this group in the back your attention?
MR. DOLEY: I'm Bill Doley from Bio Development. What we talked about was the advice on planning EA pilot system was to identify some kind of minimum standards or qualifications for the

contractors, whether it be those used by the agency or those used by the company, so that everybody would be comfortable using organizations who are going to produce a useful work product.

Then there was some discussion about flexible options; could you do some of it in-house and do some of it with a contractor or have the agency do some with the contractor and do some yourself? So just the idea that there could be flexible models where different components could be done by different parties.

Then there was also a comment to clarify the legality of the system, because it would be a precedenting approach for BRS to be using, so that everyone is comfortable that, in the end, we're using an approach that's legally bound.

Further, as far as a system that works for all stakeholders, the suggestion was to, a little bit like the IR-4, develop some kind of criteria to identify petitions or applicants which would qualify for a funded version of the EA development.

So we have the same problem here that you have with pesticides, in that institutions and universities may not have the money to hire a contractor to develop the EA. So it's not fair to them to get left out of the system because they don't have the funds to favor the contractors; so somehow to level the playing field for everybody that way.

As far as participation in the pilot, nobody thought there was any reason to have criteria, so that it should be open to anyone who wanted to use the system and maybe first-come-first-served. So there's no need for criteria.

Then as far as evaluating the pilot program, the bottom line is that they should be expedited. Are they getting done faster than they were before? So that's one criteria, this timeline and criteria related to that.

The last one, is there an increased rate of decisions being made on the petitions? So would this alleviate the backlog which is currently developing?

Another aspect of it is that even if the EA is contracted out, the other half or the plant pest risk assessment is done internally, it shouldn't become a time-limiting factor so the EAs are all done, but that part is not done. But that gets back to are the petitions being expedited or not.

Also, that the EAs should be scientifically credible so that they withstand legal challenges or whatever challenges people might throw at them, but in the end, they are sound scientific documents.

MR. COURSEY: Okay. Thank you.

Any questions from the floor? Any clarifying questions for this group over here?

Yes, go ahead.

MS. RISSLER: How could an EA be prepared before a risk assessment? It sounds to me like you were saying that there is a possibility the EA could be produced --

MR. DOLEY: The way they explained it to us, in the process of getting the petition -- a petition

for deregulation, there are two different documents produced. Two different documents are produced, one relative to the plant pest risk assessment and the other, the environmental assessment, which are two separate documents, and now they're going to be handled by two separate groups within the agency.

But maybe someone in BRS should comment on that.

MR. HOFFMAN: I think if I understand correctly, Jane was saying how could you do an environmental assessment before you do a plant pest

risk assessment, and I don't think that would be our intention. You would need to complete a plant pest risk assessment before you can do the environmental assessment.

MR. DOLEY: Okay. Thank you.

MR. COURSEY: All right. Thanks.

How about this group right here?

MR. BOTTOMS: Jeff Bottoms with Syngenta. I'm not certain we actually took the first three topics in a separate order, so I'm just going to plough through the notes we made concerning those three different topics.

One thing that we did mention was that we felt there should be some sort of fund to make sure that smaller companies would be able to participate in the program, which would include universities and public researchers.

The other one would be to make sure that the scope of the pilot was very limited so that the pilot could be conducted and then that the feasibility and the merits of the pilot could actually be evaluated prior to making a decision of what happens after the

pilot.

Another thing would be that we thought it would be a good idea to have templates and models, perhaps even checklists, so that the EA and the EIS would realize that there would be a specific set of requirements that had to be satisfied.

Again, back to making sure there was a wide range of participants in the pilot program, everything from larger companies all the way down to the very small companies, as well as any public researchers that were involved.

One thing that was stressed was to make sure it actually represents the population of the petitions and permits that were in the queue and not a forced distribution.

Another point that was brought up is to make sure that the criteria for the pilot covers where the resources are being demanded APHIS/BRS and to somehow target those EAs and EISs that are most demanding on the agency and try to contract those out as much as possible, although there was some disagreement within the group about that approach.

Do keep it voluntary and define clearly the role of the NEPA team so that a better system -- I think it was addressed by the first group -- so it would be very clear and very flexible about what was going to be done by the agency, as well as the

contractors.
Then we actually got back onto a specific question. So evaluate the pilot; metrics; make sure the quality of the documents remain high, if not even higher than what they currently are.
Does it save resources? Does it shorten the petition time, which answers sort of the efficiency question? Does it stand up to public comment challenges, as well as legal challenges? One other point that was addressed was to make sure that new traits, as well as existing types of traits, are part of the pilot.
MR. COURSEY: Okay. Thank you.
Again, any final questions from the group?
MS. COATS: How would you limit the number of participants in the pilot program so that you would look at it or how would you be sure that it was a
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representative sample of all the petitions?
MR. BOTTOMS: I believe the idea was to have a balance in between the number of participants, but not to have that number be so large that the pilot doesn't have an endpoint; to make sure it does have an endpoint so that the pilot could be evaluated appropriately at that endpoint.
MS. DUNIGAN: Please use the microphone. They're not capturing this.
MR. COURSEY: And please identify yourself.
MS. COATS: I'm sorry.
MR. COURSEY: That's okay.
MS. COATS: Isabelle Coats from BAYER Corp. Science. I'm just wondering how you practically would do that.
How would you have one petitioner be in the pilot program and another can't?
MR. HOFFMAN: For example, you could make sure that every company -- if there were too many petitions for us to handle, you could make it so that each company was represented at least once, so that's something simple that you could do, and take others, as
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we have resources for.
MR. COURSEY: Other questions from the floor?
All right. Let's go to the table over here. Thanks.
MR. LA MARTA: Jim La Marta, DSM. The first part, very similar to the first group, we hit one question about the final project; what is the benefit of going to the outsource on the EAs and, if any, what are the risks?
Are we talking about a preselected pool of contractors that would be approved by APHIS or BRS? Is there going to be some kind of a quality program, similar to what the second group had mentioned? Like the USDA has certified laboratories that you can use. How do you ensure quality?
Big question. Are there enough contractors to satisfy the demand? By the looks of the chart that you had put up, you've got quite a backlog. Are there going to be enough contractors to handle that?
How much is this going to help? How much of the EA is responsible for the delayed processing of the petition? Is this a small part of the entire process

or a big part?
What we thought is that the participants should just be volunteers who want to jump into this pilot program and we thought that people who are already have petitions in the queue that are just about to enter the EA phase, maybe they should have first shot at going through this new process.
A couple of questions that we had down on the bottom. Does it truly improve the speed of approval? Will it survive legal challenges? We've already talked lawsuits. In the end, how do you know it works? Well, everybody that's involved, all the participants are happy and it's all about customer satisfaction, I think, in the end. That's it, pretty much.
MR. COURSEY: Okay. Thank you.
Again, comments from the group, clarifying comments?
MR. PEARSON: Les Pearson with ArborGen. I guess I'm going back to this other group here and the idea of saving resources. Maybe one of the criteria to assess how well the pilot program is going, as we talked about going through this and we wanted to do

this to become more efficient than that, then maybe a criteria to look for is it actually lowers the cost of doing these things over time. So as you gain more experience, and you use successful EAs as templates, then this whole process should become more cost-efficient; just a comment made back on the previous group.
MR. COURSEY: Thanks.
MS. RISSLER: Jane Rissler, UCS. I would respectfully suggest that there are other stakeholders beyond economy. So when you talk about are all the stakeholders happy, some of us outside of the business carpet would want to be considered in terms of happiness.
MR. COURSEY: Other comments?
All right. Let's hear from this table right in front of me.
MR. ZEPH: In terms of advice, the question on advice, our basic point was to make sure the program is fair to the applicants and does not provide some sort of competitive advantage.
One way that this might work well is if you

have a fee system and a fixed time limit, then that would make sure there's consistency in those two areas. Of course, the fee system, as we've talked about, might have to be prorated based on the size of the applicant's company or institution.
Use the pilot program to actually test these ideas out, and before moving forward, make sure that you've done a good thorough evaluation of how successful the pilot was.
We spent some time talking about the advantages of this in terms of having the flexibility within BRS not to have to staff up to cover these periods where there's lots of petitions versus the value of having in-house expertise around NEPA and NEPA analyses. So we didn't come to any resolution, but that clearly has to be a key consideration.

We also talked about how, ironically, the small companies and universities may be more likely to have the new traits and the new crops that would require a more extensive EA or EIS. So they may be burdened by this in the fact that they couldn't necessarily afford to participate in this program.

Another consideration was does having three parties involved in this, contractor, applicant and BRS, provide more efficiencies to the process or slow it down. So that would be a big consideration.

Then in terms of the question around the criteria for the participants, I think, like others, we talked about it being IR-4-like or focusing on new traits, new crops as a criterion.

I think these points have been already covered in terms of measuring success, and I've mentioned that one already. So I think that's it.

MR. COURSEY: Okay. Thank you.

Any questions for this group? All right. Let's go over in the corner, please.

MR. WACH: This is Mike Wach at Bio, again. In terms of advice, we emphasized the value of other agencies' experience, not just physically how to do it, but also how the process worked for them, is it working well for them, what were trip, falls they found as they went through developing these processes.

Keep the process, as you develop it, keep it as transparent as possible. That's not just involving the public at the front end, but also explaining to the public what happened at the back end. So what happened to the pilot, how did it develop, and what happened to the EA as they were developed in this process. So give feedback at the end as well as accepting feedback at the beginning.

Make sure you have sufficient resources to manage the project. We also had sort of a descending theme at the table, which was basically opposed to using applicant-prepared EAs.

As far as including a wide range of stakeholders, consider the IR-4 model, which is for special use chemistry that may have some models or lessons to be learned for this as well.

There was a warning that it may not be possible to enable everyone to participate. It may be an impossible goal to open it up to everyone or make sure that it enables everyone to participate.

The agency should be clear about the relationship between the pilot outcomes and the system outcomes; so the pilot be a learning process as opposed to the final system, which is an active working process, and those two things may be different and that relationship should be made clear; and to echo Jane's comment about consider non-applicant stakeholders as you involve people in the process.

Requests to participate, I think we agree with pretty much everyone, a cross-section of applicant size and a cross-section of crops and traits. The pilot won't really be any good if you focus only on Bt corn or only on trees. You have to give people an

experience of developing documents and analyzing a wide range of circumstances.

Evaluating the pilot, you want public input into that criteria that you actually use to evaluate the pilot. You want public feedback on the EAs, ensuring their quality. The actual quality of the document is one criterion for a successful pilot.

The time and cost for preparation is something to weigh. It may not be the sole factor of identifying success. Evaluating how many agency resources were needed to manage the program in the first place and does the program actually free up resources or does it

tie up resources to have this program going on?

That's it.

MR. COURSEY: Okay. Thanks.

Questions for this group? Anyone?

All right. We're over to this table.

MS. ROBERTS: Cindy Roberts, Food Industry Environmental Network. Ditto on what a lot of other people have said about criteria for the third-party and public companies and the legal aspects.

We also wanted to have some kind of additional form where the companies who would participate in the pilot would give more feedback and some communication to the public to avoid the appearance of favoritism. And we were just kind of wondering, if the pilot is successful, would it become a requirement.

Again, for the second one, get feedback from all the stakeholders. It needs to be transparent; minimum standards; some way, again, for the small companies to pay; the IR-4 model; stuff that people have suggested already.

We thought maybe the USDA could pay for at least one pilot and see how that would work. Of

course, a cross-section of types of participants; types of products; wide groups of traits and crops. I think a lot of people have kind of recommended those things. That's the thing when you're the last one, all of your thoughts are already out there.

It should be an ongoing process. I think one of the gentleman -- you're participating in the BQMS, and they have a lot of surveys that they do throughout the companies that are participating, to do that.

Are you really saving time, money? Does it stand up to lawsuits and other legal challenges? The Office of General Counsel at USDA should look at the products to see how they are, but also hire perhaps some external consult to evaluate the EAs and EISs.

That's it for us.

MR. COURSEY: Okay. Thank you.

Again, any questions? Anybody?

All right. This group over here.

MS. SNELL: I'm Kristi Snell from Metabolix. Question one, advice for the USDA, we really talked about trying to increase the transparency of the whole process, in particular, for NGOs and, also, third

parties that are outside the biotech industry.

One thing that was brought up that might help is if USDA could articulate a philosophy or a policy of what actually triggers an EA or an EIS, and this would

help raise the comfort level of people outside the biotech industry.

We also mentioned that we need clearly defined timeframes for completion of process, especially so companies can help more into their timeframes, for timeframes and schedules.

Again, along that same line, we thought that if agents could talk to other agencies that implement this process, perhaps we could learn more about what is good and what is bad about this kind of program.

For question 2, how do we create a system that's fair to all parties, we believe that third parties should have a lot of input, again, NGOs, and to go outside of the biotech industry.

As far as the website, we think there needs to be a new section that's easier for others that are outside the biotech industry to understand what's going on.

Then as far as selecting who should participate in the pilot, there was some discussion on cost. How do we know that people can actually pay for this process? Should people prepay? The costs may be unknown upfront. How much do people really know what they're getting into? We also mentioned an IR-4 system to help make it more fair for smaller companies and allow universities to participate.

Then as far as what criteria should be used to evaluate the system, what comments are you getting from stakeholders? Are they comfortable with the EA process? Was the efficiency increased? Were the timelines reduced? Were resources of USDA better spent? Then, of course, making sure that quality is maintained.

MR. COURSEY: Great. Thank you.

Any questions for the last group, clarifying questions? All right. Anybody have overall comments, again, to this round?

MR. GRANT: Doug Grant, BRS, Compliance and Inspection Branch. I've got a question for Neil.

Just out of curiosity -- since I'm not with the Risk Assessment Group, I don't really know -- how frequently do we see universities or ARS or other public institutions submit petitions? Do you have a general feel for what percentage of the petitions that we see come from those sources?

MR. HOFFMAN: I would guess it's under five percent. I can only think of two offhand, 2 out of 70. So I don't -- three? Okay. There we go. That's about five.

MR. PEARSON: Your numbers are probably correct, Neil, but I would ask a question.

Perhaps there are lots of developers and universities out there who have not gone to that next step because of the perceived burden of the regulatory process. So your numbers are probably correct, but I would leave that as a question that we don't know the answer to.

MR. HOFFMAN: I think that's a good point. We've heard that over and over that people in university have difficulties taking any product through the regulatory system.

MR. COURSEY: Okay.

MR. WACH: One quick question, Neil; Mike Wach, again.

You may not have decided this yet, but is the purpose of the pilot, as you go through the pilot, you come out with the pilot with an EA or do you go through the pilot and then you're sent home and you write your EA or you contract your EA?

What is the product if you successfully go through the pilot? Do you have the document in hand or you just have the knowledge to do the document?

MR. HOFFMAN: You have the document in hand is the idea.

MR. COURSEY: Okay. Anyone else? Comment, question?

All right. Thanks. I want to remind you again that we're documenting in many ways these conversations. At the table, the BRS staff are taking notes and they will also transcribe the flipchart from your table, plus we've got a transcript from the court reporter that will be on the website after the meeting.

A request for the BRS staff at the tables. I'm going to ask you all to switch tables for the next round and the way to do that -- and, John, raise your hand up front -- is just move back to the next table. Move back to the next table. This person over here, move over to that side. So we're just going to go around one.

Folks, we're about to take a break. We have some time. We have another BRS staff person, Mitch Hall, in the back. Mitch, raise your hand. Mitch is going to help people who need authentication done. Mitch is an LRA and he assured me that you folks would know what that means. It's a notary for this kind of work. So you can see Mitch at the break, also.

Questions before we break? It's a quarter to 3:00. Come back at 2:45. Thank you.

(Whereupon, a recess was taken.)

MR. COURSEY: BRS staff, please raise your hands.

Our next session here, as you can see in your agenda, is the Biotechnology Quality Management System, BQMS. Let me introduce Edward Jhee, who is the BQMS Program Manager for BRS.

MR. JHEE: Thanks. Thanks, everybody, for being here. Thanks to everybody for attending today's stakeholder meeting and, also, sticking around after lunch for this half of the meeting.

The presentation I'm going to make on the BQMS program is going to be kind of a hollow overview of where we have been, where we are now, and where we hope to be in the future.

I'd like to begin by explaining a little bit about compliance programs and a general comment to government. Typically, a government compliance program is going to be consisting of an inspection program, an enforcement program, as well as an assistance program.

Now, back in 2006, the BRS compliance efforts largely consisted of a very robust inspection program, as well as an enforcement one. What we asked ourselves

at that time, what can BRS do to provide assistance to the regulated community. We also conducted an analysis of some of the more recent compliance incidents and noticed that there had been some missed opportunities by regulated entities to manage critical control points for the introduction of regulated articles. In addition, there also were some instances of an

unawareness. The decisions that were made by management of those critical control points may have led to the organization being put on a path or a trajectory towards noncompliance.

So we go back to our fundamental question. How can BRS provide assistance to an organization in the management of critical control points to stay in compliance?

The goal of BQMS was to assist the regulated community to develop a proactive management system that would ensure effective management of those critical control points with an end result of being compliant. In other words, BQMS efforts would assist entities in managing themselves in a proactive manner.

Now, this timeline provides a snapshot of some of our higher level progress that we've made within the last few years. As I mentioned before, some of the initial discussions of BQMS and this idea of compliance assistance began back in 2005 and 2006. It wasn't until 2007 when then Acting Secretary Chuck Conner announced the decision to develop BQMS. But as technical development happened, while that was

happening, about a year later, we announced through the Federal Register a solicitation for participation in the pilot development project.

We kicked that pilot project off this past January, and then in this past September, we concluded all of those pilot activities based on a very aggressive schedule. In addition to all of the pilot activities and the technical work in the background, we had also issued an FR notice seeking public comment on the draft audit standard and that comment period just closed last month.

Now, this next slide, as complicated as it is, it describes the methodology we used for the development of BQMS. Some of you guys may be familiar with this type of cycle. It's the "Plan, Do, Check, Act" cycle of quality management. We intended on embodying the same principles as we were developing this program from beginning and assessment.

It starts with the initial development of our plan. What did we want to do? We wanted to develop a compliance assistance program. So our thought was let's begin with developing a tool. So we developed an

audit standard that we would hope that the regulated community would use to apply the quality management principles of document and record control, communication, training, with a focus on managing critical control points for the introduction of regulated articles.

We also developed a series of draft or very rough draft guidelines, but we chose to actually integrate those guidelines into classroom training

modules, which we implemented during the "Do" phase of a pilot project.

So during the pilot project, we conducted our pilot activities, such as some training workshops. We also conducted baseline assessments on the five volunteer participants, and we also assisted with conducting internal audits and providing additional one-on-one training. Now, I'll come back to Check and Act towards the end of the presentation.

Now, the pilot development project, and I did want to emphasize development, the goal was to test the feasibility of the draft audit standard. In addition, we wanted to test the -- excuse me -- the efficacy of

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the draft audit standard, but we wanted to test the feasibility of the five volunteer organizations that had varying depth of scope and breadth and size and how they develop and implement a BQMS within their organization.

While we're thinking of a pilot in mind, we had three fundamental questions. One, what could we do to encourage participation in the BQMS audit program by industry and academia? Two, how can we facilitate participation in BQMS for those organizations that wish to enroll? And third, what's the perception by the regulated community and the public in general about the BQMS audit program?

Now, the pilot project had three major phases. The first phase was largely instructional or educational. In this phase, we conducted two separate training sessions that focused not only on the BQMS audit standard, but as well as general quality management principles.

In addition, we conducted offsite baseline assessments, or gap audits, of all five of the participants to see where they were as far as managing

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those critical control points. It was at this time where we were able to work one-on-one with the five pilot participants and I think is where some of the greatest value came out.

The second major phase was conducting internal audit assistance, where we also provided additional training and one-on-one work. And then the third phase was where all five of the participants underwent a third-party independent audit.

Now, at each phase of the pilot development project, we surveyed all of the participants in order to get captured some of the important feedback on strengths, as well as the areas of improvement. Some of the strengths are as noted here. One of the key ones was the interaction between the participants and APHIS and other USDA officials.

It was at these workshops where we were able to work one-on-one, provide group setting type guidance to the participants of the pilot project. In addition, some of our colleagues from the Agricultural Marketing Service also attended these training sessions to provide their background on quality management as well.

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Another value that the participants felt was the interaction among the pilot participants. Here is the key point that I'd like to make to you guys now.

BQMS focuses on regulatory compliance and I think when all of the pilot participants showed up at the workshops, they realized that everyone that was representing their organization was responsible for managing compliance.

So when they looked at each other, they realized there was no discussion needed about confidential business information. There was no discussion about competition among the corporate entities, because they all had one common goal, to remain compliant with the APHIS regulations. In other words, they all finally figured out that we're all in this together, so let's commiserate. Then, basically, in a nice way of saying, it was an opportunity for all the participants to learn from each other, to share their experiences on their approach towards compliance.

One of the final strengths that I want to speak about was the classroom instruction and the group exercises. A lot of the participants mentioned that

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APHIS should continue the classroom instructional model rather than implementing or integrating Web-based or Internet-type training. They just felt that the latter would be largely ineffective if we were to go down that path.

Now, with every strength comes some areas of improvement. Some of the feedback we also received was that the training and the one-on-one sessions should focus more on BQMS and a little bit less on the fundamental principles of quality management. Just start with what the heart of BQMS is, describe it, clarify it, and get it to work.

They also suggested providing documented guidelines to speed up the development and implementation process, and as a result of that request, we developed a series of templates and guidelines that we eventually will want to integrate into a workbook type program that all users would be able to use. They did mention about maintaining a classroom setting. And then a new suggestion was having class participants provide their experiences to future participants.

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Well, what did we learn throughout the pilot development project? We learned that regardless of the size of the organization, the scope of their operation, or the number of personnel that they had managing regulatory compliance, all five were able to develop, implement and begin monitoring their BQMS. This speaks a lot about the flexibility of the standard itself and how it's applicable to whatever size organization chooses to go down this path.

Now, it brings us back to the "Plan, Do, Check, Act." Right now, I would say that BRS is in the "Check" phase and we hope to transition relatively quickly to the "Act" phase, and I'll speak a little bit more on that.

During the "Check" phase, I had mentioned that we sought feedback from the pilot participants throughout the entire pilot project. We also had APHIS Policy, Programs and Development conduct an internal review of the methodology we used and the results of the pilot project.

In addition, as I mentioned, we issued an FR notice for seeking public comment on the draft audit standard. And the "Act" phase of the PDCA will be our next steps. We want to consider and incorporate the applicable feedback. We also want to determine our own internal resource capabilities. We'll assess administrative and policy decisions. We'll also be assessing confidential business information and the applicability of FOIA. And then final would be revising all of the technical documents.

Finally, the outputs of the BQMS pilot development project. It wasn't all about quality management. What we had was an output and sort of a development of a compliance assistance toolbox.

Within this toolbox, we developed guidelines and some templates that any user can use for the development of procedures that address critical control points. Templates and guidelines were also developed that addressed fundamental quality management procedures. We also revised the training workshops to focus more on BQMS and to clarify our expectations.

Now, finally, at the end of the day, BQMS and this concept of compliance assistance wants to focus on raising the awareness of regulatory responsibilities, and we intend to do that through strong education and outreach.

With that, I'll take any questions.

MR. COURSEY: All right. Thank you.

How about questions for clarification? Yes? Please state your name.

MS. EVERSOLE: I'm Kellye Eversole with Eversole Associates. I also work with the Specialty Crop Regulatory Assistance effort. I'm curious as to you mentioned that regardless of the size of the organization, you were able to apply the system that you developed.

Is it not true that Simplot was your small business, a company which is the largest potato company in the world?

MR. JHEE: Largest potato company in the world, yes, and they make Mac fries and other things. Yes, we understand that, and I think there were some eyebrows raised over the choice of Simplot as a small business.

It was the size of the regulatory compliance group. J.R. Simplot, as a corporate entity, was not certified or will not become certified under BQMS. The scope of their quality management system is for their regulatory compliance group and it actually, at that time, consisted of two people.

MR. GREGOIRE: A university was also one of the pilots.

MR. JHEE: Yes, sir. We were fortunate to have the University of Nebraska at Lincoln also choose to participate. They have a very unique structure within the Institute of Agriculture and Natural Resources. There was one associate dean that was the principal, as well as one of the lead researchers or faculty members, and a farm manager, or the manager of the research farm, that participated in their

development of BQMS.
They had some challenges, obviously, as we would expect any academic to, but we believe that the internal team that we had developed here within BRS was able to help them realize how their existing structure could fit in with what we were asking them to do with BQMS.
I think at the end of the day, they realized

that the document control system that they had developed, not we told them to do, but the document control system, the record control system, the training program they had all developed had only made their system more robust and making sure that they were staying compliant.
MR. COURSEY: Other questions, clarifying questions?
MR. STALEY: Todd Staley, Monsanto.
Ed, can you comment on the metrics that either were used or are being used to look at results of this pilot program and the impact on compliance overall for the program participants or for the program?
MR. JHEE: We are in the middle of discussing our approach to that. As we proceed with more of a strategic direction of how we want to implement BQMS in the context of compliance assistance further, that's a very important question that we do want to be able to address.
A lot of the metrics that we collected during this pilot project were largely based on understanding our quality management, understanding of BQMS and what

APHIS' expectations were; did they understand what we were asking them.
As we proceed with those and establish a baseline of our internal performance, our operational performance, we want to be able to evolve our performance metrics into how does it impact compliance or does it impact compliance.
At this time, I can't answer that question, but it is something we will be addressing.
Thanks, Todd.
MR. REDENBAUGH: Keith Redenbaugh at Arcadia Biosciences.
Can you comment on the relationship with the BQMS program and what Bio is doing with Excellence Through Stewardship, how the two programs complement each other or the toxic interaction that you expect to have with the two programs?
MR. JHEE: I can't comment on the ETS program, but I can explain to you that on numerous occasions, we've spent some time discussing some of the compatibility issues with an ETS group. It's my understanding that ETS is -- their approach is more of

a policy-based. However, they are focusing as well on quality management principles that are quite product development -- excuse me; plant product integrity.
BQMS is more at the domestic regulatory compliance level. So to make a comparison, I don't know if we can make that now for making the assessment. It would take probably some in-depth discussion between APHIS and the folks at ETS to figure out where

compatibility issues are.
We're hoping that we'll be able to meet with some of those individuals soon to be able to discuss how can there be some sort of harmonization or compatibility.
MR. COURSEY: Other questions?
Okay. Edward, thank you.
We're now going to go back into our last session of group work, so we remind you of the process again. We'll have about 30 minutes to do this. If you can identify your note-taker and flipchart person and a spokesperson, and the questions are up on the screen.
You have a new BRS person at your table, also, to answer technical questions. BRS people, identify

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yourselves, if you haven't already.
(Whereupon, a breakout session occurred from 3:05 p.m. to 3:34 p.m.)
MR. COURSEY: I think we're ready to go with report-outs. Let us start over here.
Folks, if you would give your attention to the group over here. Please state your name as you're reporting out.
MR. RATHORE: Keerti Rathore, Texas A&M University. I'm pretty new to all this stuff and this concept of BQMS, it's the first time I'm even hearing about it, and that was the general opinion on our table.
But anyway, the things that we thought were important were it would be nice to have a manual. That would be very helpful when you're starting your phase two, and we suggest what have you learned from the first phase.
It also would be helpful if we could -- people who are being paid -- these five entities that we're training in the first phase -- some of them could act as teachers for the second phase. Also, it would be

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nice to know the experience from other companies. It would be nice to have some information from the past workshops on the website, and that's about it.
MR. COURSEY: All right. Thank you.
Any questions for clarification? All right. Thank you.
How about this group right here?
MR. HOWIE: I'm William Howie, BASF. I have to give a disclaimer. I shouldn't be up here because I was one of the pilot participants. So I'm probably biased one way or the other. My group didn't see it that way.
We kind of talked about the first and second question together and what was the positive assistance to give presentations on what we experienced. And I think that was really mentioned already. But just a plug for -- actually, that will happen. If you're going to be in ASTA in December, then the five participants will be there, and there will be about a two-hour block of time, I think, December the 9th, in the morning, and there will be a chance for the press to give information. And then I think -- I know Ed's

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giving a presentation. Anyway, that will at least happen at ASTA. Maybe there will be more in these

other places.
There should be an estimate of how much resources are required so people know going into it what they're really up against, dollars and time, how much work it's going to take. And then, also, some sort of estimate -- and there's a cost estimate of what it's going to take in hours and all that, but then there's also a presentation from BRS on what's the cost of noncompliance versus compliance that you might gain from being a participant in the BQMS.
Then it would really be nice to see a completed document on what a quality manual looks like, if that's possible. There's a lot of CBI information, but maybe, maybe not. Maybe that could be arranged somehow. And the University of Nebraska, since this is public, could do -- it may be a possibility, I don't know.
So the third question, well, since I was a participant in the program press, even though it was painful and we did commiserate, we would still use it,

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even if BQMS goes away. The benefit we got out of it -- we would not maybe do the whole program, but we would certainly follow along guidelines, et cetera, if it would go away.
The benefit is increased confidence in compliance that can be communicated out. That's a big gain. There is flexibility in the system. Whether you're a small academic group or a large company, there is flexibility built into meeting all the standards.
Then I guess I'm not quite sure -- do you guys remember what the last one was? I missed that one.
MR. SCHAAF: That was basically to say that if the BQMS -- what we should do in the BQMS, and USDA should somehow translate that value to the public, and say I'm BQMS certified; what does that mean to the public?
MS. DUNIGAN: We didn't hear that last one. Could you repeat it in the microphone?
MR. COURSEY: Please state your name. Thanks.
MR. SCHAAF: This is Dave Schaaf from Arcadia Biosciences. The last point we had was if the BQMS -- to get people to get the system or to adopt BQMS, there

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really has to be a public perception that it's worthwhile.
I think one of the things that drove the management's decision to do this, to be in the pilot program, was to say, oh, yeah, we're going to get something out of this; you can communicate this to the public and then it's going to have some value. So it would be nice for the public to know it's valuable as well.
MR. COURSEY: Okay. Thank you.
Any questions for this table?
Okay. How about this group here?
MR. STALEY: Todd Staley, Monsanto. The first question in terms of increasing participation, echoing comments earlier around getting the word out more broadly to those not familiar, including the participants. So I'm glad to hear that there are some plans to do that; just getting those positive comments out and from the participants themselves.

Addressing the comments that are in place now from the public comment period and having a response to those. Focusing on some simplicity, which was kind of a recurring theme in the discussions. And on those critical control points, make it less QMS and more critical control point focused, especially for those inexperienced with QMS or that have limited resources; so kind of a streamlined approach.

Really focusing on the assistance part of the program as opposed to the audit certification piece. The discussion was around that there seemed to be very positive feedback around this classroom interaction, one-on-one opportunity with USDA, and thinking about the program, really focusing on that assistance piece.

Finally, clearly identifying those performance metrics and what additional benefit BQMS has in addition to existing compliance systems that are in place.

The second question in terms of facilitating participation for those that wish to enroll, thinking about some type of pilot experience or training for those that wish to enroll, to bring them in, again, similar to the pilot experience of one-on-one interaction.

I think addressing any outstanding concerns, the two that were talked about the most were the ability to resource the program going forward to avoid any type of competitive concerns for those in queue for the program and articulating any incentives or, again, benefit to the program.

The third, then, the perception of the regulated community, and I'll say that the table is mostly industry and so I think you'll see the flavor of these comments. The first one is that the goal of BQMS is highly supported. The perception is that it's a great goal and that compliance assistance is something that is broadly supported and continued effort should be put into it across the stakeholder board.

The perception is that because the program seems to be leaning more toward compliance requirements than it is toward the assistance, that there is potential for it to be redundant to current systems, ISO, ETS was mentioned, CLI guidance is out there; that it's really about audit; that it's an audit program more than a compliance assistance program.

It's voluntary, but is it really mandatory, given potential stakeholder perceptions globally? I think this was mentioned before. Once it's out, is it a standard that's looked at as really something that needs to be done.

Then the final comment was a perception, especially with those not familiar with it or for those with limited resources, that it would be resource-intensive.

MR. COURSEY: Thank you.

Any questions for this group? Yes?

MS. KOHLER: Susan Kohler, BRS. I see on your flipchart you have written down "Once you're in, you're in."

Could you explain what that means?

MR. STALEY: I think that was a comment around this is it really mandatory if, as a standard, it's perceived as something that's necessary for compliance versus compliance assistance. But then would that lead to, let's say by a foreign government or by another authority, that once you're in, then it becomes -- you would need to continue to do that.

In other words, there was conversation around what if a company came in, they spent resources to do this, they got the value that they saw out of the program, and then thought, "Well, we can manage this on our own now. We've got the compliance assistance piece. We'll continue to run the program," but that there would be a barrier for them withdrawing from the program, because it would be perceived negatively.

MS. KOHLER: Thank you.

MR. COURSEY: Anybody else, questions?

Okay. How about this group?

MR. BOTTOMS: Jeff Bottoms, Syngenta. I believe most of what we discussed has been mentioned already, but I'll quickly go through. One thing that was pointed out is to establish and clarify the relationship between BQMS and ETS and, arguably, any other quality management system that would meet the same goals.

Some questions that sort of arose from that discussion, being a participant and being qualified in ETS, is there a mechanism for qualifying for BQMS, which would, arguably, save APHIS/BRS resources to focus where the focus would be better served?

It was noted that BQMS and ETS have separate stakeholders, so whatever happens here needs to be taken into consideration at this point. But a benefit of resolving this situation would be to minimize any duplication between the two different parties. It would also encourage participation by the large industry and hopefully bring in resources to folks in some of the smaller companies.

One thing that was noted to improve participation would be to better delineate the benefits of BQMS. We were all struggling with exactly what those benefits would be, and I think that point came up multiple times in our discussions.

There was some discussion about the funding for the program and if you had more people that wanted to participate, then there was funding for the participation, how would that be resolved. It was noted to not create a competitive disadvantage for nonparticipants.

There were also some questions about if the program became mandatory, there needed to be a better assessment for small companies with limited funds. Again, what are the benefits?

Greater compliance. The hopeful outcome of greater compliance would be that APHIS could redirect their limited resources to those companies that aren't up to par yet.

MR. COURSEY: Thank you.

Any questions for this group? If not, let's go over here.

MR. DOLEY: Bill Doley, Bio Development. Our group, we didn't have any participants in the BQMS project, so we didn't have any inside view of how it really works. So some of the comments may not be accurate.

I guess we combined one and two because they seemed like the same question. The third question was perception of the regulated community, and I think the suggestions all came back from the perception of the system is overly prescriptive; that is, one-size-fits-all and perhaps from some other discussions that came later, maybe that's not really the case.

But what we're suggesting is that there be flexibility for each participant to participate in the way that best fits their organization and that large

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companies, for the most part, have compliance systems in place and documentation systems in place and they don't need a second system to overlay on the existing system.

Then related to that is to accept alternate documentation systems. So if a company has a good documentation system in place, it could fit right into BQMS without having to change the system to what was prescribed in the pilot.

Another suggestion was for some companies, they might like to have just an audit-only service, so that they feel like they have a pretty good system in place and they just want someone to come in and tell them what could be improved and where the holes are in the system so that they can tighten up their system to make it better.

Then to evolve from one-size-fits-all. That's the perception, that it is one-size-fits-all, to evolve into different models that fit different organizations that have different needs.

MR. COURSEY: Great. Thank you.

Again, any questions? Okay.

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MS. BAKER: This is Lisa Baker with Dow AgroSciences. Our discussion kind of jumped around quite a bit. When we looked at what do you gain from this, we had someone at our table who had participated in the pilot program and they thought it was a good validation for current and future systems that could be in place, and it was also a really good learning experience.

We thought that one of the things that helped gain participation is if you could offer better communication on the standard and what all it could offer in the future. For some of the benefits, we didn't know if it could potentially offer faster occurring or other advantages through the process. We thought that the flexibility of the system was also a good advantage.

There was a question about whether or not this could also be used to help bring some companies that were deficient potentially in their compliance process, if this could help bring them up to speed faster.

Along with everybody else, we kind of wondered if this was going to be a requirement in the future.

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There was also the question as to whether or not a

benefit could be if it would offer lower insurance rates for some companies in some aspect of their business.

We wanted to be sure that the differences in BIO ETS and BQMS were captured and whether or not these were competing principles or if they were going to work in conjunction with each other.

We wanted to emphasize the benefits to the company and not necessarily that it was just a social or in-name-only benefit. We also wondered if small companies could potentially see a larger benefit from this than some of the larger ones that might already have a quality management standard in place.

We also questioned is there better compliance or less infractions after you complete the course. So would the certification offer a better system in place for your company in total; would you see less infractions come down on you in the long run? Also, could the standard respond to the public opinion that, to some extent, some people think that there's not a lot of standards put on the industry and would this

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help solve that issue that's sometimes seen now on the Internet or other public forums.

MR. COURSEY: Okay. Thank you.

Any comments, folks? All right. Thanks.

The last group?

MR. WACH: This is Mike Wach from Bio, again. We interpreted the first question of encourage participation to sort of be why would you want to be a part of BQMS; the opportunity to be transparent.

Another, it was said in jest, but I think it's probably true, is to respond to peer pressure from others. And I think that just at our table alone, where we had several people who went through the program, they like the program, and they're selling the program just to us at the table. So I think it's a real thing to say that there's peer pressure.

It's an opportunity to improve your overall quality management programs. It provides external demonstration in terms of quality management, but some of the companies indicated that internal demonstration was very important to them. It showed all their employees internally that they were committed to

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quality management.

To better encourage participation, there might be some way to better describe what the program is, to articulate that there seems to be a no cost or low cost associated with participating and, also, relatively low resource commitment to participate.

It's sort of like the stick as opposed to the carrot. The costs that would be decreasing if you participate could be things such as fines, public relations problems, or maybe permits being denied because you're having conformity problems with quality management.

Some of our members who went through the program said that they actually streamlined their internal processes, allowing them to reduce the amounts of internal paperwork that they were using, because the BQMS forms were better. And, again, that the value instead of the cost is now something that could be a

positive. Other people have mentioned this. It's the public relations value of the certification.
Perceptions, it was brought up that -- and other people brought this up, too, that there may be a

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perception of why isn't it mandatory, why aren't there penalties associated with not meeting your audit requirements.
The confusion of conformity versus compliance, this is not unique to BQMS. As other people mentioned, either overlap, duplicity with ETS versus BQMS and other quality management systems that are out there.
Facilitating participation. The people that went through the pilot study said it was time-consuming at first. They felt they got a lot of value from their participation, but they felt that over time, with the full-fledged program, the initial time consumption would decrease.
It was suggested that there be regional implementation and training so that you don't have to travel here or that others don't have to travel to you as far to get to participate in the program, and to use lessons learned to streamline training. Ed mentioned the templates and the guidelines. Lessons learned might translate into predictions as to how many employees or resources it takes to actually do it.
Also, as people are struggling with the

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quality management systems, it might help BQMS to sort of put themselves in the same picture with other quality management programs, like ISO, to help people understand what they're accomplishing when they do BQMS versus other programs. That's it.
MR. COURSEY: Okay. Thank you.
Final group. Final comments on the group? All right.
Anyone have a reflection or final comments on BQMS? We've heard all the presentations. Okay.
A couple quick reminders for the BRS staff at the tables. If you could remember to take the flipchart notes of the tables you were at. And for the people here this afternoon, it would be two sets, correct? And you'll be transcribing those; thanks very much for that.
Thanks, everyone, for the work you did at the tables, for the thinking, the sharing of ideas, the transcribing on the flipcharts, et cetera. That was very important to all of us.
A quick note. We're going to take about a five-minute break and Mike Gregoire is going to have

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some closing comments for us. But before we take a break, I want to remind you about your evaluations. There's a one-page evaluation in your packet and we'd love it if you could complete that and leave it on the table or give it to one of the BRS staff, that would be great.
Any other announcements before a break?
Okay. Let's take a five-minute quick stretch break and then Mike will be back here with some closing comments.
(Whereupon, a recess was taken.)
MR. GREGOIRE: I just want to begin by

reflecting on some of the key things that I heard during the course of the day today, and I'm going to ask Bev to do the same. Sometimes Bev and I hear different things or we hear the same things differently. Between the two of us, hopefully we've got it covered pretty well. And after that, I'll just talk a little bit about some of the next steps.

So for me, from the morning discussion, the discussion of the program delivery issues, when we were talking about ePermits and planning reports and things like that, the planning reports issue, obviously, there was a lot of interest and concern about how do we make that work in a practical sort of way. So I think we have some work to do there to be clear about what the requirements are and how to design that process so that it works well for everybody.

On the petition process, I heard a lot of ideas about the need for better communication, to have clear guidelines about what is required in the data packages; that the information about what the requirements are is consistently communicated by BRS; that we have templates and examples of things that will help people navigate the process; that they have a point of contact in the organization that they can get information from.

Status information is very important to people; that is, to know what are the major steps in the process, what are the normal turnaround times for those steps, and we'd like to have information about where we are vis-a-vis what those standard timelines are.

I heard in a couple of different sessions today the need for more information about when the agency does an EA versus when the agency does an EIS. The relationship with other federal agencies in the process is an important factor in the time the process takes, so that we need to pay attention to those relationships and work to ensure that that's not a bottleneck. And additional staff resources would always help as well.

With respect to the NEPA process, the pilot project that we talked about, some of the things that I heard there were that the pilot project and how we evaluate the pilot project needs to address the needs of a wide range of stakeholders, not just the petitioners, but NGOs and others that have an interest in those regulatory decisions that the agency makes; that the pilot project should include a broad range of participants, entities of different size and perhaps different crops, so we get sort of a true test of how this process might work.

A lot of different suggestions on providing extra assistance to small entities. Several people talked about the IR-4 program as sort of a model of how that might be done in this pilot project. Suggestions that we be very transparent throughout the whole pilot project, not just at the beginning when the pilot project is launched, but throughout the duration of the pilot project and at the end of the pilot project; that we clearly segregate the pilot activity from any

program that's institutionalized or implemented on a long-term basis.

Concerns about the objectivity of the work that's done. One suggestion not to include applicant-submitted EAs as part of the pilot project. Another suggestion perhaps to have a peer review type of input on the documents; that we should, as part of the evaluation of the project, measure the quality, the timeliness, cost, reactions from various stakeholders and so on.

So those were some of the key things I heard with respect to the NEPA process.

Let's flip back to BQMS. Several suggestions for those that are going to be enrolling in the program in the future, if they could benefit from the experience of those that have been through the pilot

project, folks that have come into the program before them, that those experiences could be shared as a way to get people understanding and on board; to have a lot of different kinds of resources available to people on the Web, like a manual, sample quality manual, templates and guidelines and so on; that folks need to understand ahead of time what kind of resources it's going to take to do this; a lot about communications about the program. We need to communicate what the program is all about, the benefits of the program, the flexibility of the program, the value of the program, not just to the enrollees but to the public at-large.

Keep it simple. One table said focus more on the assistance part, less on the audit part. Be sure to address the public comments on the draft standards in a transparent way. Define the long-term performance measures for the program; that is, some way to identify does this really impact compliance.

Concern about public perception and whether or not the program will be a sort of de facto mandatory program, a lot of concerns about that, as well as potential redundancy with other quality management

programs, like ETS, and I think urging us to find ways to make them as compatible and complementary as we can.

The flexibility to adopt as much or as little of the program that people want to avail themselves of. A limit put on incentives, like maybe faster permitting, lower insurance rates. Also, to use this program to help those entities that are deficient in compliance to get up to speed more quickly.

So those were some of the things that I heard from the four sessions today.

Bev?

MS. SIMMONS: Well, I just want to reiterate a couple of points that Mike made and a few other ones. I think it's very clear, we heard this in April and we heard this again deciphered repeatedly throughout the day, is the emphasis on communication and how we communicate with you and you communicate with us.

I can reassure you that since our discussions in April, this has been a topic of a lot of internal discussion within BRS about how we improve that process. I know we've been undertaking some efforts in recent months to try to push more information out to

the stakeholder community. It would be useful to kind of get some sense of whether or not we're doing a good job of that.

As you might note in even preparing for this meeting, we tried to provide ahead of time a fair amount of information so that folks could have an expectation about how this ongoing communication between us might take place. So that is an area I think that we need to continue to work on.

With regard to that as well, I heard, both for BQMS and as we move down the road on this third-party contracting, maybe we need to work on some more specific outreach plans on how we do communicate, what we're trying to achieve under these initiatives and what we'll all gain collectively from pursuing them.

The other thing that I wanted to mention that I heard a couple times was reference to the international perspective on what we do in the United States, and that we need to be mindful as we continue to work through our regulatory issues that we are kind of in the spotlight and many around the globe are watching what we're doing and hoping to learn from our

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experiences. So I think we need to kind of keep that in the forefront as well.

So I wanted to mention those points.

MR. GREGOIRE: In terms of next steps, we're going to be certainly doing some additional debriefing within BRS to share with one another what we heard today and how we're going to use that as we move ahead in these different areas that we've talked about today.

We will be publishing the transcript from the meeting. That usually takes a few weeks to get back. But when we are ready to do that, we will send, via an e-mail, an alert to you that that is happening.

In each of these three different areas, the petition process, the NEPA pilot and BQMS, are kind of individual efforts. They're certainly related to one another. But as we move ahead on these, for example, with the BQMS implementation, with the pilot program implementation, you can anticipate that, at a minimum, we'd be publishing a Federal Register notice and other resource materials on our website that provides additional information about these things.

Just to make one other point about

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communications, that we have been giving a lot of thought to this. We have begun to send out e-mails to folks to let them know when new information is being posted on our website, because some of the feedback we got in April was that "I don't really want to visit your website every day and hunt for new stuff that might be posted there. Please let us know when you're doing that." So that's one of the things that we've done.

We've also contracted with a company to help us kind of retool our website to make it more user-friendly and accessible, and we gave them the names of a number of stakeholders who have expressed opinions and views to us on how that might be improved, because that was a subject of discussion in our April meeting.

So some of you may have already been contacted by this company who is undertaking this work and going

to be making some recommendations to us on how we can improve the information that's on our website and how to access it and so on.

So, again, I just wanted to thank everybody for coming today. We very much appreciate the discussion and the input that you had for us. I know this can be a taxing exercise to spend a whole day talking about some of these sort of things, but I'm very pleased that folks stuck it out for the whole day and were very generous with their thoughts and ideas and suggestions.

We thank you very much for that. This concludes our meeting. Thank you.

[Applause.]

(Whereupon, at 4:20 p.m., the meeting was concluded.)

CERTIFICATE OF REPORTER

I, JANET EVANS-WATKINS, do hereby certify that the foregoing proceedings were taken by me and thereafter reduced under my direction to typewritten form; that this transcript is a true record of the proceedings; that I am neither counsel for, related to, nor employed by any of the parties to this action; and, further, that I am not a relative or employee of any attorney or counsel employed by the parties hereto, nor financially or otherwise interested in the outcome of the action.

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JANET EVANS-WATKINS
Electronic Court Reporter