

**U.S. Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services**

**Public Meeting Transcripts
April 29 and 30, 2009
4700 River Road
Riverdale, MD 20737**

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UNITED STATES
DEPARTMENT OF AGRICULTURE

PUBLIC MEETING

9:00 a.m.

Wednesday, April 29, 2009

U.S. Department of Agriculture

4700 River Road

Riverdale, Maryland 20737

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

2 EVA RING: Could everyone please get seated?

3 And I'm encouraging everyone to sit as close as they can
4 to our front if there are spaces. There's lots of seats
5 over here at this table.

6 MIKE GREGOIRE: Good morning, everybody. Good
7 morning. We're going to get started here. I'm Mike
8 Gregoire. I'm the Deputy Administrator of APHIS,
9 Biotechnology Regulatory Services Unit. I want to
10 welcome you and thank you for participating in our
11 meeting to discuss the proposed Rule related to the
12 regulation of certain genetically engineered organisms.

13 I appreciate that you are taking the time out of your busy
14 schedules to participate in this meeting and share with
15 us your views and ideas.

16 I want to start by just talking about our
17 objectives for the meeting today and tomorrow. There's
18 really four objectives. First is to allow APHIS to
19 reiterate what our objectives were in putting forth the
20 proposed Rule.

21 We also want to highlight some of the key
22 issues with the proposed Rule that have been identified

1 by the public so far, based on the comments that we
2 received, and based on the public meetings that we've
3 held so far.

4 Thirdly we want to solicit additional public
5 input on key aspects of the proposed Rule in a
6 collaborative and dialogue-based public meeting format.
7 This meeting format is quite different from
8 meeting formats that we've used in the past, but we're
9 looking forward to working in this format. We have some
10 terrific facilitators working with us today and tomorrow
11 to make this meeting successful.

12 And, finally, we also want to use this meeting
13 to identify ways that APHIS could clarify its proposed
14 revisions to the regulations, or revise, or improve the
15 Rule to meet the objectives that we have as an agency.

16 The content and the format of this meeting
17 have been shaped by a number of different things, one of
18 which is the public comments that we received on the Rule
19 so far.

20 We also took into account the input we
21 received at the March 13th scoping meeting. I recognize
22 some folks here that were at that meeting. And I hope

1 that those of you who were at that meeting will see some
2 of the ideas that you gave us incorporated into the
3 meeting today and tomorrow.

4 And then, thirdly, we also got some written
5 suggestions on the agenda and format for this meeting by
6 the March 20th deadline we had set for providing comments
7 on those suggestions.

8 Cindy Smith, who is the APHIS Administrator
9 and is currently serving as the Acting Deputy Under
10 Secretary for USDA's Marketing and Regulatory Programs
11 Mission Area, plans to join us and participate in the
12 meeting tomorrow.

13 In addition, Secretary Tom Vilsack and Deputy
14 Secretary Kathleen Merrigan are scheduled to join us
15 tomorrow morning and kick off the meeting with some
16 remarks and talk to you. I do want you to know, however,
17 that all three of them are very deeply involved in the
18 swine flu issues, and that could have an impact on their
19 schedules. So, we do have them scheduled at this point,
20 and hopefully that will work out. We will keep our
21 fingers crossed.

22 We have a number of APHIS BRS staff here for

1 the meeting. And our role in the meeting will be to
2 present information to you on different issues and
3 topics, to answer clarifying questions, to listen. And
4 we will also be reflecting at the end of the day each day
5 on what we've heard come out of the meeting. As
6 participants we ask that you also listen closely and
7 share your thoughts and suggestions.

8 This meeting is really one important step in
9 the overall regulation development process. And this
10 process, as you know, began some time ago with the
11 development and publication of a Draft Programmatic
12 Environmental Impact Statement in 2007.

13 Last fall, in October of 2008, we published a
14 proposed Rule. We've held three public meetings during
15 the fall. We have extended comment periods a couple of
16 different times. We've received more than 20,000
17 comments on the Rule so far. And the comment period on
18 the Rule will remain open for 60 days after this meeting
19 is over, until June 29th, to allow members of the public
20 who were not able to attend this meeting, to look at the
21 transcript and supporting materials that are being used
22 at this meeting, to look at those and provide us comments

1 as well.

2 At the end of the comment period, we will be
3 examining and analyzing the comments that we have
4 received on the Rule, and determining what the next
5 appropriate steps are to move us forward for publication
6 of the final Rule.

7 At this point I want to turn the microphone
8 over to Eva Ring. Eva works for the APHIS Policy and
9 Program Development Unit. And she's our lead facilitator
10 for the meeting. Eva.

11 EVA RING: Thank you. I would also like to
12 introduce two other -- my co-facilitators who are helping
13 out these two days, Jane Berkow and Jerry Coursey, as
14 well as Mike Gregoire the Deputy Administrator. But we
15 also have a few other folks from the Deputy
16 Administrator's Office. We have Sid Abel. And Sid is
17 the Assistant Deputy Administrator. And we have Beverly
18 Simmons who's the Associate Deputy Administrator.

19 At our scoping meeting it became very clear to
20 them and to me as well that you wanted BRS to be
21 listening to you at the tables as well as just on the
22 side of the room. And they're very interested in

1 listening and hearing the exchange of ideas at your
2 tables.

3 A few housekeeping items which, if you're here
4 already you probably already know, but I'll repeat them
5 in case. The men's room is right on this side of the
6 elevator. The ladies room is on the other side. You'll
7 notice in the agenda on your tables that we do have some
8 breaks scheduled in, but we encourage you to just self-
9 break and make your own breaks as you need.

10 The cafeteria, you walk down the hallway, you
11 take the first left, and you'll come to the cafeteria on
12 your right which has drinks, some breakfast items, some
13 lunch items. I hope everyone also got offered the
14 opportunity to order in lunch for today from the
15 registration people at the desk. If you didn't, you
16 still have that opportunity.

17 You had to pay to park in our parking lot. If
18 you decide to go out to lunch, unfortunately, just as we
19 do, you have to pay again to get back in. I'm sorry
20 about that, but that's the way that it is. And you'll
21 probably have to get another badge and sign in at the
22 guard's desk again. Hopefully they'll facilitate that,

1 since they know you were here today helping us out.
2 The agenda, as I mentioned, is on your
3 tables. And really briefly I just want to refer to it.
4 We are open today and tomorrow to spending more or less
5 time, if -- as this group dictates on any particular
6 topic. But we do want to try and cover all the different
7 topics. It's an ambitious agenda. You'll see there are
8 eight different discussion topics that we hope to get
9 through. And those are based on the comments that we
10 received in the March scoping meeting, where people
11 really seemed to both want to offer more suggestions in
12 those areas, as well as to hear more from BRS. So,
13 you'll see discussion topic one, and two, three. They're
14 all on there. And as we move through the agenda, if
15 something else emerges as an obvious discussion topic
16 people want to engage around, we're open to adding that
17 to the agenda as well.

18 I wanted to share with you a little quote that
19 I saw, which one of the things I'm very thankful for is
20 that we have peers like our Secretary, or, you know,
21 Deputy Under Secretary -- who hopefully will join us
22 tomorrow, both of them -- and Mike Gregoire, who are

1 interested in hearing from you and want to support our
2 participative policy development process and regulatory
3 development process here. It doesn't always happen.

4 And I was reading through some books in the
5 last few weeks, and there was a quote that really rang
6 true to me here. It said: "Problems with regulations
7 aren't usually so much a failure of scientific risk
8 assessment, or of analysis, but usually more a failure to
9 involve the right people in the process, people who
10 inevitably will have important knowledge and perspectives
11 to contribute, people that you need to enlarge in a
12 conversation about risks."

13 For the next two days, you are those people.
14 So, I'm hoping that my talking will end in a few minutes,
15 and for the rest of the two days most of the ideas and
16 talking will be coming from you. And we really expect
17 you to roll up your sleeves and do some tough work for us
18 the next two days. So, I appreciate your being here, as
19 does BRS.

20 I also appreciate -- I think I saw on the
21 registration list that we have some of our federal agency
22 partners here as well, who will probably be mostly

1 listening at your tables. Will they stand, please, some
2 of the other folks who are here from either USDA, other
3 agencies, or EPA? I appreciate your coming and engaging
4 with us as well. Thank you. Thank you, very much.

5 I'm going to turn the floor over to Jerry now
6 who's going to go over a few ground Rules that we'd like
7 to operate under as we do this. Thanks, Jerry.

8 JERRY COURSEY: Thank you, Eva. Thanks
9 again. As Eva said, my name is Jerry Coursey. Greetings
10 to all of you and thanks for coming.

11 We were looking at the sign-in sheets and we
12 saw some other groups who we wanted to recognize, not
13 individually, but we saw that there were many developers
14 here, people from the trade industry, of course, other
15 government agencies, public interest groups, NGOs, some
16 state regulatory officials. Any group there that we've
17 missed or overlooked just in general?

18 Okay. Great. In our work for the next two
19 days we put together some guidance in what we call our
20 ground rules or in-process guidance. And this is how you
21 work together at your tables, how you work with us, and
22 also just to give you some additional information. So,

1 this is on Page 3 of your packets. And we'll just walk
2 through this very quickly. I think you've been to enough
3 meetings that you know some of these things already. But
4 as Mike Gregoire said to start off, please share your
5 thoughts, ideas, and suggestions throughout today and
6 tomorrow. It's very important that we hear from all of
7 you.

8 Of course please respect each other's
9 perspectives, even when they are different. And we know
10 that there are lots of different perspectives in the
11 room.

12 In your table groups and in the plenary
13 discussions, please speak one at a time. And in the
14 plenary discussions you will be doing those and, if you
15 can raise your hand, we'll try to recognize people who
16 raise their hands in a sequence and an order that makes
17 sense.

18 Again, in the plenary groups and the table
19 groups, please express your interests around key issues,
20 that is, what's important to you and why. What are the
21 burning issues that you're here to talk about?

22 Again, members at table groups can reach

1 consensus, but different perspectives in your report outs
2 are welcome if you can't. All right. We understand,
3 again, that there are a lot of different perspectives.
4 If you can reach an agreement and a consensus, great; if
5 you can't, please represent that in your report outs.
6 Now, on the process group, report outs will
7 come from the table groups. They will be on the record.
8 So, when you're summarizing your discussions, those will
9 be on the record. The court reporter over here will
10 transcribe those. The discussions at the table groups
11 are not on the record. All right. We'll go through
12 these and then you can ask some questions, if you have
13 some about those.
14 In the plenary groups, please identify
15 yourself when you speak so the court reporter knows who
16 you are and we can get that down for the record. That
17 will be helpful.
18 All right. At the table groups -- these are
19 just some mechanics -- please have someone identify who
20 can begin to record the key points -- the key issues that
21 you think are important in your group. That will be on
22 the flip chart. That person or another person can then

1 be the spokesperson for your group when you do the report
2 out. You've all done this many times before, but that's
3 just mechanics that we're suggesting.

4 And, as you can see, there is one BRS staff
5 person at each table group. Now, their role there is
6 just to listen to the discussion and answer clarifying
7 questions, not to be a part of the discussion, to
8 contribute in that sense. Staff cannot make decisions or
9 provide additional input at the table groups, due to the
10 comment periods still being open. That's the rationale
11 behind that. But at the March 13th meeting there was a
12 lot of interest in having BRS staff at the meeting
13 listening to the discussion.

14 After we finish a table group discussion, the
15 BRS staff is going to rotate to another table. And I
16 didn't want folks thinking that they didn't enjoy the
17 discussion, or raise some concerns. But that's the way
18 we designed it so you can have different people listening
19 to your perspectives, and the BRS staff can hear
20 different perspectives at different table groups. And,
21 of course, there are going to be scheduled breaks, but
22 you can take your own breaks and take care of your own

1 needs when necessary.

2 Any questions? Any clarifying questions on

3 these norms? All right. Thank you.

4 EVA RING: One thing I wanted you all to do

5 and I -- many of you may have already done it, but is to

6 just take a couple minutes right here to introduce

7 yourselves to others at your tables, because you're going

8 to be working along with these folks, and it's important,

9 I think, that you are able to at least share who you are,

10 where you come from, why you're here. So, please take a

11 few minutes.

12 We're going to take one more minute because

13 some folks are moving to a table where they can hear a

14 little better.

15 Okay. It looks like everybody's had a chance

16 to introduce themselves. Thank you. So, why don't we

17 get started on our first discussion topic, which we

18 didn't feel you needed any sort of presentation before in

19 order to talk about it.

20 What are your concerns about the regulation of

21 genetically engineered organisms at your table, and why?

22 This is the first topic. We wanted you to spend just

1 about 15 minutes talking to each other about
2 capturing. And we're going to start our next plenary
3 session with the results of the answers to that
4 question. So, remember the ground rules. Some of the
5 facilitators that are helping will bring over flip charts
6 to your table. If you could choose somebody who will
7 capture the thoughts of folks at your table, in 15
8 minutes we'll present out this side of the room, so,
9 begin.

10 I just want to remind everyone -- one second.
11 I'm sorry to interrupt. I see people captioning things
12 on the charts here, and I just want to make sure that you
13 remember that it's very important to have a report out of
14 the things that you're putting on the charts, in terms of
15 actually expressing what the concern or issue is that
16 people have about those topics I see you putting on the
17 charts. So, when you're expressing your concern, make
18 sure that the person understands in order to report out
19 exactly what that is. Because that's what will go on the
20 record, not what's only on the chart. Thank you.

21 One more minute, please.

22 All right. We're going to begin hearing from

1 the tables now, if you don't mind. I thought we'd start
2 at this table back here, since I can't read anything on
3 that little chart. You're going to have to talk it out
4 for us.

5 GEORGE KIMBELL: Should we go first? So, we
6 -- I warned them about my handwriting, by the way. So,
7 I'm George Kimbell from The Center for Food Safety here
8 in Washington, DC. And we had a very interesting
9 discussion at our table. I'll run through it here. Some
10 of the concerns that were raised with regards to the
11 regulation would be organisms crops.

12 We had issues about impacts to farmers --
13 economic impacts to farmers, impacts from field trials
14 from a contamination arm. The issue of post-contamination
15 monitoring of crops and field trials, and overarching
16 concerns that oversight was too narrow.

17 We had concerns that the regulatory framework
18 might be overly burdensome, that the same standards
19 should be -- or might not be applied for regular crops
20 and GE crops with regards to the safety standards,
21 environmental health -- environmental and health
22 standards, that they should be the same as other crops.

1 And the ability of the products to come to market. And
2 then the oversight being science based.

3 We had concerns that the regulations balance
4 oversight with innovation, with regards to food and
5 feed. And, again, that they be science based.

6 We had concerns that the regulations should be
7 robust to ensure the marketability of crops for grains
8 and specialty crops, particularly abroad. And that the
9 regulations should assure economic viability, both for
10 farmers and those who provide the technology to farmers.

11 And we had concerns to the public, to
12 consumers, both to their right to choose and the farmer's
13 right to sow the crops of their choice. Concerns about
14 the integrity of organic, concerns about environmental
15 impacts, concerns about the proprietary nature of the
16 science, interrelated social economic impacts, and
17 overarching concerns it lacks oversight.

18 And finally -- sorry about that -- and finally
19 concerns again with regards to the public sector, that
20 the regulations might restrict potential public good uses
21 and academic involvement.

22 EVA RING: Anyone at that table want to add

1 anything or did he capture your table's views?

2 Anyone else have any questions of this group?

3 Oh, sorry, I didn't turn this on. I think

4 that was part of the feedback, that's why I turned it

5 off.

6 All right. Do we have another group that's

7 ready to present out, wants to volunteer before I choose

8 you? Greg

9 GREG JAFFE: I'm happy to.

10 EVA RING: Thank you.

11 JERRY COURSEY: And if you've got some

12 repetition of the other group, just go over the

13 repetition as new ideas.

14 GREG JAFFE: Great. Greg Jaffe for the Center

15 for Science in the Public Interest. So, we started

16 working around the table and sort of -- to do a short run

17 and talk about what our major -- each person gave sort of

18 one major concern with the regulation of genetically

19 engineered organisms.

20 So, one of the issues was the impact on trade,

21 on production and marketing. So, when it's been approved

22 then what happens at the state level, in terms of its

1 actual impact into the market, and how that might impact
2 trade and other issues.

3 And similarly with -- along with that was this
4 issue of the federal state interactions in the whole
5 regulatory process and how that works. And there were
6 equivalent concerns about that.

7 JANE BERKOW: What exactly are those concerns
8 about? That's just a statement. What's the concern
9 about the interactions, that it won't happen or what?

10 GREG JAFFE: That it's already been --

11 TERRY WALKER: I'm Terry Walker from the
12 Arkansas State Plant Board. And the discussion centered
13 around the existence of federal regulations and previous
14 site regulations. So, if there are federal regs in
15 existence, then the states cannot take more regulative
16 steps.

17 EVA RING: Thank you.

18 GREG JAFFE: Then another one of the issues
19 was whether the system has gotten too burdensome for new
20 traits, or for developers, or for a small developer to
21 get into the system, or to have a product approved. And
22 the question is of -- how -- the regulatory burden and

1 whether that was appropriate, and what impact that might
2 have on new traits or new developers are concerned.

3 Then there was also a concern, I think,
4 raised. I think everybody seems to agree that we should
5 have a science-based regulatory system, but that's always
6 easier said than done. That's where the consensus
7 usually ends. And, so, one of the issues we are having
8 difficulty with is sort of arriving at where you draw those
9 lines of when something is science based and when
10 something isn't science based. And that was a concern
11 that was raised.

12 Another concern was that the system should
13 really be looking at safety first and foremost, and
14 whether the system really does that on a consistent
15 basis, look at safety and not look at other issues, and
16 do it to protect the public interest.

17 One other issue that I think that many people
18 around the table had was the transparency of the system.
19 I think there was some agreement that APHIS has gotten
20 much better and BRS has gotten much better over the years
21 in its transparency, but it's still not consistent across
22 the board in providing as much information to the

1 stakeholders as it should.

2 And then the last concern was that -- an issue
3 about system failure and what happens. So, if there's an
4 incident, or if there's a violation of the regulations
5 that might have impact on the market, then what happens
6 and what is the role of the regulator in that? And is
7 the regulator really paying attention to the different
8 stakeholder concerns when something like that happens,
9 and is it doing enough to prevent those from happening
10 beforehand? Is it really analyzing and understanding
11 that human failures do occur, and trying to really reduce
12 those to the maximum extent possible?

13 So, I think those were some of our concerns.

14 Does anybody have anything to add? Okay. Thank you.

15 EVA RING: Thank you. Any questions of this
16 group? Clarification?

17 Why don't we have this group up here go now.

18 MICHAEL WACH: I'm Michael Wach, yes. I'm Mike
19 Wach from BIO. And it's important I don't -- I think --
20 I'll try not to duplicate anything.

21 The first consensus idea was that the level of
22 regulation should be based on and correlated to a

1 demonstrable risk that is posed by these crops. And
2 that, in doing so, in making that correlation, we should
3 take into account the experience of the agency and the
4 experience of growers. And that includes 17,000 movement
5 notifications, 13,000 field trials, 124 different classes of
6 species that have been tested, and 1,400 different
7 phenotypes or combinations of phenotypes. There's a huge
8 database of experience that can be used to evaluate the
9 risks of these crops.

10 Also addressing the fact that many of these
11 phenotypes can be developed through conventional breeding,
12 and why should there be an unlevel playing field between
13 genetically engineered crops and crops that have the
14 exact phenotype but weren't developed in the same -- used
15 in the same means?

16 We also agreed in science, but -- science-
17 based regulations, but we had a -- sort of an addition to
18 that, and that is that these should be agriculturally-
19 based regulations. They should recognize that these
20 regulations regulate a cyclic process that has sometimes
21 very difficult to meet time frames, the regulations
22 themselves, in compliance with regulations needs to

1 coordinate with the patterns of agriculture to make
2 sense, and also to enable people to comply with them.

3 Of course no one likes unnecessary burdens and
4 unnecessary paperwork. We realize that compliance and
5 demonstrated compliance with the regulations is very
6 important. But, again, keeping with the -- coordinating
7 with agricultural patterns, clients, and paperwork
8 records that need to be asked for by the agency through
9 the regulations needs to recognize the realities of
10 research, the realities of agricultural research, and not
11 be at odds with it, which not only makes it unnecessarily
12 expensive, but also discourages people who are trying to
13 comply with the regulations from doing so.

14 Also we wanted to recognize that, if regulated
15 improperly, the regulations actually can go against
16 APHIS' goal, which is to promote and protect American
17 agriculture. And needlessly burdensome regulations can
18 actually inhibit the innovation of new traits, and also
19 inhibit the adoption of existing traits. The technology
20 is being adopted worldwide, and I think that cannot
21 happen if regulations stop innovation and stop their
22 options.

1 Oh, and lastly, predictability of the system.
2 The processes that are regulated should be such that
3 someone knows what the outcomes are going to be, knows
4 what they're going to be asked for, knows how long it's
5 going to take for that information to be processed, and
6 has a reasonable expectation of getting information out
7 of the system. Did I miss anything?

8 EVA RING: All right. Thank you. You're
9 next.

10 DANITA MURRAY: My name is Danita Murray. I'm
11 with National Corn Grower's Association. And I'll be
12 really brief, because we really I don't think have
13 anything new that hasn't been mentioned.

14 We want the integrity of the regulatory
15 process to be maintained. We'd like to continue the
16 effective flow of the regulatory system. And I guess I
17 should mention we kind of did the same format a lot of
18 you did, we went around the table and most everyone who
19 wanted to give an opinion got mentioned.

20 Under continuing the effective flow of the
21 regulatory system, we did mention specifically a
22 mandatory regulation as a key component of that.

1 We want risk categories -- or it was mentioned
2 risk categories should continue to be scientifically-
3 based. And safety for consumers was also a highlighted
4 concern, including transparency, which has already been
5 mentioned, and then coordination between agencies that
6 nothing falls between the cracks.

7 And, finally, Farmer's Choice was mentioned. The
8 system really should consider all users, and that
9 includes the farmers. That's it for us.

10 EVA RING: Thank you, very much. Yeah -- oh,
11 we have a question.

12 JIM BAIR: Jim Bair with North American
13 Millers'. I just wanted to understand better the last
14 point, please.

15 DANITA MURRAY: Jim, I haven't had all my
16 coffee this morning. How can you do this to me?

17 JIM BAIR: Sorry. We can come back.

18 DANITA MURRAY: This was my point, I think
19 that, you know, in the comments that we submitted
20 publicly for Part 340 we fleshed out a little bit more,
21 you know, some of -- some of the concerns we have, for
22 instance, where economic issues might come into play

1 corrected -- or, you know, correctly under the
2 authorities. And we just want them to stay in their --
3 in the correct context, I guess from looking at issues
4 like that. So, that would be the best example off the
5 top of my head on the lean quarter cup of coffee that I
6 can give you.

7 But, you know, I mean, we, I think, as growers
8 can -- you know, with very -- you know, it doesn't do us
9 any good if, you know, consumers aren't happy, you know,
10 with what we're growing. So, we -- you know, we really
11 do want our customers -- all our customers to -- you
12 know, to be able to be -- you know, to be satisfied with
13 the regulatory system. But at the same time, you know,
14 NCGA's policy has always been to try and provide our
15 growers with as much choice as possible in their
16 operations.

17 And, so, you know, the end that -- the ends
18 that I can't always imagine where, you know, a regulatory
19 system might chill that, you know, we have -- you know,
20 we're going to have to be concerned because there's
21 nobody else to be concerned about that. So ...

22 EVA RING: Any other questions? I'm sorry, I

1 forgot to ask that time. Of course that's when we had
2 the question.

3 BERNICE SLUTSKY: Hi. I'm Bernice Slutsky
4 with the American Seed Trade Association. As Danita
5 said, we discussed many of the same things that have
6 already been described, so, I'll go through those pretty
7 quickly. But we had a lot of discussion on impacts to
8 farmers, to consumers. And one example was impacts for
9 organic farmers, and impacts on marketing.

10 I'm going to move down here. In that
11 discussion on impacts, we also discussed the role of
12 APHIS and making a distinction between a concern that was
13 marketing, and a concern that was risk based, and what
14 APHIS' role would be. And I can't say that we came to a
15 complete consensus on this, but just to say that some at
16 our table felt that APHIS had more of a role in
17 marketing, but others certainly felt that APHIS needs to
18 maintain the integrity of their role in focusing on a
19 risk and a science-based system.

20 Predictability of the system. I think there
21 was agreement that any system that is anywhere, the
22 choice has got to be predictable, not only to the

1 industry so that they understand, you know, when they
2 make an application what's going to happen to that
3 dossier throughout the system; but predictability is
4 important to consumers, too.

5 And that's related to the transparency, of
6 course, that -- I think there was agreement that
7 transparency was important both to the users of the
8 system, the regulatory system, and those who the system
9 impacts. And, again, in the sense of the ultimate users
10 of the product.

11 We had a lot of discussion on having a system
12 that's science based. There was some discussion on
13 concerns related to public health. And I think the two
14 of these were related.

15 And also in terms of our discussion on a
16 science-based system, we talked about who develops the
17 data and how that data is reviewed. Again, I don't think
18 that there was complete consensus, other than it should
19 be science based. And there was discussion on industry-
20 based data and data that might be developed by the
21 regulatory agency itself.

22 We also discussed consumer perception and how

1 that relates to the way a regulatory agency functions,
2 and whether or not it should have an impact on how a
3 regulatory agency functions. And I guess I would say we
4 -- again, there was not consensus on this, where some of
5 the table, you know, again feel that the agency should
6 maintain its focus on a risk-based system, and others
7 that consumer perception might have more of a role to
8 play.

9 Oh, and there was consensus that the
10 regulations -- that there should not be self-regulation,
11 that -- whether a product should enter the system should
12 be mandatory.

13 Did I miss anything from my group?

14 ZELIG GOLDEN: Can I just say one thing?

15 BERNICE SLUTSKY: Sure.

16 ZELIG GOLDEN: My name is Zelig Golden. I'm
17 with The Center for Food Safety. And the one thing I
18 would add is concerning public health. And we had a long
19 discussion about this was -- on whether or not the crops
20 that are approved under the regulations, whether or not
21 the -- that the food safety testing is adequate; and a
22 concern that because there's no mandatory safety testing

1 under the FDA's Rules, that APHIS might have a particular
2 role concerning public health, and whether or not that is
3 adequately addressed in the Rules. And that is a big
4 concern of some of the consumers.

5 NEHRA NARENDER: Just one additional point. I
6 think we had a lot of discussion on the safety issues.
7 And I think we sort of agreed around the table that the
8 safety standard should be applied to all kinds of food
9 products, whether it's a product of a continued crop or
10 whether it's new.

11 EVA RING: Could you identify yourself,
12 please? It helps the --

13 NEHRA NARENDER: Yeah. I'm Nehra Narender
14 ArborGen.

15 EVA RING: I think we have just a few more
16 tables that have not shared yet. Over here.

17 KRIS KRING: I'm Kris Kring with Bayer.
18 I think we have pretty much had very similar
19 conversations to all the other groups. We do all agree
20 that it should be science-and-risk based.

21 Again, the conversation that we kind of went
22 down was coming from the regulations, if there would be a

1 appropriate place to deal with cooperation between the
2 federal agencies, be it, for example, the FDA the Human
3 Health. We agreed that all the companies' products that
4 do go through the FDA process, that safety is not
5 currently an issue of any of the products. But still how
6 can BRS kind of be a leader in the cooperation between
7 the federal agencies? And then also reciprocity between
8 governments. You know, so, example, the US and the EU.
9 I'm not sure if these regulations are the exact place,
10 but is there a way that BRS can help with these two?

11 We did -- one of the things we said, that the
12 biotech traits should be treated like other contaminants,
13 rocks, bugs, other crops that you'll find. And we all
14 agreed that the regulations to help the confidence of the
15 public, but also for the makers of the products, be
16 transparent and clear; and that, you know, maybe
17 guidelines can help -- you know, help in that
18 transparency process. Anything else?

19 EVA RING: Thank you very much. Oh, here we
20 have a question over here.

21 DAVID LEE: David Lee from Edenspace.
22 I just had a quick question on what you meant by

1 that the traits should be treated like other
2 contaminants. I apologize for not knowing exactly how
3 rocks and other contaminants are treated normally.

4 KRIS KRING: Well, for example, you know, in a
5 commodity crop you get so much rocks --

6 DAVID LEE: Oh, okay. So --

7 KRIS KRING: -- or bugs that can be in your
8 product. And, so, a same treatment of GM -- you know, so
9 much, you know, BT-corn in your other corn.

10 DAVID LEE: Okay.

11 KRIS KRING: You know, just like any other
12 product.

13 JERRY COURSEY: Was everybody able to hear
14 that?

15 EVA RING: Thank you. We have one more table
16 back here. No?

17 You set the stage very nicely for our follow-
18 up question, I must say. It's going to be a challenge.
19 First of all, Jane's been trying to capture some of the
20 things that we've been hearing. And this is not perfect,
21 but it looks like there -- I appreciate it when folks
22 said that we had the same concerns. And whenever you can

1 just sort of list the ones that you agree with that the
2 other groups had, it helps us to have a weighing of how
3 important some of these things were. So, thank you.

4 And, Jane, did you want to --

5 JANE BERKOW: Yeah. I just kind of was
6 picking up some major themes that I was hearing. And I
7 kept hearing science-based, science-based, science-based
8 a lot, in terms of -- and caveats making sure that it's
9 met with risk, however that gets defined. And then also
10 an interest -- oh, an interest in making sure that the
11 regulations focus in on agricultural production, and so
12 that it's not sort of something that feels disconnected
13 from, yeah, well, people are out there growing things.

14 And also at the same time not to be so
15 burdensome so that the folks that are involved in
16 creating genetically type crop, particularly for smaller
17 groups, have a fair playing field to participate in
18 supporting the growth of the industry, and supporting
19 production and use of it in agriculture.

20 And then I also heard a lot about the
21 importance of coordinating among federal agencies so
22 things didn't fall into the cracks. And also along with

1 that a lot about transparency, making sure that whatever
2 it is that we did with regulations, that they were
3 understandable by both the consumer and the production
4 farmers. And that -- let's see, transparency. And along
5 with that, too, is the consistency, the importance of
6 regulations being consistent so that everyone who
7 participates and are impacted by them understands what --
8 what's going on with regards to the regulations.

9 And safety. Did I mention that? I think that
10 was also brought up again and again from the standpoint
11 of consumers, as well as the impact it might have on the
12 environment and things like that.

13 And then also going back to the reports of the
14 impact on agriculture production. I heard a lot about
15 organic farmer and making sure that -- the importance of
16 clean crops in that regard, and marketability of crops in
17 both -- in the US and abroad.

18 So, those are some of the major themes that I
19 kept hearing over and over again. Does that resonate
20 kind of with what you were saying?

21 EVA RING: Okay. Thank you. Thank you, Jane.

22 All right. Well, our follow-up question that

1 I told you I'm interested in hearing your discussion
2 around is: After having heard all the concerns of the
3 various groups -- are you going to put this up?

4 JANE BERKOW: Oh, I'm sorry.

5 EVA RING: What do you think at your table are
6 the biggest challenges -- if you just want to say one
7 challenge, that's fine as well -- that APHIS faces in
8 regulating genetically engineered organisms, given all of
9 these concerns.

10 What are -- I really want you -- if you can
11 maybe discuss this for a little while, but I really want
12 you to capture and report out the biggest challenges you
13 think that they face, because we will be addressing those
14 challenges over the next two days. Thank you.

15 Okay. We have one more minute, please.

16 Okay. Thank you, very much. We're going to
17 start our report out and then you can have a break.

18 We're going to start over here, since this was one of the
19 last tables the last time, you can be first this time.

20 And I'd like to remind everyone, please
21 identify yourself when you talk. We know you represent
22 your whole table when you're talking; and then, if you at

1 the table want to add or clarify, identify yourself as

2 well. Thank you.

3 KRIS KRING: Again my name is Kris Kring. I

4 think we thought the main issue was the balance that

5 APHIS has to get between the system for consumer public

6 confidence, which may even include nonscientific risk-

7 based concerns versus a science and risk-based system

8 which is also functional. I mean, what we mean by

9 functionality is that, you know, products can get through

10 on a timely basis and the system can keep working and you

11 don't hinder the industry. Kind of like what we said,

12 particularly some of the smaller players.

13 We talked about another problem is the

14 coordination that they have to do with other agencies

15 because of their authority limits. So, you know, APHIS

16 will only have and BRS will only have certain statutory

17 limitations that they have to abide by, and, so, they'll

18 have to work with other agencies.

19 And then a third one we sort of came up with

20 is kind of around the public perception issue, that

21 there's this -- there seems to be a perception that the

22 current system is not an open system, though it really

1 is. For example, I mean, all petitions are publicly
2 posted, but, I mean, I don't think anybody really ever
3 goes and looks at our petitions. And, so, it's sort of,
4 again, perception problems and trying to overcome that.

5 EVA RING: Thank you. Any clarification
6 questions? Anyone want to go next?

7 ZELIG GOLDEN: We'll go.

8 EVA RING: Thank you.

9 ZELIG GOLDEN: I'm Zelig Golden, The Center
10 for Food Safety. And we have lots of issues. We
11 captured six here on the board. The first, what
12 constitutes sound science? So, is science then provided
13 by industry or should there be APHIS doing science or a
14 third party doing science? We're just going to -- in
15 general what's the standard for sound science? That's
16 what seems like a big issue.

17 The second is regulations, communication with
18 innovation. And as technology evolves how to develop
19 principles that keep up with the technology.

20 The third is, how to best use the resources
21 within a risk-based system.

22 And a fourth is how to allow commercial

1 production of genetically engineered organisms while
2 protecting sensitive markets, such as organic, and the
3 food safety concerns that may be involved with genetic
4 engineering crops, so, balancing the two and keeping the
5 market separate.

6 How to distinguish different products, meaning
7 in the regulatory system should there be different
8 standards for food products, for example, versus nonfood
9 products? And the burdens that would be associated with
10 regulating different products. Essentially should there
11 be a one-size-fits-all approach or not? And we
12 definitely do not agree on that.

13 And the last one is, should APHIS include
14 marketing and public health issues in the regulations?
15 And is that the purpose of the Plant Protection Act?
16 Anything --

17 EVA RING: Thank you. Any questions of this
18 group?

19 JIM BAIR: I'm Jim Bair with the North
20 American Miller's Association. Our group identified
21 three main topics. The first was complexity. And given
22 the dozens and hundreds of new traits in the pipeline,

1 the concern was: Does the agency have the expertise to
2 review all of those in a timely basis, and will that have
3 a chilling affect on the technology or conversely
4 will it also increase people's concerns about
5 food safety, for example? You know, there will be so --
6 such a big burden placed on the agency, will people
7 perceive that they're, you know, giving expedited
8 review?

9 A second subpoint under that was interagency
10 coordination between USDA, EPA, and FDA. I think we
11 agreed that there hasn't been good coordination to date,
12 and what will that coordination look like five years from
13 now when all of these new traits are really coming fast,
14 and they're not just single traits, but multiple stacked
15 traits, and output traits.

16 Resource capacity, does it -- I think it's
17 sort of a repeat -- but does the agency have all of the
18 resources, in terms of people, and money? You know, it
19 was also identified that, perhaps, APHIS was -- had more
20 resources than the other two agencies when it came to
21 coordinating their reviews.

22 Managing stakeholder interests and concerns.

1 The question was given as explosion of traits that is
2 probably coming, does the current regulatory -- does the
3 current statutory mandate, is it able to accommodate all
4 of these new traits that will be coming? Does -- the
5 statutory framework that was created years ago, and what will
6 look like the dark ages in five years. So, do -- does
7 the statute accommodate the agency's -- and all of the
8 concerns of stakeholder interests?

9 And then, finally, is the agency able to
10 explain the change in a way that's comforting and
11 reassuring to all of the stakeholders, particularly the
12 consuming public? It's a highly technical issue. And you
13 can look at the Federal Register Notice, and even people
14 who do this for a living, it's kind of hard to follow a
15 lot of it. It's not always highly technical the
16 underlying issue, but also the way you explain, how is
17 this proposal different from what we're doing now? And
18 do that in a way that people can understand it. Because,
19 if they don't understand it, they're not going to be calm
20 and reassured.

21 EVA RING: Thank you. Any questions,
22 clarification for this group?

1 Jerry, since you're close to this group in
2 front of you, why don't they go next.

3 JERRY COURSEY: The report out they
4 just did.

5 EVA RING: Oh, they did it? This one then.
6 I'm sorry.

7 JERRY COURSEY: Folks over here.

8 JENNIFER ORENDI: Good morning. I'm Jennifer
9 Orendi from Keller and Heckman. Just really quickly.
10 Unfortunately I just realized that we didn't write down
11 our points, because we got into a very spirited
12 discussion and brought up two points that are very
13 overlapping with our neighboring groups.

14 First, there are just industry concerns that
15 some of the proposed regulations, and some of the ideas
16 that are being funded by APHIS could possibly discourage
17 further scientific research. So, there's definitely a
18 concern about over regulation or hyper regulations.

19 And our second main area of discussion was how
20 APHIS can contend with the stigma of the current food
21 safety issues that have come to light just in the
22 regular, if you will, food stream in the past year. How

1 can APHIS play a role and should be playing a role in
2 demystifying what GM products really mean for consumers.

3 EVA RING: Thank you. Any questions? In the
4 back. How about all the way to the back.

5 JERRY COURSEY: Eva, there's a question.

6 EVA RING: Oh, I'm sorry.

7 MICHAEL WACH: No, not a question. I was just
8 volunteering to go next.

9 EVA RING: You want to go next?

10 MICHAEL WACH: It's not a question.

11 EVA RING: I'm sorry. Go ahead.

12 MICHAEL WACH: Okay.

13 EVA RING: Since you have illustrations.

14 MICHAEL WACH: It's the benefit of reaching
15 consensus early AND trying to explore certain members
16 artistic propensities.

17 We have two challenges here. One is a very
18 big picture one, and that is that APHIS is an emergency
19 response agency. And that means that it is dealing with
20 big picture, big emergency for the real public health and
21 plant health costs like the swine flu, BSE and the
22 screening. And BRS may often get the short shrift. When

1 there's a lot of high-level important emergency response
2 going on, BRS may not get the attention it needs from
3 agency and departmental leadership. Which focused on all
4 sorts of things, including all the other things that were
5 mentioned today.

6 So, we go from very high level to very
7 practical. And we feel the other practical challenge for
8 the agency is in compliance, just the time, money, staff
9 resources, the cost of all those things to comply with
10 what we felt are probably the biggest day-to-day
11 challenge for the agency that we see. We see that,
12 perhaps, developing processes that respond to the legal
13 requirements, developing expertise and utilizing that
14 expertise, developing the right documentation. And that
15 can supply a legal challenge. It's probably on a day-to-
16 day basis the biggest challenge that the staff meets,
17 basically -- even though it doesn't really have anything
18 directly to do with the regulations we're talking about
19 today. Any other animals you want to draw?

20 EVA RING: Thank you.

21 MICHAEL WACH: Sure.

22 EVA RING: Here's a question.

1 GEORGE KIMBELL: Oh, more of just a comment
2 actually. I'm at -- George Kimbell with The Center for
3 Food Safety. I mean, with regards to legal compliance, I
4 think the point is to comply with the statute, not to, as
5 you put it, sort of survive legal challenge. So --

6 EVA RING: Since you have the mic --

7 GEORGE KIMBELL: Yeah.

8 LES PEARSON: Okay. I'm Les Pearson with
9 ArborGen. I think we're seeing a lot of the same things
10 coming through. I'm just going to go through our list.
11 I think one of the biggest challenges we identified, a
12 lot of people spoke about new things coming through, and
13 the rate of new traits and new products coming through,
14 and just dealing with the volume that BRS's resources
15 will be able to deal with new products, while maintaining
16 an appropriate level of oversight.

17 Also the challenges of balancing competing
18 interests, innovations, markets, and marketability,
19 especially with novel products coming onto the market.
20 And I can't read my own handwriting. So, again,
21 appropriate regulations, especially when looking for
22 global food and feed applications. And --

1 RACHEL LATTIMORE: I think the balance -- it's
2 similar to what some of the groups folks said --

3 LES PEARSON: Okay.

4 RACHEL LATTIMORE: -- about balancing.

5 LES PEARSON: So, balancing that with the
6 concept. So, we have the swine flu, and the BSE, and
7 then balancing that against all the other things and
8 through all of the food security process.

9 Again, the idea of globalization and how to
10 differentiate between the promise of biotechnology and
11 the hype that's -- perhaps, has been out there.
12 Maintaining organism with integrity. So, again, we're
13 repeating some of the things we've heard earlier on today.
14 And the public's right to choose.

15 Resourcing across USDA. And, again, we've
16 heard that from several people already. And then this
17 one, the thing about the government's fundamental duty to
18 promote a technology that's been thoroughly tested, and
19 has been shown to satisfy environmental and health
20 concerns, and the duty of the government then to promote
21 that kind of technology for the future.

22 Another one was: How does APHIS deal with

1 untruthful claims, or claims of absolute no harm, and
2 then the challenge of how to deal with that kind of
3 standard lookagains (ph).

4 One interesting thing that we're about to look --
5 is the process we're going through today, and have been
6 going through over the past several months, how we
7 turn this process into actually the new regulations.
8 And, so, discussion of how we're meeting today and trying
9 to get to a consensus, but really turning the entire
10 public comment period process into substantive changes in
11 the regulations.

12 And, again, finally coordination among
13 agencies and other authorities. And I guess other folks
14 captured that, so ...

15 EVA RING: Any questions for this group?
16 Thank you. And I think we have one more table.

17 LARRY ZEPH: My name is Larry Zeph with
18 Syngenta. And our relatively small group focused on
19 one major issue that we thought was a big challenge for
20 BRS, and that is to develop an effective communications
21 strategy around the regulatory program with the public
22 and the stakeholders. Because we all know this is an

1 area that gets a lot of media attention, so, it's a
2 ongoing challenge to maintain, et cetera, when you're --
3 particularly a regulatory program being challenged in the
4 public and the press. So, obviously there's a proactive
5 and -- well -- and most of the time probably is spent on
6 reactive steps. But a good example we talked about a lot
7 is, when issues come up in states, APHIS has to work
8 maybe with both a company and a state to react and
9 effectively communicate to the public about an issue
10 that's come up.

11 EVA RING: Any questions for this group?

12 I'm sure BRS or Biotechnology Regulatory
13 Services appreciates your appreciation for these elements
14 and identification of them, so that they're interlined as
15 we work through the rest of the two days.

16 We're going to take a 15-minute break now.

17 And I'd like to remind you -- because I forget this
18 sometimes -- if you use your cell phone or your
19 Blackberry on the break, to turn it off when you come
20 back in here so that we cannot be interrupted. Thank
21 you. We'll come back at 10 after. There's some
22 refreshments in the back.

1 (Pause in proceedings.)

2 EVA RING: I'd like to ask everyone to take a
3 seat. And, BRS folks, direct to another table, please.

4 Okay. Just a reminder to turn off any
5 electronic equipment. Has everyone found their seat?

6 Now I'd like to introduce Clint Nesbitt. He's
7 the Chief of Staff of Biotechnology Regulatory Services.
8 He's going to give you a short presentation on the Plant
9 Protection Act that was requested at our scoping
10 meeting. And you will have a five-to-ten minute period
11 of time to ask any clarifying questions. Thank you.

12 DR. CLINT NESBITT: Can everybody hear me
13 okay? Okay in the back?

14 So, the next portion of our public meeting is
15 really going to be divided into two segments that are
16 sort of interrelated.

17 For this first section we're going to focus
18 primarily on the Plant Protection Act, that is the
19 authority that APHIS has at its disposal for regulating plant
20 pests and noxious weeds. And this afternoon after lunch
21 we'll come back to this topic again and talk in a little
22 more detail about how APHIS is proposing to apply that

1 authority to genetically engineered organisms.

2 So, for now before lunch we're going to focus
3 primarily on the Act itself. And we'll come back to the
4 issue of how we're going to apply it after lunch.

5 I decided I was going to stand down here so
6 that I could be close to you guys instead of hiding back
7 here on the stage behind the podium.

8 So, APHIS' current regulations, as you know,
9 were first promulgated in 1987. And they -- let me see.
10 I have a couple of slides in there, I think. One more.
11 Thank you.

12 And they were set up to establish the -- to
13 regulate the Importation, Interstate Movement and
14 Environmental Release of Certain Genetically Engineered
15 Organisms. In particular the regulation covers those
16 organisms which are, or for which there is reason to
17 believe, are plant pests. APHIS promulgated the
18 regulation originally under the Federal Plant Pest Act of
19 1957, and the Plant Quarantine Act of 1912. Both of these
20 authorities give the Secretary of Agriculture the
21 authority to regulate the movement of articles which are
22 likely to result in the introduction or dissemination of

1 plant pests. So, these are sort of plant pest

2 authorities.

3 So, in 2000 the Plant Protection Act combined

4 both the two Acts that previous regulations were based on

5 -- the current regulations are based on, with several

6 other related authorities, including the Noxious Weed Act

7 of 1974 and several others. So, it sort of consolidated

8 all of the various authorities related to regulation of

9 plant pests and noxious weeds into one overarching

10 authority.

11 The Plant Protection Act, as you can see on

12 the page here on the slides, it grants the Secretary of

13 Agriculture the authority to -- now this is a quote --

14 "Develop regulations in order to protect, control,

15 eradicate, suppress, prevent, or retard the spread of

16 plant pests or noxious weeds." So, that's sort of the

17 intent of the scope of the Act.

18 Now, under the Plant Protection Act, the

19 definition of a plant pest is: "Any living stage of any

20 of the following" -- and according to the list below --

21 "any of the following that can directly or indirectly

22 injure, cause damage to, or cause disease in any plant or

1 plant product." And things that are included in the list
2 you see here, there are things like protozoans, nonhuman
3 animals, parasitic plants, bacteria, fungi, viruses, or
4 viroids, infectious agents on pathogens, and any article
5 similar to or allied with any or the articles specified
6 in the preceding subparagraphs, meaning the list above.
7 So, if you will forward that.

8 Now, APHIS has a long history of using the
9 regulatory authority for the Plant Protection Act and its
10 predecessors to regulate the plant pests and articles that
11 will be like the plant pests throughout the United
12 States. And here are a few examples of these that I'm
13 sure you're all familiar with, or at least heard of.
14 This is a picture of an Asian longhorned beetle on the
15 left. These are potato cyst nematodes in the center.
16 And on the right is a photograph of citrus greening,
17 which is all the rage these days. That's a bacterial
18 disease that's spread by insects.

19 So, we move on to the Noxious Weed Authority
20 in the regulation, I mean, in the Act. A noxious weed is any
21 plant or plant product that can directly or indirectly
22 injure, or cause damage to any of these plants: Crops,

1 including nursery stock and plant products, livestock,
2 poultry, or other interests of agriculture, irrigation,
3 navigation, the natural resources of the United States,
4 the public health, or the environment.

5 So, you can see the way noxious weeds are
6 defined is very different than the way plant pests are
7 defined in the Act. So, if we move on to the next slide,
8 please.

9 APHIS also has a history of regulating noxious
10 weeds under this authority and its predecessors. And
11 here are a few examples of things that are federally
12 considered noxious weeds that APHIS is currently or in
13 the past has used -- or has regulated under this
14 particular authority.

15 The photograph you see on the left is dodder,
16 which is a parasitic plant. The photograph in the
17 center is of giant salvinia, which is an aquatic fern
18 actually. And on the right is a photograph of a field
19 that's been infested cogongrass, which is a form of
20 grass.

21 So, these are just some examples to give you a
22 little bit of perspective of at least the historical

1 precedent that APHIS has had in using the Noxious Weed
2 Authority to regulate things that we determine to be
3 noxious weeds. So, if we can move on to that last
4 slide.

5 So, as you know, the reason we're here today
6 is because APHIS is proposing to revise its regulations
7 to incorporate, in addition to those plant pest
8 authorities, the noxious weed provisions from the Plant
9 Protection Act.

10 So, before we move on to the specifics of how
11 APHIS has proposed to do that, first I'll take a couple
12 of clarifying questions about the Act itself. But then
13 we're going to have a little bit of discussion to explore
14 sort of the application of this to GE organisms. And
15 then we'll come back to the specific proposal that we've
16 made after lunch.

17 So I guess with that I can -- where's our
18 moderator -- I'll take a couple of clarifying questions,
19 and then we'll move into some discussion.

20 EVA RING: Are there any questions for Clint
21 about the authority?

22 ROBERT BOONE: Good morning. My name is

1 Robert Boone. And I would just like to pose to you an
2 examination, a careful look at your definitions of plant
3 pests and noxious weeds. While you were explaining
4 those, I said, well, sometimes in my life I've been a
5 noxious weed or a plant pest in my day. Perhaps I'm a
6 plant pest right now. But I say to you, this -- the way
7 this language is written, it's like we're at war against
8 nature. We're at war against nature. And we are a part
9 of nature. And I say that we don't realize that we're a
10 part of nature, but we really are. And there are other
11 ways to get about feeding ourselves that don't include
12 cancer-producing chemical agents and other manipulations
13 of nature that we don't know in which way of what result
14 we're going to create.

15 And, so, I always like to think about the
16 principle of least amount of harm, and to do the job
17 without going into areas where we aren't sure where we're
18 going. Like today one in three of us in this room will
19 probably come down with cancer, a serious cancer. You
20 know 75 years ago cancer was a very minor thing, very
21 minor, and it was only eight years ago it was one in five
22 who would get cancer. So, what is it going to be in five

1 years more?

2 The reason we're having this cancer problem is
3 for this same war against nature. It's the war -- it's a
4 very limited perspective on how we see ourselves in the
5 world. And we want to chemical, and make it convenient,
6 and to do things that are really harmful to ourselves and
7 we don't realize it.

8 So, during lunch I would invite you to think
9 about how you personally -- this war in your heart.
10 Because that's where it comes from is from ourselves, how
11 we are at war with nature, and how we can make peace with
12 nature and not perpetrate this war. Thank you.

13 DR. CLINT NESBITT: Thank you for that
14 perspective, Mr. Boone.

15 Do we have any other questions? Over here.

16 ZELIG GOLDEN: My name is Zelig Golden. I'm
17 from The Center for Food Safety. And a quick question
18 under the Noxious Weed Authority.

19 DR. CLINT NESBITT: Yes.

20 ZELIG GOLDEN: You gave some examples of the
21 things that you've done in the past. And I'm just
22 curious to know APHIS' perspective on if Noxious Weed

1 Authority is related to a certain band of known noxious
2 weeds, or if it also is -- under its regulatory authority
3 it's required to look at new potential noxious weeds, or
4 things that could become noxious weeds. And there's some
5 examples that we could think about, but we'd talk about
6 that --

7 DR. CLINT NESBITT: Sure.

8 ZELIG GOLDEN: -- after we see what the Rule
9 says.

10 DR. CLINT NESBITT: Well, I think historically
11 the way that APHIS has used the Noxious Weed Authority is
12 that you sort of know that something is a noxious weed
13 because of its behavior, either someplace outside of the
14 United States or because it's already here in the United
15 States and is starting to have this kind of damage. So,
16 it's sort of you're already able to observe the potential
17 harms, and damages, and injuries that this plant is
18 causing, and that comes to the attention of the
19 authorities and then we choose to regulate.

20 But as far as I know, I don't know whether its
21 been used to sort of predict whether something will be a
22 noxious weed. Historically I don't know if APHIS has

1 used it that way. It's sort of like, when you see
2 something that is behaving like a noxious weed, and
3 enforce regulation upon it.

4 KEITH REDING: In the definition it says a
5 product that can directly, not may directly.

6 DR. CLINT NESBITT: Yes. Yes.

7 KEITH REDING: So, maybe that answers your
8 question.

9 DR. CLINT NESBITT: Yeah, that's a good
10 point. Thank you.

11 EVA RING: You'll have the definitions -- by
12 the way, thank you for sharing that -- at your table on
13 Page 4 of your packet.

14 Any other questions for Clint?

15 DR. CLINT NESBITT: Any other questions about
16 the Act itself?

17 EVA RING: About the Act. Thank you, Clint.

18 DR. CLINT NESBITT: Okay. So I think I'll
19 turn it over to Eva now --

20 EVA RING: Yes.

21 DR. CLINT NESBITT: -- for some discussion.

22 EVA RING: Jane has put up on the screen the

1 question we'd like you to address at your table. So,
2 this last comment that you made over here at this table,
3 you might be able to address it actually in this
4 question. Considering the authority that Clint has just
5 described to you under the Plant Protection Act, are
6 there any particular organisms, or some characteristics
7 of organisms that you think do pose risks and should be
8 covered by the regulation; if so, which ones, what risk
9 do they impose?

10 And contrarily we also want you to ask
11 yourselves a second question, which is -- considering the
12 authority: Are there some that you consider so safe that
13 they can be excluded from regulation or be deregulated?
14 So, why would you think that? We want you to share the
15 rationale behind what you offered here as suggestions
16 under those categories. And you have half an hour to
17 discuss this, because we think it's going to be a good
18 discussion at the tables. Thank you.

19 Okay. Excuse me. I'd like to interrupt for
20 just one minute. I was checking our schedule. We are
21 almost a half hour behind where we thought we'd be. So,
22 I was wondering if everyone would mind terribly, since we

1 did bring in the -- most of you, at least -- we brought
2 in the lunch, if we cut lunch to 45 minutes instead of an
3 hour for one thing; is that all right? Anybody have a
4 major issue with that?

5 And, if the people who are reporting would
6 mind seeing Jane at some point during that 45 minutes
7 with your notes, she's going to try and expedite the
8 report-out process a little bit as well. And this is
9 Jane.

10 So, what we thought we'd do is break for lunch
11 as we had planned at this time, because the sandwiches --
12 for those that did order sandwiches -- are in the back on
13 the table organized by category. Apparently you'll see
14 your sandwich and then you can pick whatever chips or
15 cookies that you'd like. So, we'll plan on reconvening
16 at quarter of. Thank you.

17 Oh, for those of you who weren't here in the
18 beginning when I gave directions, if you didn't order a
19 sandwich or you came in late, the cafeteria is right up
20 the hall past this room, take your first left and it's on
21 the right. Thank you.

22 (Pause in proceedings.)

1 EVA RING: We're going to convene again, so,
2 please take your seats. We have a few new people I --
3 that I saw walk in that weren't here this morning. So, I
4 just want to let you know that what we are doing right
5 now is, we received a presentation on the Plant
6 Protection Act. And that's the Act under which BRS
7 derives its authority to regulate genetically engineered
8 organisms. And the tables have all been doing a work
9 group task and answering two questions; basically
10 considering its authority, what organisms should be
11 covered by the regulation, that people at the tables
12 believe should be covered, and why, and what things --
13 what organisms do we consider to be so safe that they do
14 not need to be covered under the regulation and -- or
15 could be deregulated. So, those are the questions that
16 were posed to the tables. And now the tables are going
17 to report out what ensued with that discussion. Some of
18 the folks have given their table discussions to Jane,
19 some didn't. So, we didn't really get a whole
20 compilation of it. I'd like you all to report out your
21 goals, and Jane will try and capture the essence, the key
22 points for those that she didn't get.

1 Could we start with the table all the way in
2 the back, since you didn't get to Jane again. So, if
3 you'd start reporting the answers to your question there.

4 Thank you.

5 LARRY ZEPH: Okay. We had a long discussion.
6 It was very good. And what we did on -- as far as
7 organisms that need to be regulated, the first question
8 was basically APHIS can boil that down to questions
9 around survivability of the organism or toxicity, which
10 fits very nicely in the language of the definition.

11 And then clearly in terms of what could be
12 exempt from regulation as well or excluded would be those
13 organisms that have a track record of safety. And that
14 would be more of a case-by-case analysis. Clearly, that
15 would have to be something that would have to be either
16 sorted out in the regulations or just case-by-case also.
17 We talked too a lot about how there's a lot of gray areas
18 still for developers, for example, to decide whether they
19 fall under these definitions under PPA. Certainly
20 certain bacteria and microbiology, et cetera, it can be a
21 challenged to determine whether they would be even
22 regulated under this statute. So, clearly that would be

1 something that would have to be either sorted out in the
2 regulations or just case-by-case also.

3 We thought also it's important to -- in
4 determining either what could be exempt, or what should
5 be regulated, it's not just the characteristics of the
6 organisms, but how it's used that should be factored in.
7 And that's it.

8 EVA RING: Thank you. Any clarifying
9 questions? All right. What other groups did not get
10 their notes up to Jane? Could you report out your
11 results? Thank you.

12 RUSSELL WILLIAMS: We put most of ours -- I'm
13 Russell Williams, American Farm Bureau. We put most of
14 ours in the form of questions, because there was kind of
15 a lack of understanding of what the specific terms mean,
16 and what they would mean going on into the future.
17 Something like: If the introduction of a GE plant
18 negatively impacts -- of course as a farmer changes
19 operation -- it should be considered a noxious weed. And
20 these are kind of congenital to impacts, not direct
21 physical damage to a plant, but change -- introduction of
22 a plant changing economics or operations.

1 We wanted clarification on what it really
2 means, direct or indirect harm. Does one come first?
3 Does direct harm have to come first for them to qualify,
4 indirect and (inaudible)
5 Should GE plants be subject to the same
6 regulations and safety standards as other organisms
7 covered by this authority? So, are we specifically
8 looking at GE organisms as being different, or is the
9 authority enough that it can cover all types of organism,
10 regardless of the nature?
11 Does low level presence constitute a noxious
12 weed? Are market damages enough to regulate under this
13 new authority? Does indirect harm -- any direct harm
14 stand alone; if so, what's the trigger for indirect
15 harm?
16 In the definition we wanted clarification on
17 what other interests related to agriculture means.
18 Should we expand interstate movement exemptions for
19 things like research materials, stuff like that? And the
20 examples of this Arabidopsis plant. And another question
21 was should there exist a process for partial regulation?
22 And I think the only thing that we pretty much

1 agreed on, is that there should be an expedited way to
2 transfer, facilitate research material when we research
3 institutes with the university and the lab.

4 EVA RING: Thank you. Any clarifying
5 questions?

6 All right. I'm still going to go around and
7 just have you summarize your key points, even if you gave
8 your remarks, because I'd like to have it on the record,
9 what the groups talked about as well. So, who would like
10 to go next?

11 ZELIG GOLDEN: Should we still go through it?

12 EVA RING: Yes.

13 ZELIG GOLDEN: Zelig Golden for The Center
14 for Food Safety. And some issues first, you know,
15 direct, indirect effects, as the other group said,
16 whether they should be independently addressed. And
17 specifically there's been a precedent by APHIS to require
18 direct effects first in order to get to indirect
19 effects. And a question was raised whether or not --
20 given that GM was a different technology since the
21 original application of the regs, maybe direct effects,
22 indirect effects should be assessed individually without

1 relationship. And indirect economic effects -- or
2 physical effects, should those be independent?

3 And then we identified three basic categories,
4 federal lists -- federal listed weeds should be covered,
5 plants with traits like those on the federal list should
6 be covered, and then emerging traits should also be
7 covered. And one specific example is herbicide tolerance
8 and the indirect effects that it has on the environment.

9 And a question was, should there be a
10 presumption -- there should be a presumption of risk
11 where potential exists in new traits. That's it.

12 EVA RING: Thank you. Do we have a -- any
13 questions? Over here. You'd just like to go next.
14 Please.

15 KRIS KRING: Well, we agreed that regulation
16 was proper. And that, you know, using the NAS definition
17 of genetically modified is the trigger. It should be --
18 we believe it should be trait-based analysis, you know,
19 also plant biology.

20 We do believe there should be an exclusion
21 list. And, again, it would go into APHIS and then the
22 exclusion list would be looked at. So, it's not a -- we

1 don't believe a developer would say the exclusion and not
2 put it in, so, just be clear.

3 So, and then criteria develops. And we
4 believe history -- say use could be one for some of the
5 common first generation ones. And our reasoning is that
6 these have really been scrutinized, even more than
7 traditional other kinds of plants that even come out of
8 traditional breeding. So, there's a lot of evidence to see
9 if it is or is not acting like a plant pest or noxious weed.

10 Another one may be -- another category for
11 exclusion may be intragenic DNA. I'm going to skip this
12 point because after we talked about it we thought it was
13 outside the scope.

14 We do believe that you should have to have a
15 direct physical loss, and that the historical precedent
16 should be, again, that biotechnology should be treated
17 the same as, you know, the historical view, that there is
18 not a reason to treat it differently from a scientific
19 view, but that it should be looked at. Thanks.

20 EVA RING: Thank you. Any questions? All
21 right. Another group that would like to go next.

22 RAY DOBERT: We don't have our notes written

1 down. My name is Ray Dobert with Monsanto. We didn't
2 write them down on the board.

3 We had a discussion with regard to the initial
4 applicability and appropriateness of using the plant
5 pests definition to -- as a policy matter to get
6 genetically engineered organisms into the scope of the
7 regulations. And there was general agreement that it was
8 -- it fit the need at that point in time when the
9 regulations were initially developed.

10 We had a discussion, then, around a particular
11 product which is under review currently, the alpha
12 amylase corn. And there was some discussion with regard
13 to how would one work through integration of the plant
14 pest potential of that product. There was concern raised
15 with regard to issues that it would raise for the starch
16 industry, and the impact it would have on the value of
17 corn.

18 The next stop that we talked about is -- you
19 know, as a potential solution for something that the
20 particular plant pest or noxious weed characteristics
21 were difficult to determine would be a commercial permit,
22 something that would still remain regulated under APHIS'

1 authority, that might be an appropriate option.

2 We have a little bit more questions again with
3 regard to, so, what are the specific harms that APHIS is
4 trying to prevent? You know, what are -- how does APHIS
5 characterize those? What would be the things that they
6 would be trying to prevent, if they fell outside of
7 potential damage to the environment, or impact to
8 agriculture? How -- you know, we sort of just raised
9 questions that APHIS would need to be able to come to
10 some conclusions around that.

11 There was a general -- everyone I think
12 generally agreed that it was preferable to get
13 genetically engineered organisms within the regulations,
14 and then specifically go through the process of excluding
15 particular organisms, or classes of organisms. We had a
16 little bit of a discussion with regard to things that
17 might produce the same protein, or having some of the
18 same characteristics. I think that's just about it.

19 EVA RING: Any questions? Yes.

20 DANITA MURRAY: My name is Danita Murray, with
21 National Corn Grower's Association. When you mentioned
22 amylase effecting potentially valuable corn, can you just

1 elaborate on what that means?

2 Hey, you've had your coffee, Jim.

3 JIM BAIR: The particular -- and this is in
4 the public documents, so, we're not talking about
5 anything here. But there -- alpha amylase is a very
6 powerful enzyme. And its purpose is to break down
7 starch. So, for food manufacturers, the corn starch is
8 the principle ingredient. So, any kind of, for example,
9 extruded snacks, corn-based breakfast cereals, taco
10 chips, brewer's grits for the beer industry, batters and
11 breadings on things like fried chicken, fried shrimp, and
12 so forth. If that starch has been degraded by alpha
13 amylase, it would render the corn product -- either it
14 would dramatically diminish its value or destroy its
15 value. And, so, there is a coalition of industry groups
16 that has submitted comments on -- to the petition to
17 deregulate that particular event, expressing concern
18 about that and that alpha amylase enzyme in this
19 particular trait.

20 EVA RING: Thank you. For clarifying that.

21 Is this table -- which tables have not gone? Did you
22 raise your hands? We'll start it right here.

1 MICHAEL WACH: Thank you. Our flip charts we
2 have an error. We struggled for about 20 minutes just
3 trying to answer the questions which -- you know, coming
4 up with characteristics and organisms that should or
5 shouldn't be within the regulations. We certainly felt
6 that the decision had to do with the species and the
7 trait, but we couldn't really get past that to say which
8 species, what groups of species, what traits, what groups
9 of traits.

10 And then our discussions, we went in a
11 different direction, and that was the same way that BRS
12 has decades of experience working with genetically
13 engineered organisms. There's another program at APHIS,
14 the Plant Pest Quarantine Program, that has even longer
15 years of experience, many decades, working with the
16 determination of something being a plant pest or a
17 noxious weed. And it would be unwise for BRS to set up a
18 separate system that either would be duplicative or in
19 conflict with determinations -- very similar
20 determinations made by another organization that has
21 already got expertise, processes, guidance in place. And
22 that the best we could come up with was that those --

1 that there be -- if there is going to be a separate
2 system, that it be developed parallel and in close
3 consultation so that you don't have two different
4 programs within the agency potentially deciding the same
5 question differently. And that's where we got in your
6 discussion. I don't know if there's any other --

7 JERRY COURSEY: Can you folks hear?

8 (No.)

9 DAVID LEE: Okay. I'm sorry. To follow up on
10 what Mike just described, in that we also discussed a
11 little bit that there should -- there should also be
12 options for mitigation -- mitigating factors. So, for
13 example, if a product is identified as having weed
14 characteristics, that doesn't necessarily mean it can't
15 be fully developed, further tested, there just should
16 also be options for mitigating factors.

17 EVA RING: Thank you for clarifying. This
18 table over here.

19 CLAUDETTE DEATHERAGE: I'm Claudette
20 Deatherage from Monsanto. We, like this table, struggled
21 also with the questions. And I think we kind of combined
22 the two questions as we went along. And we certainly

1 were looking -- the outcome was that we agreed and really felt
2 that, yes, APHIS does have the authority to regulate
3 it -- and we stopped to GMOs -- to regulate GMOs under
4 the Plant Pest Act. And they should continue to do so.
5 And we felt that the history of safe use was really a
6 primarily factor in that degree of regulation.

7 Do you want to add something?

8 DANITA MURRAY: Yeah. But in that discussion
9 on, you know, APHIS having initial authority to be, you
10 know, the authority to regulate GMOs, I -- you know, we
11 just wanted to make it clear that, you know, we don't
12 intend that APHIS, you know, would always find these GMOs
13 to be plant pests or noxious weeds. I mean, it's just
14 that they have the initial authority over these types of
15 products. And I think that's important.

16 EVA RING: Any questions for that group? Have
17 we gotten everybody? I think what's happened here is
18 interesting, is -- first of all, I want to say that, if
19 you struggle with the questions and you do decide on --
20 at your table that there is something else that you can
21 get your hands around and address, that is fine. BRS
22 made it clear to me that, when I give the instructions

1 for you to answer certain questions at the table, they
2 really rallied around something else they really wanted
3 to talk about and report out on, that's fine. We sort of
4 like to keep to the overall topic, but it could be a
5 different aspect that you start to engage around, and
6 that's okay.

7 I also think what's happened here is the next
8 question -- some of you already made a good start in
9 answering the next question, which will follow the
10 presentation that Clint's going to give you now about --
11 a little more detail about the application of the Noxious
12 Weed Authority, that part of the Plant Protection Act.
13 He wanted to tell you a little more now. And then we
14 were going to ask you another question, which many of
15 you, I think, have made a good start at answering.

16 DR. CLINT NESBITT: So, as Eva said, we're
17 sort of continuing this deal of discussing the Noxious
18 Weed Authority, and we're moving on from just -- from
19 literally what the Plant Protection Act says, and giving
20 more of the specifics of what it was that APHIS proposed,
21 sort of our goals for proposing to incorporate the
22 noxious weed provisions into our regulations. And also

1 to kind of explore a little bit into what our thinking
2 was at the time, the reaction that we've gotten from the
3 public comments so far to kind of reiterate to you sort
4 of what we're hearing about our proposal. But also to
5 kind of summarize from you sort of where we are right
6 now, in thinking sort of what our permanent thinking is
7 about this particular topic based upon the comments that
8 we have so far. And then I think you will sort of
9 continue with this topic and discussion quite a bit
10 further.

11 So, to begin with I just want to start by
12 saying that the goals of incorporating a Noxious Weed
13 Authority of the PPA into the proposed regulations is to
14 recognize the new laws, both the Plant Pest and the
15 Noxious Weed Authority provided by the statute.

16 In particular we were seeking to prevent
17 potential gaps in oversight. For example, for those
18 organisms that may be unlikely to pose a plant pest risk,
19 but which could pose a noxious weed risk. It enabled
20 APHIS to consider a broader range of harms, such as those
21 that could be posed by noxious weeds, things like entry
22 or damage to public health and the environment, for

1 example.

2 We had hoped that it would improve the clarity
3 and transparency of the way that we do our risk
4 assessments.

5 And, finally, we propose this in order to
6 enable APHIS -- this is start of a minor note, but it's
7 an important one -- it enables APHIS to regulate
8 nonliving material derived from a GE plant, if APHIS
9 concludes that such material is likely to pose noxious
10 weed threats. So, that's just more on the flip note in
11 the bigger scheme of noxious weed things, but nonetheless
12 it's an important point.

13 So, in terms of sort of where we were at the
14 time we made the proposal -- as I think several other
15 people have mentioned, APHIS does have a long history of
16 using the Noxious Weed Authority to regulate plants and
17 the impacts of plants. And we do feel, when we proposed
18 the Rule and still now, that the experience and
19 precedence that have developed -- been developed by
20 APHIS' Noxious Weed Program, for example, will provide a
21 guide for how we regulate GE plants under the same
22 authority.

1 So, it's important to note -- and I think
2 maybe Mike Wach was the person that sort of raised this
3 issue, that APHIS must consistently apply this authority
4 to GE plants and the way that we've been applying it to
5 non-GE plants. So, this sort of follows that our intent
6 is that, any kind of noxious weed risk assessment that we
7 would do under this authority for GE plants, would have
8 to be similar to and consistent with the same kinds of
9 assessments that we're currently doing for noxious weeds
10 under the Federal Noxious Weed Program.

11 So, in response to those comments, we got a
12 very broad range of different opinions, sort of from both
13 ends of the spectrum and everywhere in between.

14 In addition to responding to the issue of
15 whether or not to incorporate the Noxious Weed Authority,
16 most of the comments on the topic were more about how we
17 were going to incorporate this regulatory. In general
18 many of the commenters focused on sort of a very broad
19 range of significantly powerful impacts that are
20 encompassed within the noxious weed definition. Things
21 like, what does the interest of agriculture mean, and
22 what does public health mean, and impacts to the

1 environment and those types of things.

2 In general -- and this is, again, a very broad
3 generalization -- but the industry and trade groups
4 tended to raise concerns that APHIS should narrowly limit
5 its interpretation of the noxious weed definition. So
6 that it was clear, for example, the economic or aesthetic
7 impacts alone, in the absence of physical, significant
8 damage, didn't make something a noxious weed. So, I
9 think I kind of heard that same thing echoed in this
10 group.

11 On the other hand some other groups were
12 arguing more that they wanted APHIS to go the other
13 direction, and to interpret it as broadly as possible, as
14 inclusively as possible, especially with regards to how
15 we interpret things like impacts of the environment, to
16 public health, marketing, or product quality impacts,
17 such as indirect impacts on organic agriculture, for
18 example.

19 So, finally, one of the issues seemed to be
20 centered around this basic question of where APHIS would
21 set the bar, for what -- how noxious does it have to be
22 before we decide that it's a noxious weed? That seems to

1 be kind of the heart of the public comments that we've
2 gotten so far. And many people felt that if, as we
3 argued in the proposed Rule, that we intended to set the
4 bar more or less the same way that we set it for regular
5 non-GE noxious weeds, that it might in effect set the bar
6 too low for genetically engineered plants. And that in
7 effect only those plants that are so noxious, are so
8 weedy that they're almost noxious weeds to begin with,
9 really only those things might stay within the regulatory
10 authorities. So, again, this is sort of the feedback
11 that we're getting from the public.

12 So, moving on to my last slide, just to kind
13 of summarize where we're currently thinking about that
14 kind of feedback that we've gotten from the public. I
15 think we do still intend to incorporate the Noxious Weed
16 Authority into the proposed regulations. When we think
17 of doing so, allow regulatory oversight of GE organisms
18 that may not fall currently within our jurisdiction,
19 which is based on the Plant Pest Authority. APHIS does
20 also consider that the proposed provisions could improve
21 clarity and transparency of how we do our risk
22 assessments, and it would enable us to consider a broader

1 range of factors that could be potentially injured by a
2 genetically engineered plant, if it were determined to be
3 a noxious weed.

4 However, it's important to note -- and this is
5 kind of the point that I made earlier and I think others
6 have sort of been trying to get at -- we feel that it's
7 not justifiable from a regulatory or a scientific
8 standpoint to hold GE plants to a different standard than
9 non-GE plants when we're using the same statutory
10 authority for both. So, we just can't have that kind of
11 double standard.

12 So, given that, APHIS feels that we do need to
13 develop better or clearer criteria and decision making
14 standards in order to better inform the public of how it
15 intends to apply the APHIS -- the Noxious Weed Authority,
16 sort of where that bar is going to be. And that we also
17 think that those criteria and standards will likely need
18 to be put into the regulations themselves.

19 So, with that I think we have actually a
20 handout that kind of summarizes the information about
21 sort of our current thinking, and summarizes some of the
22 information that I just gave you. And we're going to use

1 that in a couple of discussion questions, I think, to --

2 EVA RING: Just one, one question.

3 CLINT NESBITT: One question to start the
4 next discussion.

5 EVA RING: I think -- do we have the papers
6 that cover this? All right. As we give presentations
7 the way that Clint just did, you all -- instead of
8 getting a copy of the words on the PowerPoint, BRS has
9 been good enough to actually produce papers that cover
10 that and more. And they'll provide them at the time of
11 each discussion that you're going to have. So, they have
12 a paper here on the Noxious Weed Authority, and what he
13 just explained about how they're going to interpret that
14 and the intent.

15 And that's for your reference, as you attempt
16 to answer this next question, which is: Given the
17 breadth of the definition that you just heard, do you
18 think that there are practical constraints if you -- in
19 regulating genetically engineered plants using the
20 noxious weed provision?

21 Obviously, given some of your remarks in the
22 session right before this, I think that you might. So,

1 if you would be so kind as to either extract from what
2 you already talked about some of the things that you
3 already came up with in your answers to this question,
4 and also deliberate a few more constraints that you think
5 there might be to using the Noxious Weed Authority to
6 regulate genetically engineered organisms. Is that
7 clearer?

8 All right. Let's see, how long are we given
9 for this? About 20 minutes you think? I think 20
10 minutes max. Thank you.

11 We're going to take one more minute, so,
12 please try and wrap up.

13 Okay. We're going to begin our present-outs
14 now. We're going to start with this table up here.

15 DANITA MURRAY: We really only had a few
16 major, major discussion points. One was, again -- you
17 know, again echoing some of the thoughts that have --
18 that you as a group come up with prior. One was, you
19 know, certainly that current regulations seem to be
20 adequately directing the regulation of GMOs, so, that --
21 stick with the current program.

22 Another big concern was the -- you know, when

1 it comes to practical aspects, was it over -- you know,
2 the overly broad nature of the definition of what a
3 noxious weed is. The issue of -- you know, I brought up
4 the issue of -- two issues, actually, one of, you know,
5 just, again, economic harm, not being simply enough to
6 get a determination that an organism is a noxious weed.

7 And then, finally, we're going to just kind of
8 copy Mike over here. One of the issues we brought up
9 that we didn't know a lot about but crossed our minds
10 was, you know, unintended consequences for the PPQ side
11 of the noxious weed question. You know, if you have
12 concerns that a definition is too broad for GE, you know,
13 where do you -- how do you make sure that decisions get
14 made on the application of that definition on this side
15 that don't somehow negatively effect something on the PPQ
16 side? But we didn't have any PPQ experts here, and I'm
17 certainly not one. So, it was more of a question with
18 yet no solution.

19 EVA RING: Any questions for this group? All
20 right. Why don't we move over here.

21 MICHAEL WACH: Okay. Well, in essence we sort
22 of went through a lot of discussion and sort then echoed

1 what we heard in Clint's presentation. But the first
2 constraint or question we had about this -- the use of
3 this new authority is, what is the consequence of a
4 noxious weed determination? Basically is it -- is that
5 the end of the thought process for the agency, or will
6 there be discussion of mitigation to find the measures
7 that allow -- the same way that they do now for plant
8 pest risks, they analyze whether or not field trials and
9 deregulation can occur in ways that do not result in the
10 release of a plant pest, and would there be a similar
11 two-step determination for a noxious weed.

12 Then we -- again, latched on to something that
13 Clint talked about, and that was the development of
14 criteria and standards. And Clint's slide mentioned that
15 these would be good in the regulations, which then
16 brought up a question for us, since there -- the -- when
17 they've got their mind wrapped around what those will be,
18 what is the process for developing those? Will that be a
19 process -- some sort of a process where there will be
20 just an open discussion, sort of like what we're doing
21 now?

22 And repeating ourselves and other groups, that

1 however this develops, that it not develop in any way
2 that would conflict with existing authority, existing
3 analyses, existing process and the expertise within the
4 agency. Is that pretty much it?

5 EVA RING: Any questions? Thank you.

6 TERRY WALKER: As has happened all day, we
7 have a lot of the same topics or concerns that have been
8 expressed at other tables.

9 First off we decided that under this authority
10 there really is no history for GE plants to be judged
11 against, as far as whether they are noxious weeds or not,
12 or a weed in the statute. So, we have this new ground.
13 And APHIS will have to be -- or BRS is going to be
14 concerned and try to remain within the parameters of what
15 the statute say.

16 Explain the authority, and in parenthesis,
17 cautiously. You don't want to interpret the statute so
18 broadly that you get into a lot of other areas and bring
19 on more than what you can handle. The broad
20 interpretation of the statute could encroach on authority
21 of other agency's expertise. It would be aiming to avoid
22 duplication of effort, while at the same time leaving the

1 issues to subject matter experts.

2 A discussion came up about trying to regulate
3 associated industries because the product is a plant
4 product. And, so, you want to be careful about how
5 broadly you get into that area.

6 One of the constraints is explaining the
7 evaluation and determination of noxious weed status to
8 the public and to the effected parties. There has to be
9 some basis. I think it was talked about earlier, to put
10 that criteria and those factors in this -- in the
11 regulations, and that's probably a pretty important
12 point.

13 APHIS needs to explain the standard of a
14 determination, is it an absolute assessment or comparing
15 it to conventional crops? So, is this going to be
16 something that there is some history to compare it to, or
17 is it going to be judged on its own merits? The Noxious
18 Weed Authority is not designed to evaluate GE crops.
19 It's being used to accomplish that task and, so, there
20 are problems associated with approaching it in that
21 manner.

22 Anything else?

1 EVA RING: Questions?

2 KRIS KRING: We struggled with this question
3 quite a bit. We kind of looked it at it as if it's code-
4 fined with traditional crops what's already addressed in
5 the GE studies, animal feed studies. So, a lot of that
6 data is already there. So we actually thought about it
7 more on maybe future products that are coming out and
8 closing that gap. And the example we used to help
9 ourselves was maybe an aquatic plant used for a biofuel,
10 or a pharmaceutical, or whatever use, and that could then
11 effect the navigable waters or irrigation. And, so, that
12 helped us kind of understand kind of the need for
13 addressing it.

14 EVA RING: Thank you. Any other questions?

15 RACHEL LATTIMORE: We struggled a little bit
16 as well with what was intended by practical constraints.
17 And, so, we, again, had some differences of opinion and
18 phrased the, some of these things in the form of questions.
19 And some on one side or the other. But we certainly agreed
20 that the agency does have broad discretion. And, you
21 know, that led to a discussion about discretion was --
22 you were going to exercise. An example was given about

1 how within EPA's regulation pips under FIFRA , there
2 are different data and testing rules for GE plants, but
3 there is the same statutory safety standard. So, you
4 know, that example was put out there as something that
5 the agency might look to.

6 For GE crops the question was raised, should
7 market preferences be considered in determining what is
8 or is not a noxious weed? And also the issue was raised
9 as to whether APHIS should be considering environmental
10 impacts of crop systems as a whole. And the example
11 given was herbicide use, should that be considered
12 something that -- again, maybe a different aspect of the
13 discussion before about agencies, and authorities, and
14 that type of thing.

15 EVA RING: Are there any questions?

16 NATALIE WEBER: I'm Natalie Weber from
17 Pioneer Dupont. We -- I guess we had probably a lot of
18 similar things from the other tables. We felt that the
19 definition was way too broad. But, I guess, had a little
20 discussion about, you know, what -- can we boil it down
21 to real safety concerns with real impacts on the
22 environment and so forth? But then I guess ultimately

1 the existing system has been working for non-GE noxious
2 weeds, you know, and that system why should it be
3 different for GE crops. And, you know, and in a way the
4 determination system will help pinpoint specific
5 criteria, because it's very difficult to define those
6 things for the noxious weed definition.

7 EVA RING: Thank you.

8 NATALIE WEBER: Thank you.

9 EVA RING: Any questions? Jerry.

10 JERRY COURSEY: Anyone over here?

11 BERNICE SLUTSKY: Well, we had a pretty lively
12 discussion, I think. So, some of our points will be,
13 again, in the form of questions, because we had -- I'd
14 say we weren't in complete agreement on all of it. But
15 one fundamental question I think we had, and that's the
16 first and the last point, I think, essentially is how
17 should APHIS apply their Noxious Weed Authority, and
18 should they do it uniquely to genetically engineered
19 organisms or not? So, should it be paralleled with
20 (inaudible) implemented their authority or should it
21 not?

22 And kind of associated with that is, how do

1 you -- and they should maintain a consistent standard
2 once applied to the regulatory process.

3 Some more practical issues were the amount of
4 data or information that's already available to make a
5 determination in this area. Should the agency go beyond
6 weediness, you know, applicants now provide data associated
7 with weediness and should there be additional data
8 beyond weediness. And then another practical implication is
9 how and should the agency monitor after deregulation.

10 And I guess one specific issue that was raised
11 in how the Noxious Weed Authority would be applied to
12 genetically engineered crops, and that is how to address
13 issues associated with organic farming.

14 EVA RING: Thank you.

15 MALE SPEAKER: Well, you can see here all of
16 our comments, which categorically represents our
17 thinking. But I think -- now hearing all of the rest of
18 the tables' comments, it kind of solidifies the things
19 that we were kind of surrounding but not really
20 articulating too well. So, we spent most of our time
21 talking about the definition and how broad it is, and the
22 possibility of creating some type of a way for claims of

1 indirect harms to natural -- the environment or to the
2 natural resources of the US. That was concerning. But
3 that was about it. That was our main focus. And, like I
4 said, everything other tables have said we kind of agree
5 with.

6 EVA RING: Thank you very much. Did anyone
7 have any other comments that you felt you didn't get to
8 make as your table presented out? I think this will lead
9 nicely into Dave's -- you'll be interested in Dave
10 Heron's presentation now. Dave is the Assistant Director
11 of the Policy Coordination Division in Biotechnology
12 Regulatory Services. And he's going to give you a little
13 talk about the scope of the regulation as proposed, and
14 also talk with you a little bit about the criteria that
15 they're proposing to help determine which GE organisms
16 are described, which genetically engineered organisms
17 should be included on the regulation.

18 DAVID HERON: Thanks, Eva. It's interesting
19 to hear how the discussions at the tables are making this
20 natural progression, as Clint outlined earlier, from the
21 Act to the regulations. And I think some of you are
22 already to that point in your discussions about, let's

1 focus on the regulation. So, that's where we're changing
2 gears a little bit now. We're going to focus on how the
3 scope is described in the regulation. And -- thank you.

4 So, under the current regulation, when it was
5 set up in 1987, the scope, which organisms are subject to
6 the regulation, is all embodied in the definition and the
7 term called regulated article. And under the proposed
8 Rule what we've done instead is to take the criteria and
9 package them in a different way. So, under the current
10 regulation, this regulated article definition reflects
11 the authority that the regulations were developed under,
12 focusing on the Plant Pest Authority, and the Federal
13 Plant Pest Act, and in the Plant Quarantine Act, as
14 you've heard about that earlier today.

15 So, then, if we go to the next slide, under
16 the proposed regulation, the scope, we dropped the term
17 regulated article and instead tried to use terms a little
18 bit closer to what people would be used to using. And
19 we're just talking about genetically engineered
20 organisms. And then it's broken down into the plant
21 pests criteria and noxious weed criteria.

22 And through this, the goal is to align the

1 scope of the regulations with the authority that we have
2 under the Act. So, we -- as we've just been discussing,
3 we have the authority to regulate plant pests and not
4 just weeds under the Act. So, that's why it's set up
5 this way. Then the scope criteria, we'll turn to those
6 after I get through these slides. We'll turn to those in
7 detail in your handout. Then, as I said, the scope
8 criteria is set out in terms of the plant pests, and the
9 criteria that would make them come in under the
10 regulation for that, and also for noxious weeds. And an
11 aspect using both sets of criteria is, if the
12 characteristics of the genetically engineered organism
13 are unknown or uncharacterized, that they would fall
14 under the regulation. And even though our intent was to
15 make these criteria as clear as possible to someone
16 reading them, in the real world people come to us -- and
17 even under the current regulations saying, I read this
18 definition in the regulated article but I'm not sure if
19 this thing that I'm working with or I want to work with,
20 is this considered a regulated article under your
21 regulation? So, we described in the proposed regulation,
22 that if anyone had any question about how to apply these

1 criteria, in terms of genetically engineered organisms,
2 they could come to us and consult. And we could do this
3 initial evaluation to tell them whether they fell within
4 the regulation or not.

5 The other thing that we tried to clarify, too,
6 was that it was not up to the individual person in the
7 public to -- whose determination would say whether
8 something was under regulation or not, it was the APHIS
9 administrator.

10 We got -- if we go to the next slide. This is
11 one of the areas where we got lots of comments on the
12 scope. And the comments that we received on the scope
13 follow under these three named areas. One was the
14 description of the scope criteria. A number of
15 commenters said that this lacked clarity. They thought
16 this was unclear on how this would be applied. And they
17 thought this would actually undermine our ability to
18 effectively regulate. They thought that the -- this made
19 it possible for people to look at the criteria and the
20 regulation and come to their own conclusion, and go about
21 their business, and APHIS would never know that they were
22 supposed to be under the regulation.

1 We had a number of commenters who said that
2 they thought the criteria as described in the proposed
3 regulation made it sound like it was a voluntary program,
4 that someone could look at those criteria, decide for
5 themselves, and they didn't have to come to APHIS to make
6 sure whether they fell under the regulation or not.

7 They thought the -- this also presumed an
8 ability to do this analysis based on the criteria in
9 their own hands to decide whether something -- whether
10 they fell under the regulation.

11 So, if we go to the next. So, one of the
12 things that is clear in all of this, it's clear that the
13 criteria -- the scope criteria need to be clarified so
14 that they are unambiguous; and also to make even more
15 explicit that it's not a member of the public who
16 determines whether something falls under the regulation
17 or not, it's the APHIS administrator.

18 And, of course, as we've talked about already
19 today and we've just been discussing about the provisions
20 in the Plant Protection Act, the criteria need to be
21 consistent with the authority that we have under the
22 Act. So, we're trying to balance all of these needs in

1 revising the criteria.

2 So, as we move to the next discussion session,
3 we're going to be focusing on the sheet in your package.
4 That is the next one in the series. We just looked at
5 the definitions from the Plant Protection Act, if you
6 flip to the next page it should say at the top,
7 (inaudible) for the Proposed Rule. And then it says
8 excerpted from scope and general restrictions. Okay.
9 This is the same text as in the Proposed Rule, spread
10 out to make it a little bit easier for you to read and
11 work with it at the tables.

12 Let me just quickly walk through these
13 criteria, and then we'll turn it back over to Eva and Jerry
14 to start the discussions. So, you can see that the
15 activities that fall under the regulation are the same:
16 it's "Interstate Movement and Release into
17 the Environment." That part doesn't change. And then the
18 rest is which GE organisms. And it's broken down into
19 the plants up top. And everything else, the nonplants,
20 nonvertebrate at the bottom. So, we're looking at the
21 first one, genetically engineered plants. If the
22 unmodified parent plant in which the GE plant was derived

1 is a plant pest or noxious weed; or the second criteria,
2 the trait introduced by genetic engineering could
3 increase the potential for the GE plant to be a plant
4 pest or noxious weed; or, three, the risk that the GE
5 plant poses as a plant pest or noxious weed is unknown;
6 or the administrator determines that the GE plant poses a
7 plant pest or noxious weed risk. So those are for the
8 genetically engineered plants.

9 The criteria under number two for the
10 genetically engineered nonplant, nonvertebrate organisms,
11 are; if, one, the recipient organism can directly or
12 indirectly injury, cause damage to, or cause disease in
13 plants or plant products. And that's the text taken from
14 the definition from what a plant pest is in part as to
15 cause those types of damages; or, two, the GE organism
16 has been engineered in such a way that it may increase
17 the potential for it to be a plant pest; or, three, the
18 risk that the GE organism pose as a plant pest is
19 unknown; or, four, the administrator determines that the
20 GE organism poses a plant pest risk.

21 So, that's -- those are the criteria as put
22 forward in the proposed Rule. People have commented on

1 -- we've received lots of comments on these.

2 What's been interesting is, although we've had
3 lots of disagreement with the criteria in general, it
4 depends on someone's perspective which part of these they
5 dislike the most. So, we're hoping that it's part of
6 this mix that we have here will be able to give you a
7 chance to discuss from your perspectives and you can hear
8 the various perspectives, and maybe we can have some
9 ideas on ways to make these a bit clearer.

10 With that I will turn it over to Eva. But
11 maybe I should first give you a chance to ask me
12 questions you might have. Hearing none, all yours.

13 EVA RING: Anytime you're developing a
14 regulation, what falls under that regulation is
15 critically important. So, I think this is a very
16 important conversation you're going to have at your
17 tables right now, as you seek to answer whichever of
18 these questions you want to get your hands around. There
19 are four that are going to be posed to you here. And we
20 have about half an hour. And, if I feel that you need
21 more time, we'll have more time.

22 The first is, the criteria you have in your

1 hands. Do these criteria adequately describe those
2 organisms that you think should be included and excluded
3 from the regulatory process? If not, why, why not? So,
4 that's the second question: If not, what could APHIS
5 do? They just don't want to know that they don't, they
6 want your suggestions on how APHIS could further clarify
7 the criteria so that it could be consistently and
8 uniformly understood by those who would need to
9 understand it.

10 And, if there are any particular entities that
11 you want to highlight that you think need to understand
12 it, that's fine as well.

13 The third question is, just in general, what
14 other concerns? You've been given the opportunity to
15 voice any other concerns you have about this scope as
16 it's currently laid out in the proposed Rule.

17 Fourth, do you have any suggestions or any
18 other approaches that might work better to assist this
19 determination in what should be regulated? Have you
20 experienced anything else that you think might work here
21 as well?

22 So, they're asking advice, any kinds of ideas,

1 or thoughts, or recommendations you have for
2 consideration there as well. So, there are four
3 questions. You can start with whichever you want. We'll
4 start with saying half an hour and we'll see how it
5 goes. And we greatly appreciate your input in this
6 discussion topic about this scope. Thank you.

7 JERRY COURSEY: Eva, can we have the BRS staff
8 rotate, please?

9 EVA RING: Sorry. We forgot. We're supposed
10 to remember.

11 JERRY COURSEY: BRS staff, rotate.

12 EVA RING: I tell you what, we've decided to
13 have a break. When you're ready, just take a 15-minute
14 break and we're going to report out at 3:10.

15 (Pause in proceedings.)

16 EVA RING: Okay. I'd like to start by polling
17 the tables here on the first question.

18 Could I see a -- for those who are going to
19 report out from your tables, could you raise your hand if
20 your table felt that the criteria adequately described
21 which organism should be included and excluded; and, if
22 so, how and why?

1 The question is: Did any tables feel the
2 criteria are adequate? Okay. Do I hear a yes? All
3 right. So, I'm taking that to mean there was -- there
4 were no tables that felt the criteria were adequate. So,
5 I would like to move right away, then, to the second
6 question, save some time.

7 So, what should APHIS do to further clarify
8 the criteria so they could be consistently and
9 uniformly understood? I'd like to start with that
10 question before moving on to other ideas you have. Did
11 anyone -- any tables have any suggestions about things
12 APHIS could do to clarify the criteria? I'm sure you had
13 some things.

14 ZELIG GOLDEN: I'm Zelig Golden from The
15 Center for Food Safety. So, the criteria as established
16 are clear, insofar as whether or not APHIS should
17 regulate that crop. However, in the first instance the
18 trigger for whether or not the regulation should apply in
19 the first place should be -- should concern all GE
20 crops. And, so, we actually proposed some language. The
21 first step should be the question: GE crops should be
22 subject to regulation unless the administrator determines

1 otherwise.

2 And in step two under the section (inaudible)
3 would then be the criteria that it was. And, so as far
4 as the criteria are all encompassing, we agree on that,
5 but they shouldn't be determined whether or not APHIS
6 should consider regulating the crops. APHIS should
7 consider regulating everything that is genetically
8 modified, period, and then use those criteria to decide
9 whether or not to apply this -- its regulatory system on
10 the crop. So, it's a two-step process.

11 EVA RING: Any questions about that? All
12 right. Do you have any other -- so, you think they
13 should be clearer than they currently are, is that what
14 you're saying?

15 ZELIG GOLDEN: I think we agree that the
16 criteria as written are clear, but they shouldn't be the
17 threshold questions of whether or not APHIS --

18 EVA RING: Everything should be subjected to
19 this criteria

20 (Speaking at once.)

21 ZELIG GOLDEN: It's -- I'm not sure what's
22 your question. But that APHIS -- it should mandate that

1 APHIS makes a determination and no one else, there should
2 be no self-determination.

3 EVA RING: Any other groups have any
4 suggestions for how though to clarify the criteria?

5 BOB HARRIMAN: Yeah, I am Bob Harriman from
6 Scotts. I guess we disagree as to the criteria
7 being clear. I think the confusion was created by the
8 unknown terminology, sort of, you know, opening the --
9 leaving a big risk to whether arguably the unknown
10 language covers everything, maybe it does, maybe it
11 doesn't. In our -- I guess our proposed solution is that
12 what APHIS needs to do is come from the other direction
13 and go ahead and define no risk that would be outside the
14 scope of the reg, and provide specific examples in the
15 preamble in the Rule, or perhaps as you go forward some
16 sort of case-by-case guidance document type basis so
17 that -- you know, the default assumption, again, is
18 everything is covered. But given the exemption out of
19 things that don't provide an unknown risk, that those
20 could be exempted out with as much specificity as
21 possible.

22 EVA RING: Thank you. Any questions about

1 that or clarification? All right.

2 KRIS KRING: We had the same concern about
3 unknowns. We kind of read it that (inaudible). We
4 weren't -- and we weren't -- we had really struggled
5 about what that point was trying to get at. So, our two
6 suggestions are, delete it, because we think the fourth
7 is the catch-all that could -- would cover it, the
8 current administrator determines. Or we didn't know that
9 maybe what you were trying to get at is the crop and
10 trade combination of the regulated plant potential. So,
11 we thought maybe that was what you were trying to get
12 at. So, we had a real hard time with that number three
13 also.

14 EVA RING: Any questions about that? Other
15 comments about how to clarify the criteria from the other
16 tables?

17 All right. Then we're going to move onto the
18 third question. What other concerns did your table have
19 about the proposed scope? Who would like to share?

20 BILL WENZEL: Bill Wenzel with Farmer-to-
21 Farmer Campaign on Genetic Engineering. And we were
22 pretty much in accord with everything that was said up to

1 this point in time. I think the only other thing that --
2 a couple of things that we talked about was that there is
3 some confusion about the deregulation process, and
4 that -- it needs to clarify there is some end to
5 regulation process as we move into the new system. And
6 if there's some confusion around the terminology of
7 commercialization and deregulation that it would help to
8 clarify it a little bit.

9 The only other comment that we had is that it
10 seemed like we took care of a lot of the issues, but in
11 the context of the proposed Rules, that there's a
12 question about those broad face exclusions that are
13 contemplated, but there is a movement toward what is
14 being proposed by most of the groups sitting around the
15 table, I think that cures most of those issues.

16 EVA RING: Any questions? Thank you. Other
17 groups have some -- any other concerns that you talked
18 about?

19 ZELIG GOLDEN: Yeah, Zelig Golden for The
20 Center for Food Safety. And there's two other issues in
21 the scope. One is the -- I think what Bill from Farmer-
22 to-Farmer was saying about non regs status. There's

1 question for us about whether or not nonregulated status is that the
2 right way to go? It's the way we've been doing it. But,
3 for example, post-commercialization is concerned about
4 monitoring certain risks after commercialization. And as
5 the GAO said in his recent November 2008 report, it's
6 difficult, if not impossible, to track certain effects in
7 the agriculture environment to the economy. And, so,
8 maybe a better approach would be do a comprehensive
9 permitting system for all, when we -- you know,
10 experimental field trials like we have. An answer
11 would be a commercial permitting system in lieu of a
12 nonregulated status. So, that's one we brought up.

13 And the second one is a conditional
14 exemption. There's a concern that it creates a loophole
15 in the scope of regulation. That is, as written the
16 conditional exemption allows for -- it's language
17 identical to nonregulated status, except it's called an
18 exemption with conditions. And that seems all right
19 except that once the conditional exemption is applied, it
20 would then allow for a modification of those -- that
21 exemption. For example, taking away the condition
22 without any public process, and that could create de

1 facto nonregulated status without the environmental
2 review public process as currently required. So, that's
3 a very big concern.

4 And on the conditional exemption, there's also
5 a concern that calling it an exemption isn't the right
6 terminology, but rather calling it a conditional approval
7 like I think the EPA does might be a better way of
8 framing it.

9 EVA RING: Thank you. And you answered a
10 little bit of number four question as well. And I
11 encourage anyone, really, if you don't understand a
12 suggestion somebody is making, to ask for clarification.

13 Any other concerns that tables had? Yes.

14 KRIS KRING: Oh, we just had a few other small
15 comments. I think we understand the wanting to change
16 the terminology of regulated article, but we think GE
17 plant isn't appropriate, because not all GE plants will
18 stay regulated. So, we thought it's more -- it seemed
19 like from -- that it's the article part you had more of
20 the trouble with, so, we might suggest saying regulated
21 plant, regulated organism.

22 And then we would suggest building an

1 exclusionary mechanism. And I think we kind of discussed
2 that in an earlier session. And then we also just think
3 some additional guidance documents might help clarify the
4 scope, too. And that's all that was said. I'm done.

5 EVA RING: Thank you.

6 MALE SPEAKER: We had a fair amount of
7 discussion on the scope issue on the problem of the
8 permissive language in the proposal regarding
9 consultation, and the way in which that implies at least
10 that we're talking about a voluntary system. While that
11 may not have been APHIS' intent, it seems to have
12 created that interpretation in some quarters within the
13 regulated community, and perhaps at least a significant
14 within the international arena where we think it could be
15 extremely damaging for that perception to persist.

16 So, we think that needs to be corrected. And
17 I think a related thought we had was that consultation is
18 fine. And we think that it ought to be as transparent as
19 possible.

20 EVA RING: Thank you. Any questions or
21 clarification? Did any other table discuss other
22 concerns that you had? Right up here, Jerry.

1 CLAUDETTE DEATHERAGE: Some of the concerns
2 that we had talked about was, one, that we felt really
3 that the issue of viable versus nonviable material really
4 needs to be a part of the scope and it needs to be well
5 defined.

6 And, again, building on an exemption list
7 based on history should be included in the scope and
8 mandatory. Maybe you can speak to that one, mandatory --

9 Okay. Discuss -- and also guidance. We
10 really want to emphasize that, no matter how much you
11 really try to define this, and get it down, and get it
12 scoped out, firm guidance and direction from APHIS is
13 really needed to carry this out properly.

14 Also where does the scope of authorities --
15 you know, be very specific about the breadth of the scope
16 of the authority, in terms of where does it start in
17 terms of the organism and where does it end, in terms of
18 the life of what happens with that organism to product.

19 EVA RING: Thank you. Any other concerns to
20 question number three, answers?

21 I'm going to move on to question number four.
22 What other approaches might work better to determine what

1 should be regulated?

2 Did anyone have any discussions about some
3 alternative approaches, other than the criteria-based one
4 that was presented? I don't know if people just didn't
5 get to that one or that -- all right. Well, thank you.
6 That was very -- a very useful discussion. And I -- oh.

7 ZELIG GOLDEN: Just one clarification, I
8 heard you say the criteria-based proposal that was
9 discussed. And I just want to be clear, that the -- if
10 you're referring to what we proposed here, the initial
11 trigger would be all GE crops that APHIS would have the
12 --

13 EVA RING: Right.

14 ZELIG GOLDEN: -- authority to regulate
15 everything. As far as criteria, it would just simply be
16 required to consider whether or not it should be --

17 (Speaking at once.)

18 ZELIG GOLDEN: I just wanted to be clear.

19 EVA RING: Thank you.

20 ZELIG GOLDEN: Okay.

21 EVA RING: Did anyone have any other comments
22 after hearing all of those concerns of the different

1 tables? I don't want to -- sometimes I don't give you
2 time to react probably. Every once in a while you'll see
3 me write something over on the chart, it's something that
4 I'm putting as a parking lot for, if we have time to
5 discuss more of your specific thoughts about something,
6 like BRS or APHIS will have to provide additional
7 guidance or more firm guidance. And sometimes I want to
8 get underneath that a little bit for BRS to know exactly
9 what you're thinking about there. I hope we have time to
10 talk about that.

11 Our fifth discussion topic is really on the
12 regulation of organisms engineered to produce
13 pharmaceutical and industrial compounds. Dave Heron is
14 going to talk about this a little bit before we move to
15 our next discussion.

16 DAVID HERON: Okay. Thanks, Eva. We're
17 coming up to a topic now where it is actually going to
18 span day one and day two. Is the power on? We're coming
19 up to the topic that's going to span day one and day
20 two. I bet you heard me on the back with the volume
21 turned up.

22 And we have -- many people just refer to these

1 as pharma plants, but the -- in the paper that you'll --
2 is being passed out now just goes into a little bit more
3 of the formal language. If we lapse into calling these
4 pharma plants in our discussion around the table, that's
5 fine. But we're really talking about plants that are
6 engineered to produce compounds for pharmaceutical or
7 industrial uses. Some people use abbreviations for this,
8 but it -- so, we're all clear that it's both plants
9 engineered to produce pharmaceutical and industrial
10 compounds, okay?

11 This is one area of the proposed regulation
12 that we've had the greatest number of comments on. Over
13 14,000 comments mentioned on this alone, just in the
14 first comment period that ended the end of November. So,
15 this is still a very -- this is a topic of very great
16 interest in people who have commented on this.

17 Part of this is derived from the fact that in
18 the current regulations this -- these types of plants,
19 genetically engineered plants, are described as a
20 specific subset of genetically engineered plants that are
21 not eligible for the notification procedure. So, they're
22 handled under the permitting procedure. And I think this

1 is the way that many people approached the proposed Rule,
2 and they expected to see a distinct class described as
3 just the same way as in the proposed Rule. And that --
4 that's one flavor of comment.

5 And then we have the greatest number of
6 comments around the whole issue of whether these should
7 be allowed or disallowed in certain plant species.

8 So, as we get into the discussion today, and go
9 into tomorrow, we'll use an approach similar to what
10 we've used so far. And we're building off of the
11 discussions we've had about the authority that's in the
12 Act to regulate plant pest and noxious weeds, looking at
13 the definitions that are in the Act for plant pest and
14 noxious weeds, and how that relates to these types of
15 plants.

16 Now, the regulation of these types of plants
17 authorized by field test permit under this regulation that we're talking
18 about, the 340 regulation, the first field tests were
19 actually done back in 1992. And these were very small
20 experiments really at proof of concept in the early
21 years. And as things progressed there was more
22 consideration that this could actually be a platform for

1 producing these specialty compounds.
2 And in 2003 we issued a policy statement to
3 describe to the public our policy, because we had lots of
4 questions coming from the public about, what is the
5 approach you're using when you do these field tests? And
6 we described how we're using very stringent confinement
7 procedures to minimize the chance that any of this
8 material could inadvertently get into food or feed
9 supplies.

10 We've understood from the comments that we've
11 received that this is still an issue of great concern to
12 stakeholders. And we hope that the discussions today and
13 tomorrow on this topic will help illuminate a way that we
14 can move forward on this. So, we're very interested in
15 learning about your concerns, and understanding them, and
16 finding some way that we might be able to move forward.

17 Of course, regardless of the approach that we
18 will take in the Proposed Rule, our goal is still focusing
19 on maintaining the safety for any of this material, the
20 genetically engineered plants.

21 And with that, maybe I will just turn it over
22 to Eva with just those brief remarks. We'll get started

1 on some general questions, some homework questions.
2 You'll have the advantage of being able to do homework
3 tonight. Those who come tomorrow who weren't here today,
4 they'll have to do their homework instantaneously. But
5 let me turn it -- turn it over to Eva at this point.

6 EVA RING: I think we may not have homework.
7 Let me just ask you to fill out the answer to two very
8 simple questions before you go. We're on a good time. I
9 know I don't like to do homework.

10 DAVID HERON: Well, I was hoping for an
11 assignment.

12 EVA RING: So, in order to help inform
13 Biotechnology Regulatory Services and APHIS about the
14 concerns, what exactly are your concerns about the harms
15 and risks of organisms that are here to produce
16 pharmaceutical and industrial compounds? And what are
17 they based on? I would add. So, if you could talk about
18 this at your tables for maybe about 20 minutes. Then
19 we'll have some follow-up questions tomorrow to further
20 delve into this. But that's the basic beginner
21 question. Thank you.

22 All right. We have a volunteer to start.

1 GREG JAFFE: We had a discussion about farms
2 at risk around biofarming. And I guess, as you know, one
3 of the major things of that risk, what is the liability
4 if there is a containment failure? And that's sort of
5 the drive of the whole issue here, and the fact that that
6 liability may be very significant. It may be much more
7 significant on a different scale than if another kind of
8 genetically engineered crop, if there's containment
9 failure there.

10 And, so, you have some regulations, but the
11 issues here are, well, what happens if you have pollen or
12 gene flow that leads persistence in the environment for
13 entering products as contaminants. You may not have a -- you
14 still will have lots of impacts, commercial business in
15 particular that people are very concerned about. You're
16 also going to have mixing -- another recipe mixing for
17 human error. You can contain things in the short term,
18 but in the long-term there's always a chance somebody --
19 there will be a mistake and mixing will be getting out.

20 So, we looked at sort of the beginning of the
21 briefing paper from APHIS and it talks about, well, their
22 job is not to look at the intended use of the product,

1 but to look at the product and the risks. But I think
2 the issue that our group came to was, the issue is not
3 the intended use, it's the unintended use. And we think
4 that APHIS is responsible for addressing the unintended
5 uses of things. That's the whole reason they have
6 containment and all these other things is because of the
7 unintended. It's the persistence. It's the contaminate
8 getting out. So, I think you, therefore, have to look at
9 the intended product to get at the unintended use. But I
10 think that -- where we were going at here is, really what
11 happens when there's a containment failure and -- so, I
12 think the risks -- the pathways are the same as risk
13 pathways for other kinds of genetic engineered products,
14 but the potential liability is much greater, and the
15 commercial risks are much greater, and the ability is
16 that unintended use of these products that needs to be
17 better assessed in the regulatory process. Okay.

18 EVA RING: Thank you. Were there any
19 questions or clarification here? What about this table
20 back here, Jerry, right next to you.

21 ZELIG GOLDEN: So we discussed a little about
22 biopharm risks. And, you know, the obvious point is that

1 there are human health and environmental risks from
2 contamination from biopharm crops.
3 The first issue that we brought up is
4 distinguishing between true safety risks versus purely
5 market concerns. Some at the table think that market
6 concerns should not be at play and something that should
7 be played exactly organic.

8 The second thing, we need a criteria for the
9 committing process to be enforced, and then assess the
10 environmental and health risks. As is proposed, simply
11 refer back to the permitting scheme that's being
12 proposed, and I think that -- we agree that there needs
13 to be a specific set of criteria for the biopharm crops,
14 specifically what type of conditions would be applied,
15 such as spatial variability, isolation distances, et
16 cetera.

17 Some thought that we should regulate it based
18 on risks, so assess each property individually. For
19 example, we each -- we've got a hypothetical. So, you
20 have a plant that's promulgated but it doesn't have seed
21 and, you know, the compound is only coming out of
22 vegetative matter then it's low risk and it gets treated

1 differently than a plant that has -- produces seeds, and
2 pollen, and could contaminate vis-à-vis seed mixing or
3 pollen flow to the environment.

4 Where there's any risk of seed mixing, some
5 believe that there should be a very high standard, such
6 as containment. You know, we'll suggest some standards
7 later about that. Heightened standards for risk
8 assessment and conditions applied was one idea that was
9 discussed. One question that came up was the 2006 draft
10 guidance on biopharmaceutical crops. It's unclear
11 whether they were applied, and, if the Proposed Rule
12 would scrap that or it didn't apply. Some thought it
13 would be very important for them to continue to apply,
14 because -- and stricter standards on biopharms.

15 And then distinguishing nonfood crops and food
16 crops with biopharming. So, where food crops are planted
17 with pharma. We discussed a presumption that such crops
18 were planted with strict confinements, and that
19 presumption will be lifted if and when a risk assessment
20 showed that there were zero -- or no zero risk of
21 contamination. And our proposal was that field testing
22 or commercialization open fields will only be allowed if

1 it was not in food, or if it was food it would be in
2 contained facilities only.

3 EVA RING: Thank you. Any questions for this
4 group?

5 Dave, you want to hand the mike to that table
6 right there? Thank you.

7 KRIS KRING: So, we did start with the
8 fundamental agreement that it should be safety based and
9 not use based. But we do think in this climate --
10 current climate that cooperation across the agency is
11 essential. And especially the FDA and Human Health
12 Safety be on board up front when it's used in food crops
13 in particular. We assume that they -- you know, the new
14 ones will the isolation and containment issues will be
15 the higher end categories. But it is definitely do
16 include in particular transportation harvest to the
17 mill. You know, can they be devitalized before they
18 move? You know, if they're going across country from a
19 field to a mill, are they being devitalized first,
20 considerations like that.

21 We talked about using food crops versus
22 nonfood crops. And, while we don't think that should be

1 part of the regulation, could there be some guidance to
2 help companies, especially newer companies, consider, you
3 know, why I'm using a certain crop, and can I use another
4 crop? Now, if it's for a scientific reason, you're
5 getting a food crop and, you know, the protein expresses
6 that way in that food crop and not in the others, then we
7 say it should be allowed. But, you know, help people and
8 companies work through that. So, maybe some type of
9 guidance on that.

10 And, again, what we were just saying, that may
11 not necessarily be a scientific risk reason, but other
12 reasons, you know, help and guidance. So --

13 EVA RING: Thank you. Any questions for that
14 group? Dave, could you give it to this table over here
15 up front?

16 NATALIE WEBER: All right. Well, we had
17 several points that were already raised so far. I guess
18 the involvement, and possibly with the FDA in evaluating
19 the safety, and it's possibly, you know, from some
20 understanding of what goes on at the EPA and establishing
21 tolerance for these. And I guess the other thing that I
22 guess this table mentioned, too, about evaluate based on,

1 you know, what the trait is, and not what the
2 classification is of the product.

3 And then another table mentioned, too, the
4 liability of, you know, confinement and, you know, I
5 think beyond what the regulation proposes here, I think
6 there needs to be other infrastructure and statutes in
7 place in order to probably gain the acceptance and
8 continuation of this technology. Because I think the
9 biggest thing is that liability from the farmer's
10 standpoint.

11 EVA RING: Any questions? Yes. Oh, you want
12 to go next. Thank you. Sure.

13 LARRY ZEPH: And now it's an Army of one.

14 EVA RING: I'm not going to ask why.

15 LARRY ZEPH: But we -- sorry. We did talk
16 about one other aspect of all these points, and that is
17 that this part of the regulation is an area where BRS
18 has, you know, a very good track record. Obviously
19 they've been issuing permits for many years now. And
20 although things have been found in the wrong place from
21 time to time, we all admit that there really have been no
22 safety issues. And we need to recognize that that track

1 record should support the system that's being proposed in
2 the proposed regs.

3 EVA RING: Thank you.

4 Jerry, could you just pass the mic around to
5 the table? And then it will be that table back there.

6 GEORGE KIMBELL: George Kimbell, Center for
7 Food Safety. So, most of ours have already been
8 mentioned, so, I'll go, I think, quickly through them.
9 Food supply contamination, harmed farmers from that.
10 Environmental impacts. Better coordination with FDA and
11 the adequacy of oversight. We -- some of us, we talked
12 quite a bit about that -- with regards to pharma crops it
13 depends on particular substances, their safety profile,
14 how their expressed, and their regulatory status and
15 issues of how that is balanced out in uses oversight.
16 Enforcement we talked about, and potential contamination
17 group and adequate enforcement.

18 And then finally I think this goes on -- also
19 something was said earlier, the premise of the document
20 here that was handed to us with regards to APHIS'
21 oversight and the implementations of the EPA here,
22 because the concerns that have been raised are perception

1 and marketability concerns. Some of us disagreed with
2 that premise and thinks they actually -- that these
3 concerns are based on health and environmental impact
4 concern among others, which fall under the EPA/APHIS'
5 authority.

6 EVA RING: Thank you. Any questions for this
7 group? I think Jerry we have these tables up here.

8 CLAUDETTE DEATHERAGE: Thank you. We have
9 answered that question with more questions. And the
10 concerns that we raised with our questions are as
11 follows -- thinking -- at times trying to think from the
12 consumer point of view. And, so, one obvious question
13 is: With these kind of trials is there or is there not
14 an elevated toxicity difference? That's a concern. If
15 it gets -- if it loses containment. And where do those
16 genes come from anyway? That's -- are they from plants
17 or aren't they? And how has the corn or the other crop
18 been engineered? How different is the process? What
19 about the level -- what about the potential level of
20 exposure, again, toxicity levels? Will consumer
21 education help that? We were on the fence about that.
22 How valuable -- how quickly and how valuable that would

1 be, as far as educating us. And we would -- we have some
2 concerns that we -- one of the things that we think would
3 help would be for APHIS to share broadly what they've
4 learned in the past few years about pharma compounds in
5 the field. What have been the results of that?

6 Evidently it's positive, but that would be good to know a
7 little bit more broadly.

8 And the basic question that comes down to it,
9 if a mistake happens, and mistakes do happen, what is the
10 risk? Or what is the perception, how -- you know, the
11 perception of that risk, how serious is that? And, so,
12 that's a concern. Anything you want to add?

13 EVA RING: Thank you. Any questions of this
14 group? All right. You're our last table here.

15 WENDELYN JONES. We crystallized it all down.
16 And there's two things -- but it's trait, not
17 use.

18 And the second point is recognition that
19 confinement is important with these types of products.
20 We had a number of pull off of other comments that were
21 made. We had -- actually had a very interesting -- almost
22 a debate at the table. Highlighting the difference

1 between risk assessment and the scientific risk
2 assessment that needs to be done on the pharmaceutical
3 plant with the industrial provision plant versus the risk
4 management options that APHIS can then apply to any
5 specific plant. And that it may be appropriate, given
6 that APHIS does have some -- well, it has to, by nature,
7 respond to public perception pressures. That there may
8 be occasions when, you know, a normal 660 foot isolation
9 should be increased, not always, though. And that was
10 the discussion we had.

11 DAVID LEE: Just because we were discussing
12 some specific examples that actually really helped me
13 understand what we're talking about. In some cases --
14 well, we mentioned trait not use. You know, it's more
15 important to look at the actual trait rather than to see,
16 well, that's an industrial use trait. An example we came
17 up with was, you know, a plant producing gust, it's possible
18 theoretically extract the gust and use it in an industrial setting.
19 But just because you're doing that doesn't necessarily
20 mean that the crop should be more highly regulated
21 than the plant just being thrown out for research purposes,
22 because that could lead to inconsistencies in regulations.

1 EVA RING: Thank you. We always appreciate
2 illuminating the examples. That helps. Thank you.
3 Any other reactions, comments after hearing
4 all of this on this topic? You'll notice on our agenda
5 next BRS did want to tell you what they heard from you
6 today. They want to repeat it back to you, give you some
7 of their thoughts of what they heard, and make sure that
8 you have the opportunity to say yes, or that's right, or
9 there's something else that you may have missed. We're
10 going to give them that time right now.

11 I also want to just let you know again, just
12 in case there's any misconception, Jane is helping to
13 capture things so that we can organize things into themes
14 ourselves. However, everything -- she's not capturing
15 everything. Everything is being captured by Natasha over
16 here for the public record, everything that you all are
17 saying. So, I didn't want you to think just because Jane
18 -- you see what Jane was typing and it wasn't everything
19 that you were saying, that's just for our purposes.

20 MIKE GREGOIRE: All right. Bev Simmons and I
21 are going to do this piece. I'm going to be working off
22 my chicken scratch notes, and it's entirely possible I

1 would have missed some things in the process of my note
2 taking. But as Eva said, we have a complete transcript
3 and Jane's notes as well.

4 So, we began the session today just talking
5 about the general issue, what concerns people have with
6 biotechnology regulation. And some of the key things
7 that I heard during that discussion is that, it's
8 important that we have a science-based regulatory
9 structure, that the regulations are risk-based, that they
10 are clear, consistent, and predictable, and that we do a
11 better job communicating what those requirements are to
12 the people we regulate, as well as to the public in
13 general.

14 We heard a lot about the marketing and trait
15 impacts of when these regulated organisms get out of
16 confinement. That's a very important issue and concern
17 that people have. I heard a lot today, in the opening
18 session and throughout today about the importance of
19 interagency cooperation, and that that's an area that
20 could be improved and strengthened. I heard about
21 impacts on organic production several times today, and
22 also heard about concerns with respect to regulatory

1 burdens.

2 I would say about the concerns that we heard
3 today, that some of those are germane to the regulation,
4 or might be addressed through the regulation, but other
5 of these issues may not require a regulatory change, or
6 may not be solved through this regulation, but may need
7 to be dealt with in other ways, either by APHIS, or other
8 agencies of USDA, or those agencies in the Coordinated
9 Framework.

10 We then talked about what challenges BRS
11 faced. And I think people were pretty astute about the
12 challenges that we face. I think one of those is
13 balancing all of this input, and all of this interest
14 that there are around these issues.

15 Secondly that the regs need to be written in
16 such a way, and we have to be staffed in such a way that
17 we can adapt to the changes, and the technology, and the
18 science. And those are very important things.

19 Again, interagency cooperation, the importance of the
20 interagency cooperation. And coordination came up in
21 this area as well, as did the importance of being
22 transparent in communicating and strengthening that as

1 well.

2 People also -- I heard people acknowledge the
3 resource constraints that BRS has. So, I can tell you as
4 the Deputy Administrator, those -- I see -- those
5 challenges that you see for us, I see those for us as
6 well.

7 I'm going to jump down to the noxious weed
8 discussion. I think that is an area in particular where
9 there is a really wide variety of interest and views. We
10 have, on the one hand folks are saying, don't even go
11 there, don't bring that authority into the picture. And
12 then the other end of the spectrum is not only do use
13 that authority, bring it into the picture, but use that
14 authority more broadly than you have proposed to use it
15 in the regulation.

16 That issue I think in particular is going to
17 be one of the most challenging issues to deal with as we
18 move towards a final Rule. That's one -- at least from
19 what I've heard so far, is the issue that's one of the
20 most divisive issues with respect to this proposed Rule.

21 On the other hand the scope of the regulation,
22 I think we managed to get everyone to agree on that, and

1 that is nobody liked what we proposed. And there
2 generally seemed to be consensus in the room about being
3 very clear and unambiguous about what the Rule should
4 cover, what sort of things are subject to the regulation,
5 and that it should be the -- clear that it's the agency's
6 decision, and not the decision of individual developers.

7 So, on that particular issue it seemed like
8 there was -- people are -- have more common interests and
9 ideas than some of the other issues. I will say to you,
10 however, we didn't really get into this in our
11 discussions, that it's better to bring things under
12 regulation then to get them out from regulation.

13 And we're going to continue the pharma
14 discussion tomorrow. So, all I'll say about -- what I've
15 heard on that so far is that this Rule needs more than
16 what it has now with respect to this issue, at least a
17 lot of unanswered questions, I think, and you've heard a
18 lot of different suggestions on how that might be
19 improved and strengthened. So, those are some of the
20 things that I heard today. And I'm going to ask Bev now
21 to come up and share her thoughts as well.

22 BEVERLY SIMMONS: Thank you. I agree actually

1 wholeheartedly with Mike's assessment. I wanted to just
2 kind of capitalize the sound bites that I heard and I'm
3 taking away from this discussion. One, this morning I
4 guess I heard that we need to -- or it's important that
5 we have a standard for sound science, that that's going
6 to be very important, that we all have a common viewpoint
7 of what the basis of the science we're using for this
8 regulation.

9 The second sound bite is whether or not
10 there's some common thought about whether or not there's
11 statutory sufficiency for us to regulate biotech products
12 into the future. I think that was something we came
13 across in a number of the discussion points today, and
14 that's something we need to think about.

15 I want to reiterate we heard about interagency
16 coordination. And I do want to thank my colleagues from
17 EPA who did come today. I think it's important that we
18 continue to talk among ourselves about how we can improve
19 that, and also improve our communication to the public on
20 how we do coordinate. I think there's a lot more that
21 maybe happens that's not evident and, so, we need to, I
22 think, find ways to share that more broadly with our

1 stakeholders.

2 And that just leads into the general sound
3 bite about communication at large. And I'm going to
4 quote from Greg Jaffee who I think put it very, very
5 clearly -- at least to me -- that we need to do a better
6 job of explaining change. And, so, that's something I
7 think we need to think about as we move forward on this
8 Rule, how we explain change to all of our stakeholders.

9 I also heard that we need to do a better job
10 -- or at least start thinking about how we're going to
11 put together appropriate guidance that would accompany
12 this proposed Rule, that would help stakeholders
13 understand really what we intend to do, as far as
14 implementation. And I would expect that, we would
15 consider how we would have public participation and
16 development of any kind of guidance that we want to move
17 forward on.

18 I heard some new concepts or terms today.
19 Maybe they're not new to other people, but this notion of
20 a commercial permit kind of got my attention. And, so, I
21 think it -- at least for me it would be interesting to
22 have a little bit more understanding of what that concept

1 is and when it may or may not be appropriate. So, those
2 are kind of the sound bites that I took away from today's
3 session.

4 EVA RING: Thank you, very much. Did anyone
5 want to add anything that you would have wished that they
6 would have said that they may not have? I thought that
7 was a pretty good summary, so ... all right. Well, I
8 want to thank all of you for your participation today.
9 It's been a long day. And there have been a lot -- there
10 have been many excellent ideas presented today for
11 consideration. And I hope that you've all learned
12 something as well through this format of working at the
13 tables with people who have different views. I feel that
14 that must have happened, but I hope that you feel that as
15 well.

16 Tomorrow is another ambitious day. The thing
17 that I wanted to tell you, is that because we have the
18 honor and privilege of having our Secretary of
19 Agriculture, our Deputy Secretary, the Deputy Under
20 Secretary coming here, it's really important to be on
21 time. So, you know, they will probably be here right
22 before 9 or 9:00, so, please try and get here as early as

1 we can tomorrow if possible.

2 We also have the two homework questions that I
3 was hoping -- that since we had a little time here you
4 can just answer now and put in that big black box that's
5 on the chair over there against the wall. I asked for a
6 box, I got a box. So, I'm going to pass these out to
7 you. Does anyone have any questions about -- what I was
8 going to do is just real quickly reiterate what is
9 tomorrow. Excuse me.

10 KEITH REDING: I'm assuming today is tomorrow
11 for these questions. Because the question is yesterday.

12 (Speaking at once.)

13 EVA RING: Yes. What was the most
14 enlightening for you today? Today is yesterday.

15 (Speaking at once.)

16 EVA RING: And while those are passing out,
17 I'll just run really quickly what we're going to be going
18 over tomorrow. We're going to continue this discussion
19 about the pharmaceutical and industrial use plants.
20 We're also going to talk about -- low level presence is
21 another discussion topic tomorrow. Public participation,
22 transparency. And, again, BRS will summarize for you

1 what they've heard from you through the whole meeting.
2 So, they're very important topics that I -- and anything
3 else that emerges that we may want to talk some more
4 about. I think a few things have emerged today that it
5 would be great if we could have a little more time to
6 talk about them.

7 Is there anything that you would want to
8 suggest, any view that we add to our agenda tomorrow that
9 you would hope we would talk about that you haven't seen
10 an opportunity?

11 All right. And I'm going to give you this
12 time to please answer those two questions before you
13 leave. Thank you again for coming. And I very look
14 forward to seeing you tomorrow.

15 (Whereupon the meeting for the day was concluded.)

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UNITED STATES
DEPARTMENT OF AGRICULTURE

PUBLIC MEETING

9:00 a.m.

Thursday, April 30, 2009

U.S. Department of Agriculture

4700 River Road

Riverdale, Maryland 20737

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

2 MIKE GREGOIRE: Good morning, everybody, and
3 welcome to Day 2 of our public meeting to discuss our
4 proposed biotechnology regulations.

5 We have a very full day planned again for you
6 today, so we're going to get right down to business,
7 and I'm going to begin by introducing Cindy Smith, who
8 I think many of you know.

9 Cindy is the Administrator for the Animal and
10 Plant Health Inspection Service and she's currently
11 serving as the Acting Deputy Under Secretary of
12 Marketing and Regulatory Programs, that mission area of
13 USDA, where she is responsible for overseeing the work
14 of the Agricultural Marketing Service, the Animal and
15 Plant Health Inspection Service and the Grain
16 Inspection, Packers and Stockyards Administration.

17 Cindy was actually the first Deputy
18 Administrator of the Biotechnology Regulatory Services
19 Unit and initiated the effort to strengthen and improve
20 the regulatory program and our regulations that we are
21 discussing yesterday and today.

22 So without further ado, Cindy, welcome.

1 CINDY SMITH: Thank you, Mike. It is really
2 great to be here. I feel like I'm coming home again,
3 both back to APHIS and back to the biotech regulatory
4 area, which is something that has been a strong
5 interest of mine for some time.

6 I have the pleasure to introduce our Deputy
7 Secretary Kathleen Merrigan. Prior to Merrigan
8 being confirmed as our Deputy, she was an Assistant
9 Professor and Director of the Agriculture, Food and
10 Environment Program at the Friedman School of
11 Nutrition, Science and Policy at Tufts University in
12 Boston.

13 She's also a former Ag Marketing Service
14 Administrator. Before that, she was a senior analyst
15 for the Henry A. Wallace Institute for Alternative
16 Agriculture. She also served as the chief science and
17 technical advisor to Patrick Leahy and during that time
18 helped to develop the Organic Food Production Act.

19 She has a Ph.D. in Environmental Planning
20 Policy from MIT, but the most important thing I think I
21 can tell this audience about her is that it was on her
22 second day on the job as the Deputy Secretary for the

1 full Department of Agriculture that she sat down and
2 read every single one of the policy papers that you
3 have just received and you'll be receiving today.

4 So the message I get from that is that you
5 have a very focused supporter in terms of the work that
6 we want to do as biotech regulators and I really look
7 forward to the opportunity to work with the Deputy
8 Secretary in this area.

9 With that.

10 ASSOCIATE SECRETARY KATHLEEN MERRIGAN: Thank you, Cindy.

11 Good morning. I see a lot of familiar faces out in the
12 crowd and that may be because I'm a veteran of these
13 sort of meetings.

14 When the Secretary and I walked in and we saw
15 those white pages and we said, "Oh, my goodness."
16 We're familiar with this process, and it's a really
17 important process in terms of trying to pull together
18 diverse viewpoints to help us figure out this next
19 generation of regulations for APHIS, incredibly
20 important work.

21 I think I started in biotech with a keystone
22 dialogue back in 1987, went through that whole process

1 and then I was with the stakeholders at the Ag Biotech
2 Forum. I see Gregg Jaffe is here. Ray Dobert, you
3 were a part of that, maybe others in the room. I don't
4 know if, Michael, if you participated in that.

5 But we see a lot of value in bringing people
6 together with diverse viewpoints to try to get at all
7 the issues and you had a very productive day yesterday,
8 as I understand it. Today, we're asking you to really
9 tackle some difficult issues around notification and
10 permitting.

11 We're asking for your views on really tough
12 questions having to do with this next generation of
13 plants that have pharmaceutical properties, potential
14 industrial uses. We're asking you some really hairy
15 questions about low-level presence and how that fits
16 into our thinking about these regulations that we want
17 to finalize in the near future.

18 So tough work ahead of you but a really
19 important job and the Secretary and I couldn't be more
20 pleased to show up at your meeting in the midst of
21 everything that's going on, H1N1 has taken over USDA,
22 as you might imagine, but the work that you're doing

1 here is really important. We want to support you. We
2 want to listen to what's being said and work with
3 APHIS, with Cindy and her team, they're doing a great
4 job, to bring this to some sort of completion in the
5 not-so-distant future, is that correct?

6 I know that this has been a very active
7 comment period. We're still in the public comment
8 period, and bringing together the experts in this room
9 is really going to help us reach the next stage of our
10 deliberations and so I appreciate all of that.

11 It's my pleasure to introduce to you Secretary
12 Tom Vilsack, although he really needs no introduction
13 in this crowd, but as I think most of you know, he was
14 the Governor of Iowa before he meandered over to USDA
15 and joined the Cabinet and there biotech is a big, big
16 issue in his state. So he's got a lot of experience.
17 He's long in the tooth, as we say, in these arenas, and
18 I think he's going to work quite closely as well with
19 Cindy.

20 We're going to try to work this together and
21 help figure these things out. He was confirmed on the
22 very first day a Cabinet official can be confirmed, on

1 January 20 . He hit the ground running. There has not
2 been a moment of peace in his life but he's an
3 incredible hard-worker. He brings these huge notebooks
4 home every night and studies up and comes back the next
5 morning. He got in the car this morning. He didn't
6 even quite get out the hello before he started asking
7 questions. That's the kind of guy he is.

8 Coming from an academic environment, I thought
9 I would miss that kind of constant questioning,
10 constant learning stage, and I find that I'm right back
11 in it right here in Washington, D.C., with a terrific
12 leader by my side, and so without further ado, I
13 introduce you to Secretary Vilsack.

14 [Applause.]

15 SECRETARY TOM VILSACK: Well, let me, first of
16 all, start off properly.

17 Good morning, Kathleen.

18 [Laughter.]

19 SECRETARY TOM VILSACK: I realized I didn't
20 actually say good morning when I got in the car.

21 And good morning to all of you, and I want to
22 take this opportunity, it's, I think, the first public

1 opportunity that I've had to thank Cindy for her work
2 and effort. You know, it's difficult enough to have
3 one job but then when you're asked to basically step in
4 and be the Acting Under Secretary for an extended
5 period of time, it puts a lot of pressure and burden on
6 an individual and Cindy has been in my office quite a
7 bit for a multitude of issues and has really done a
8 good job for us, allowing the new people in our office
9 to sort of get into the swing of things.

10 So, Cindy, thank you very much for your hard
11 work.

12 And I'm here today, first and foremost, to
13 thank all of you for the work that you're doing today.
14 You know, these are, as the Deputy indicated, very,
15 very extraordinarily important but also extremely
16 difficult issues.

17 I think it's safe to say that biotechnology,
18 regardless of where you may stand on the nature of
19 biotechnology, the science is here to stay. The
20 question is how should it co-exist with other ways to
21 participate in what's important for our country and for
22 the globe and that is producing enough food and fiber

1 to feed six billion people and that number continues to
2 grow, and as we deal and learn more about biology and
3 as we deal and learn more about science, one thing we
4 know for sure is it's constantly changing and it's very
5 difficult because it's constantly changing for a
6 regulatory structure to be able to respond and adjust
7 appropriately and so here you are today to try to
8 figure out whether or not it in fact can create a
9 system in which different ways to approach agriculture
10 can co-exist and, if so, how and how do you set up a
11 regulatory structure that has enough flexibility so
12 that it can respond appropriately to science as science
13 mature and as we gain greater understanding of science.

14 The biotechnology rules, for all intents and
15 purposes, have not seen this kind of significant review
16 and update for around 20 years. So a lot has changed
17 obviously in that time period, and the Obama
18 Administration, the president has been very clear to
19 his Cabinet members. He wants processes to be
20 transparent.

21 Just the other day, I was in a meeting and I
22 couldn't figure out why there was a staff person, a

1 particular staff person in this meeting. All
2 throughout the entire meeting I'm thinking why is my
3 advance guy sitting in this meeting. I mean, he's the
4 guy that arranges for me to get to places and why is he
5 here and as the meeting ended, I sort of asked
6 somebody. I said, "Why is Roan in this meeting? I
7 mean, he's an advance guy. He's a scheduler. He's the
8 guy who takes care of making sure I get to places on
9 time." "He was there for one reason, sir. If anybody
10 started talking about the stimulus bill, he was
11 supposed to shut off the conversation because the
12 ethics rules that President Obama's put in place
13 prevent you from talking about the stimulus to any
14 registered lobbyist."

15 You know, it's that minute, it's that
16 detailed, and it's that specific in terms of how we
17 want to act on behalf of the public.

18 So, first and foremost, the process has to be
19 transparent and we're here today to reinforce that
20 message, and it also has to be participatory. The
21 President feels very, very strongly about the necessity
22 of trying to get as much input from people who have

1 interests and concerns about issues that involve their
2 lives and their government and that's because he wants
3 to reconnect people with government.

4 As you sit here today, you may be thinking of
5 yourself as facilitators in a regulatory process, but
6 you are also sort of citizens reconnecting with your
7 government and helping to shape your government, and
8 the president is very anxious to see more of that take
9 place in America because for far too long we've been
10 sort of separated from our government. We've looked at
11 government as something that's the enemy or something
12 that is not to be respected or something that's not to
13 be appreciated. You all are engaged in a process that
14 allows for that reconnection to take place.

15 And he also wants it to be collaborative which
16 is why the people in this room have perhaps come from
17 different perspectives as relates to these rules and
18 regulations, but to the extent that reasonable people
19 sitting in a room like this, dedicated to trying to find
20 difficult but oftentimes common solutions can actually
21 achieve really good regulations, good direction.

22 APHIS needs that direction. We've received

1 over 20,000 comments about the proposed rules and some
2 of them have suggested that we need to be more clear
3 about the rules, and some have suggested that those
4 rules need to be more flexible, and in some cases the
5 comments have suggested less flexibility. But I think
6 it's very instructive in the process that people are
7 engaged in this issue and have very definite opinions
8 about it and your job, with the help of facilitators
9 and these white boards, is to try to figure out where
10 the common ground is, and the importance is that we
11 have a system that allows folks to co-exist, that
12 allows folks choices, that allows folks to pursue their
13 dream and their hopes as relates to how land in this
14 country is to be used and how we're to feed our
15 population and how we are to continue to make
16 opportunities to feed the rest of the world.

17 Let me finish by saying that yesterday I was
18 in a breakfast meeting with Secretary Clinton. She
19 hosted a first-ever meeting at the State Department of
20 congressional leaders, of other Cabinet members, and
21 other government officials focused on food security.

22 As we begin the process of rebranding the

1 United States to the rest of the world, one area where
2 we'll be able potentially to do that is in the area of
3 food security, a different approach, not just simply
4 providing the excess food that we can grow and produce
5 in this country in the form of emergency aid but how we
6 provide the technical assistance and the knowledge and
7 the information that allow people to grow what they can
8 grow best and hopefully create opportunities for their
9 trade, as well, to grow revenues and grow incomes and
10 grow the capacity for people to have available food and
11 access that food and be able to utilize it properly.

12 The work you're doing here may be about the
13 United States, it may be about the USDA's regulations,
14 but the reality is it has a global impact because there
15 will be people who will ultimately follow and try to
16 learn from your experiences and your discussions here.

17 So this is pretty important work in and of
18 what you're doing for the country but now you've also
19 got some responsibility to try to figure out how to do
20 it as well as you possibly can because it will have an
21 impact on the rest of the world.

22 So the Deputy and I thought it was appropriate

1 for us to be here this morning to thank you. We're not
2 going to be able to respond to very many of the
3 questions that you might have simply because it's still
4 in the process of open comment. We're still trying to
5 solicit information, still trying to get your thoughts
6 and ideas.

7 I don't know that there are any preconceived
8 answers. That's what this process is about, but we did
9 want to tell you we are both supporting each other in
10 this effort, and we're very, very anxious to see your
11 work.

12 So with that, let me stop and I guess we open
13 it up to questions, and I told Kathleen that any
14 question that's tough goes to her. She is, by the way,
15 the one with the Ph.D., not me.

16 So questions. This is a kind crowd. Let me
17 open it up to say questions about anything related to
18 USDA. How's that? There we go. That was enough.

19 RAY DOBERT: I wonder if you'd comment,
20 Secretary, a little bit about the recent -- you've made
21 recent comments with regard to the importance of
22 assuring that export markets remain open to U.S.

1 commodities, especially those commodities which include
2 biotech-derived products.

3 SECRETARY TOM VILSACK: Sure.

4 RAY DOBERT: Just how that work is going and
5 what the goals are for that work.

6 SECRETARY TOM VILSACK: Okay. Thanks for the
7 question.

8 Let me start by saying that part of our
9 responsibility at USDA, as I see it, and one of the
10 reasons I took this job was to make sure that the
11 people of the United States fully understand and
12 appreciate that the USDA is not solely about the
13 producer community.

14 I think oftentimes the perception is that
15 we're about farmers and ranchers and we are, but we
16 like to think of ourselves as an every-day/every-way
17 Department, and if you look at the massive scope of what
18 USDA is involved in, from providing broadband to
19 helping to build houses, helping to furnish healthcare
20 clinics, to equipping fire stations, to doing
21 wastewater treatment, to food safety, to food
22 assistance, you see that our responsibilities are much

1 broader.

2 Part of those responsibilities do involve,
3 however, us having a keen understanding of what's
4 happening in terms of agriculture in the country and so
5 every five years we do a Census and the Census
6 basically was just completed. I think I was in office
7 for less than a month and I had brought in this big
8 huge book and I started reading it which is what I do
9 when people put big huge books on my desk.

10 I started reading it and I saw five basic
11 trends which are important for people generally to
12 understand about what's going on out there in the
13 countryside.

14 The first trend is that there is an enormous
15 growth in what I'll refer to as small-income farm
16 operations. Now remember, farms are defined fairly
17 liberally in this country as any activity that has more
18 than a thousand dollars in sales. So it doesn't take a
19 lot to be a farm, but we had a 108,000 new farming
20 operations in that small-income area of less than, say,
21 \$5,000 in sales.

22 Well, who are these people? These folks are,

1 I think, growing, for the most part, fruits and
2 vegetables and nuts and they are a critical component
3 to the future of USDA and, for that matter, the future
4 of the country.

5 We want to encourage their growth and
6 expansion which why is you're seeing us talk a lot
7 about more nutritious food in the diets of children,
8 particularly as we reauthorize school lunch and school
9 breakfast. We're going to try to link those local
10 producers up with local purchasers, particularly
11 institutional purchasers. That's one trend.

12 The second trend was the farms in the middle,
13 the farms that have somewhere between \$10,000 in sales
14 and maybe a half million dollars in sales. We saw a
15 decline in their number, about 80,000 fewer operations
16 than there were five years ago.

17 Now some of those operations migrated into
18 larger operations, but for the most part I think we saw
19 an actual decline in that number.

20 So USDA has to think, continue to think of
21 ways in which we can support those mid-sized and mid-
22 income-sized operations so that we keep populating and

1 repopulating rural communities.

2 One way we're going to do that, try to do that
3 is a continued effort to do what the President has
4 asked us to do which is to expand the reliance in Farm
5 Country on biofuels and renewable energy. We want to
6 do audits of farm operations to figure out ways in
7 which farmers might incorporate renewable energy into
8 their operations, might be able to produce renewable
9 energy and therefore create additional income
10 opportunities for them that may not exist today.

11 Then there are the large operations, the
12 operations that have more than \$500,000 in sales. They
13 are what most people refer to as "production
14 agriculture." Those folks are extremely important, in
15 that five percent, the top five percent of those farms,
16 about a 125,000 of them, produce 75 percent of the food
17 that we eat.

18 The question is how do those folks survive?
19 One of the strategies for their survival is the
20 capacity not just simply to grow what we need but also
21 to be able to export whatever surplus we have to
22 countries that are not capable or not able to grow what

1 we can grow in great abundance.

2 Likewise, we have to be able to import into
3 our country those things which we don't grow or raise
4 in abundance. That's the notion of trade.

5 The reality is that when you look at what's
6 being grown in America today, a substantial percentage
7 of the grains that are being grown are GMOs and there
8 are, indeed, differing opinions about that worldwide.

9 What we are seeing, I believe it's fair to
10 say, is a recognition on the part of many globally that
11 we are headed towards a train wreck in terms of our
12 capacity to grow enough and raise enough food and the
13 rising world population and so more countries now are
14 looking at how science can be part of the answer to
15 that and so there's become a bit more acceptance of
16 GMOs from countries in South America, from some African
17 countries, from a few Asian countries, and even many of
18 the Eastern European countries are growing in
19 acceptance.

20 And so the question is how does America work
21 with our friends to overcome whatever barriers may
22 exist, real or not, in other countries so that we have

1 trading routes that are free and where the barriers
2 that are not artificially constructed and we've got
3 work to do on this. We have relationships that have to
4 be built. There needs to be a trusting relationship
5 that's built with this new Administration, with
6 existing administrations, which is why I traveled to
7 Italy two weeks ago to visit with the G8 ag ministers
8 and several other ag ministers of other countries to
9 begin that dialogue and conversation.

10 I think it's already in a sense, if you will,
11 -- I'll take a little side route here. I think it's
12 bearing fruit already. Those relationships are
13 important because when the H1N1 outbreak occurs
14 initially, Japan in particular made a very strong
15 statement about the capacity and the safety of American
16 pork products and they weren't going to ban those
17 products.

18 That ultimately impacts those hard-working
19 farmers out there are just trying to do what they do
20 and trying to help raise their families and help feed
21 our families.

22 So part of the strategy is involved in

1 building relationships, finding out what those barriers
2 are, trying to educate folks as best we can that
3 whatever rules, whatever regulations, whatever barriers
4 exist have to be science-based, and if they're science-
5 based, if there's a problem with the science, we need
6 to solve it. If there isn't a problem with the
7 science, then people shouldn't be constructing
8 artificial barriers.

9 I think there's a growing recognition on the
10 part of many in the EU generally that perhaps they need
11 to rethink or take a slightly different view than what
12 they have with GMOs. Is this going to solve the
13 problem? Is this going to open up that market widely?
14 Perhaps not. Will there still be a strong desire on
15 the part of folks to know precisely where food's coming
16 from and precisely what it's made of? Absolutely.

17 In fact, we are in USDA talking about know
18 your food/know your farmer because I think consumers in
19 this country are becoming more aware every day of the
20 need for their awareness about what they're consuming,
21 what their families are consuming.

22 So that's the third trend, large increases in

1 the production agricultural side, about 40,000 new
2 operations in that side.

3 Two final trends for your benefit. One has to
4 do with the aging nature of farmers in this country and
5 as we think about trying to migrate those small
6 operations into mid-sized operations, just think about
7 the fact that right now the age of farmers in five
8 years, the average age went from 55 to 57, so we aged
9 two years on average in five years. That is not a good
10 trend, and the reason we aged is because we had, I
11 believe, a 30-percent increase in the number of farmers
12 over the age of 75 and a 20-percent decrease in the
13 number of farmers under the age of 25.

14 Now, you know, I don't know about you but if
15 I'm 75, God bless those folks who are still farming.
16 That's hard work, but I don't know that we can continue
17 to rely on 75-year-old farmers to produce the food that
18 we need to eat. So we need to figure out ways in which
19 we can encourage beginning farmers.

20 One of the things we did is announced more
21 additional resources for beginning farmers. We had the
22 stimulus money that came about. About 50 percent of it

1 went from direct-to-farm loans went to beginning
2 farmers. So we're trying to figure out ways in which
3 we can keep people on the farm, encourage young people
4 to get into farming and migrate those people who are
5 small entrepreneurs and getting started, making them,
6 you know, sustain their operations.

7 The last trend has to do with rural
8 development and that trend is that a substantial
9 percentage of farmers today and farm families require
10 off-farm income to survive.

11 At least almost half, 900,000 of the 2.2
12 million farmers in the country today, 900,000 of them,
13 they themselves, the farmer, not the spouse but the
14 farmer has to work at least 200 days off the farm to
15 keep the farm.

16 So what was probably true when I was kid,
17 which was that the countryside's economy was ruled by
18 agriculture, is probably reversed now and that is that
19 the rural economy allows farmers to stay in business.
20 So USDA's got to be about not just helping that
21 producer and farmer out but it also has to be about
22 producing job opportunities in rural areas so farmers

1 can stay on the farm so what we don't end up with is a
2 half a dozen really mega humongous farms that are
3 controlled by a small number of people.

4 Well, that spurred some thoughts and ideas.

5 JIM BAIR: Good morning. I'm Jim Bair from
6 the Millers Association.

7 The power of biotechnology has caused huge
8 shifts in planning decisions for growers. For example,
9 in North Dakota where they never used to grow corn and
10 soybeans, biotech is now allowing them to grow corn and
11 soybeans.

12 Coupled with the biofuels push, what's
13 happened is we already import 100 percent of the oats
14 we consume in this country and we're importing more and
15 more quantities of wheat every day as we push food
16 grain production offshore.

17 So I'd be interested in your comments, Mr.
18 Secretary, on how we can reconcile and help the public
19 to understand that we grow fewer acres of wheat today
20 than we did in 1898. So how do we reconcile these
21 production shifts with the consumer's desire to not be
22 dependent on imports for basic staple food commodities?

1 SECRETARY TOM VILSACK: You know, that's an
2 interesting question you've asked and let me answer it
3 a couple different ways.

4 First of all, when I went over to Italy to
5 talk about food security, the one thing that was
6 impressed upon me in preparation for that trip is that
7 the American view of agriculture is not necessarily to
8 promote the concept of self-sufficiency.

9 We have a lot of our trading partners who are
10 sort of wedded to the notion that they ought to be
11 self-sufficient in their capacity to produce their own
12 food. The problem with that is if everybody maintains
13 a self-sufficiency attitude, then basically what we
14 have is no trade, no inter-relationship, no interaction
15 with the rest of the world because we're all sort of
16 taking care of ourselves and not worrying about what
17 other folks are up to. So the U.S. view has always
18 been that we want exchanges. We want trade to take
19 place and we want people to do what they do best.

20 So I'm not so sure that Americans have sort of
21 bought into the notion that they want to be totally
22 self-sufficient in terms of their food production. In

1 fact, I think we import more food than we -- I think
2 that we import more than 50 percent of the food that we
3 consume.

4 Secondly, sort of on the opposite end of that
5 answer is the notion that we want to maintain diversity
6 in what we grow, and I think what we're going to see is
7 a move back to that and the reason, I think what's
8 going to move us back to that, is the discussion about
9 climate change.

10 I think as we begin the process of looking at
11 cap and trade systems, we're going to see people make
12 perhaps different decisions than they've made in the
13 past because there's going to be an economic reason for
14 them to think about the possibility of rotation of
15 crops that they haven't necessarily been thinking about
16 up to this point.

17 They may be economically incented to think
18 about rotation of crops, to think about using their
19 land differently than they have been using it, not
20 because it's the simplest, easiest, cheapest thing to
21 grow and therefore the easiest way to make a profit
22 from your farming operation, but because you're

1 actually being rewarded for doing something different
2 each year or doing something differently than you have
3 done it in the past.

4 What am I talking about? If you've got a cap
5 and trade system, you're putting a price on carbon.
6 You put a price on carbon, it makes fossil fuels a bit
7 more expensive than they've been. As part of that cap
8 and trade system, you're going to have an offset
9 process. You're going to have a way in which those who
10 can't meet their cap or can't purchase enough credits
11 to emit whatever they have to emit to stay in business,
12 they're going to be looking for the purchasing of
13 offset credits and one great opportunity for purchase
14 of offset credits is agriculture and forestry because,
15 as we know, it's much less of a problem than a lot of
16 other industries.

17 You've got nitrous oxide and methane which are
18 two key problems for agriculture, far less on the CO₂
19 side, but you've got power companies, you've got heavy
20 manufacturing where they are really concerned about how
21 they're going to meet their requirements.

22 There will, I believe, be a system in which

1 farmers will be paid to fertilize their farms
2 differently. They may be paid for raising different
3 cover crops. They may be paid for trees that are
4 growing on their property. They may be paid for ways
5 in which to produce livestock differently or to feed
6 livestock differently.

7 There is a lot of interesting research being
8 done on feed to livestock in terms of reduction of
9 methane from basically the digestive process that it goes
10 through. All of that may change the calculation
11 farmers are going to make over time. So you may
12 actually see a move back towards greater crop diversity
13 than you see today.

14 At the same time that's going on, there's
15 going to be a continued effort, I think, for Americans
16 to rethink their own personal diets and that of their
17 families because we're faced with an obesity epidemic
18 in this country that is absolutely affecting and
19 impacting our children.

20 Somewhere between 30 and 35 percent of our
21 youngsters are either at risk of being overweight or
22 are in fact overweight. We've seen Type II diabetes

1 which is not necessarily genetic, it's something that
2 comes with the lifestyle, we're seeing a rise in that
3 among children, and we're seeing a healthcare system
4 that is burdening our economy to the point where we're
5 not going to be able to sustain it.

6 That's going to lead people to focus on
7 strategies for reducing healthcare costs and one way to
8 do that obviously is more nutritious eating focused on
9 prevention and wellness and that's going to, I think,
10 lead to a desire on the part of Americans to consume
11 hopefully more fruits and more vegetables, you know, a
12 more balanced diet than they are consuming today. That
13 may also lead to different strategies and different
14 choices being made.

15 So I think we're sort of in an evolutionary
16 circumstance and situation where we have sort of two
17 major movements taking place. One is to continue
18 trying to figure out how we're going to feed an ever-
19 increasing population as the amount of land available
20 for production shrinking and at the same time how do we
21 make sure that our diets are more nutritious than
22 they've been and how do we do a better job in

1 preventing illness and disease through wellness and so
2 you've got that going on. It's complicated.

3 Yes, sir? One more question, I'm told. Okay.

4 Did I have two hands up? We'll do two more.

5 NEHRA NARENDER: Okay. I'm glad you opened it
6 up for, you know, all kinds of questions.

7 I know for President Obama, energy and, you
8 know, the biofuel and bioenergy was very high on the
9 agenda, and now some can argue that the oil prices have
10 gone down, they're one-third what they were before.

11 I just want to know if the President and
12 yourself, you still have the same type of commitment
13 and the long-term vision for the biofuel and bioenergy.

14 SECRETARY TOM VILSACK: Well, you know, I've
15 only had one job interview in my life. It was the one
16 I had with him. I married the boss's daughter, so that
17 was a relatively simple way to get a job --

18 [Laughter.]

19 -- in my law practice and so I was very keenly
20 aware of listening to my boss when he offered me this
21 job and he said two things to me at the job interview
22 after he said, "You're my guy," and I sort of fumbled

1 around and I said, “Excuse me, sir? Your guy?” He
2 goes, “My Secretary of Agriculture.” He said, “You
3 have to go through the vetting process.” He said,
4 “Don’t tell anybody but you’re my selection.”

5 So then my heart’s pounding about 200 beats a
6 minute and I’m just really excited and thrilled. He
7 said two things. Number 1. “I want our children to
8 have more nutritious diets.” He said, “Whatever we
9 have to do, we have to get our kids more physically
10 active, focused more on fruits and vegetables, get more
11 nutrition in their diets because we can’t sustain
12 what’s going on here in the country.”

13 That’s the first thing he said to me. He
14 didn’t say, you know, I’m worried about crop prices or
15 I’m worried about farm subsidies. He said more
16 nutrition for our children and he understood
17 intuitively that at USDA two-thirds of our budget goes
18 to food assistance. If you look at our job in terms of
19 money, that’s what our job is, food assistance, right?

20 The second thing he said to me, he said, “We
21 want to make sure that we continue to promote renewable
22 energy and fuel.” The reason he said that, the second

1 thing, is that he is aware of the fact that there are
2 23 oil-producing countries in the world, 15 have peaked
3 in production. You've got a China economy that
4 continues to grow while the rest of the world's
5 contracting. You've got an Indian economy that will
6 grow over time because eventually it will have the
7 youngest workforce in the world and over take China and
8 there will be a lot of activity going on in that part
9 of the world, and then you've got these African nations
10 that at some point in time, as they get their act
11 together, there's going to be economic activity and
12 it's all going to be -- it's all going to need energy.
13 It's going to need power and a lot of it's going to be
14 still relying on fossil fuels, regardless of what the
15 world does about climate change.

16 So there's going to be greater demand with
17 less supply. So obviously the price of that commodity
18 is going to go up and so, you know, what we have to do
19 is move Americans away from looking at gas prices today
20 to realizing that it's in our long-term best interests
21 from an economy standpoint to begin transitioning our
22 economy away from as much of a reliance on fossil fuels

1 that we had.

2 The third thing he said to me in our first
3 Cabinet meeting, this big Cabinet meeting and we talked
4 about a whole series of issues and I was sitting right
5 next to him and he turned to me as he was about ready
6 to leave, and he said, “Oh, by the way, I want you to”
7 -- he said, “This is long term, but I want you to work
8 hard to reduce farmers’ reliance on fossil fuels.”

9 So my boss has given me three direct
10 instructions. So I’m on a plane with him the other day
11 flying to Iowa. He repeats those three instructions.
12 So that tells me he’s focused on those three things.
13 So that means I’m focused in part on those three
14 things.

15 I realize that we cannot, and I’m coming from
16 a corn country, I’m coming from a country that has
17 built 20 some ethanol production facilities based on
18 corn, we are not going to be able to sustain biofuels
19 long term on corn. We are going to have to transition
20 to second- and third-generation feedstocks and then,
21 ultimately, we’re going to have to transition to
22 completely different kind of combustion systems and

1 different kinds of ways of transporting ourselves here,
2 there and everywhere.

3 But in the meantime, we're going to look at
4 biofuels. In the meantime, we're going to try to
5 accelerate research on alternative feedstocks so we're
6 using waste product from corn production, we're using
7 grasses or we're using woody biomass or we're figuring
8 out how to better manage our forests and use that
9 timber that we're going to be extracting from our
10 forests so that we don't have these massive wildfires
11 in a proper way to manage forests to provide more
12 fuels.

13 So you're going to see a continued effort,
14 make no mistake about that. The Farm Bill that was
15 passed in 2008 has a substantial amount of resource
16 designed to fuel biofuels, the biofuels industry, and
17 you have a tremendous amount of money coming through
18 the stimulus, through the Department of Energy, to do
19 the same. So there's no question about that,
20 regardless of what the oil prices do.

21 Quickly, sir.

22 ZELIG GOLDEN: Thank you again for being

1 here. My name is Zelig Golden from the Center for
2 Food Safety and I represent folks who eat organic food
3 and farmers who grow organic food.

4 Concerning the rules, we're curious to know
5 how in the effort of coexistence with the knowledge
6 that when genetically-engineered crops are created,
7 it's inevitable that they get into non-GM crops and
8 organic standards prohibit GM crops, so we're curious
9 to see how we're going to protect the organic food
10 sector.

11 And as a corollary, during the campaign
12 President Obama suggested that he'd be a proponent of
13 labeling for GM food and I'd like to hear just what the
14 position of the USDA is on that currently.

15 SECRETARY TOM VILSACK: Well, let me answer
16 that question. I've not had a chance to talk to the
17 Deputy about the issue of labeling and so I'm a little
18 bit hesitant to give you a specific answer on that
19 without having a chance have her weigh in on this.

20 I don't really want to comment on any aspect
21 of the current rulemaking process that you all are
22 engaged in because we really are interested in your

1 best work, helping to create our best work.

2 But let me just say this. The two of us, I
3 think, I think it is fair to say and if it is not,
4 she's absolutely -- she can stand up and go that's not
5 right.

6 We are strong believers in the need for
7 maintaining and expanding and growing our organic
8 industry. There are two reasons. One, because there's
9 a lot of consumer demand and I think there will be
10 increasing consumer demand for it. Two, economically,
11 it's one of the fastest-growing aspects of our ag
12 economy and, you know, the reality is the consumers are
13 happy, at least at this point, some consumers are happy
14 to pay a slightly higher rate which means producers get
15 a slightly -- well, in some cases, a significant return
16 on their investment which is why you're seeing a lot of
17 these small entrepreneurial activities get involved and
18 engaged in organic farming. They need to stay in
19 business. They need to be given the opportunity to
20 expand. They need to be given the opportunity to have
21 that choice.

22 The challenge for all of us is to recognize

1 that we are not tomorrow or in the foreseeable future
2 going to be a land of only organic agriculture and
3 that's -- you all may disagree with me on that, but the
4 way I see things, that ain't going to happen. If it
5 happens, it's going to take a long, long time, right?

6 So the question is how do we create structures
7 and systems and regulations that allow you the choice
8 that you have made for yourself which I value and I
9 think is important and at the same time recognize that
10 production agriculture farmer somewhere down the road
11 has made a different choice?

12 I wish I had -- if I had all the answers to
13 this, shoot, I wouldn't have this job, I'd be selling
14 myself off as a consultant and making a ton of money.
15 But that's a challenge you all have, is you have to
16 help us move that dialogue, move that problem-solving
17 one step closer to figuring that problem out and, you
18 know, it's complex because you are dealing with
19 liability issues, you're dealing with economic issues,
20 you're dealing with a whole series of issues that are
21 very, very hard, and you are dealing with people that
22 are very passionate on both sides.

1 It isn't just -- you know, the passion is
2 often expressed on the organic side, but there is
3 passion on the other side, as well, and that's
4 sometimes a tough combination in which to get answers
5 which is why we create structures like this and
6 processes like this to figure out how do we move that
7 forward.

8 You may walk out of here at the end of this
9 day and you may have worked hard and you may feel like
10 you haven't found the answer, but if you get us one
11 step closer to the answer, that makes your work
12 beneficial and helpful and it's an evolving process.

13 I don't think we're going -- you know, I think
14 it's an evolving process, which is why we're doing this
15 and probably should have done it more than 20 years
16 ago. We waited 20 years to do it. We should be doing
17 this in a way in which we are able to -- those answers
18 are able to evolve over time.

19 So, you know, I want coexistence. You all
20 have to figure out how to help us get there because
21 that's the world, that's the real world we live in.
22 Those choices need to be protected on both sides

1 because people are going to continue to make those
2 choices and it's not today an either/or situation.

3 Thank you all very much.

4 [Applause.]

5 SECRETARY TOM VILSACK: Let me thank Mike
6 Gregoire for his work here in terms of overseeing this
7 and Kevin Shea, thank you. You're also an Acting
8 Administrator. You're sort of like doing the same
9 thing that Cindy's doing. So I want to thank both of
10 you for your involvement with this and for the work
11 that you're doing for us.

12 Thank you, all.

13 [Applause.]

14 MIKE GREGOIRE: We're going to take a 15-
15 minute break at this point. We have coffee and food in
16 the back there. Help yourselves. We'll get back
17 together in 15 minutes.

18 [Recess.]

19 EVA RING: Would everybody please take their
20 seat again? Thank you.

21 [Pause.]

22 MIKE GREGOIRE: Okay. If everybody can take

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1 their seat, we're about to get started up again,
2 please?

3 I thought we would just diverge momentarily
4 from our agenda to reflect on what the Secretary said.
5 I guess for me it reinforced the importance of what
6 we're doing here yesterday and today and I think that
7 he is in fact very committed to a transparent and
8 participatory and collaborative process. He's very
9 open to what this rule might look like in the end, and
10 I thought he made very strong remarks about co-
11 existence.

12 So I thought we would take a few minutes now
13 if anyone else wanted to reflect on what they heard
14 from the Secretary or make any sort of remark based on
15 the presentations that we heard this morning and then
16 I'm going to turn it over to Eva who's going to talk a
17 little bit about reactions of the participants here to
18 yesterday's meeting and the things that were left in
19 the drop box last night.

20 If anyone would like to say anything about
21 what they just heard or comment on the Secretary's
22 remarks?

1 [No response.]

2 EVA RING: Hard act to follow. That's what I
3 say.

4 [Laughter.]

5 EVA RING: I want to say thank you to all of
6 you, also, who put your comments last night in the drop
7 box because it really helped us to see whether we're on
8 track and where people still feel challenged.

9 I wanted to share just a few of the insights
10 that we got from those and you can hear your fellow
11 colleagues, what they had to say.

12 Many folks, in answer to the question, what
13 was the most enlightening moment for you yesterday,
14 better understanding of the limitations that APHIS
15 operates under, based on the authorities that they do
16 and don't have, interesting to learn industry's
17 perspective regarding a lot of practical considerations
18 around the issues that we raised.

19 Several felt that most regulations were
20 largely reasonable and practical and with input some of
21 the issues could be minor, that people probably thought
22 were larger before they came here. People appreciated

1 the format for discussion. They liked hearing the
2 points of view of other stakeholders about the
3 regulation and their issues.

4 It was nice to see that there was consensus on
5 some concerns across different interest groups and
6 people appreciated where there was specificity around
7 things, where they were unclear at first or something
8 was initially said that was vague and they were able to
9 get more specifics, and there were a lot of other types
10 of more specific comments.

11 I also wanted to share with you things that
12 people felt they were still challenged by. Even though
13 they appreciate that there is some consensus around
14 some issues, there's still a challenge of continuing to
15 reconcile the diverse needs and concerns of all
16 stakeholders which I guess, as Mike said, I heard the
17 Secretary also say was a challenge for us all to co-
18 exist and respect each other's right to choose. So you
19 sort of reiterated that to me.

20 The noxious weed challenge and how it will be applied.
21 Over and over in these
22 forms, I saw a request for guidance that would be

1 clearer. It's a challenge to provide guidance that
2 everyone will understand, know what they need to do,
3 understand the regulations.

4 Several people still felt challenged by the
5 fact that there's this concern about biotechnology-
6 derived products being subjected to a different
7 standard than non-GE products.

8 Sorting out what role, if it's not APHIS's
9 role, will others have then to look at and deal with
10 economic impacts, marketing impacts, as somebody asked
11 the Secretary, environmental health and safety.

12 People still wanted to have some -- some felt
13 challenged by definitions not being clear and actually
14 suggested on these forms perhaps some things like case
15 studies, examples that would be somehow, I guess,
16 either in the guidance or provided through the
17 regulation that would help people understand.

18 Challenge to inform people about what you're
19 just learning, an overview of this meeting about the
20 authorities, the Plant Protection Act and this Weed Act
21 regulations, restrictions, especially the public, and I
22 appreciated that that one table yesterday put on their

1 public hat and answered the group questions as if they
2 were a member of the public because that sort of
3 grounded me and I think all of us in terms of how
4 challenging that whole thing is of imparting knowledge
5 and explaining things in a way to someone who hasn't
6 been in the field, so that they can feel comfortable
7 with it.

8 The regulatory process can still be
9 streamlined. It says we've had a lot of experience
10 over the years and yet the process itself doesn't seem
11 to be getting easier or better. That was a comment
12 that was made, and there was still a challenge in one
13 person's mind about noxious weed authority being the
14 catchall category that would be able to solve
15 everything.

16 I thought that we really appreciated all those
17 comments and your taking the time to provide that
18 feedback to us.

19 Yesterday -- how many new folks do we have
20 here in the room today that weren't here yesterday?

21 [Show of hands.]

22 EVA RING: Okay. Just a handful. Yesterday,

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1 we had gone over the fact that these were our
2 objectives. I'll just put them back for you, to
3 provide you information. Acknowledge issues and
4 concerns that you all have, and APHIS is going to
5 continue today to provide current thinking on several
6 issues that have been identified that are the topics of
7 this meeting.

8 Yesterday, for those of you who weren't here,
9 we talked about the authority of the Plant Protection
10 Act, the noxious weed authority in there. We talked
11 about the scope of the regulation as it's laid out in
12 the proposed rule. We began discussion of plants that
13 are engineered to produce pharmaceuticals and
14 industrial compounds. We're going to continue that
15 discussion right now. That's where we are.

16 What had happened yesterday was groups at the
17 tables identified what concerns they have about that
18 particular topic and everyone presented and that's
19 where we sort of left off.

20 Jane has been kind enough to go through, make
21 a very good attempt, I think, at summarizing into
22 different themes and categories what you did come up

1 with there because we're going to build on that in our
2 next exercise.

3 So for those of you who weren't here, I'm
4 going to turn it over to Jane just to summarize for you
5 for a minute what people came up with during that last
6 exercise.

7 JANE BERKOW: Is John here?

8 EVA RING: Yes, and I'd like you to present
9 first where we left off and then, yes, John Turner,
10 Policy Coordination Director, will give a short
11 presentation before our next exercise.

12 JERRY COURSEY: Eva, let's do the norms real
13 quick.

14 EVA RING: Oh, yes. I had asked Jerry --
15 thank you for reminding me -- to just reiterate for the
16 new folks and for all of us who are here, some of the
17 norms that we went over yesterday and on my part I'd
18 really like to express appreciation for the way
19 everyone interacted yesterday and contributed. It was
20 -- I've facilitated a lot of meetings and it's very
21 unique to have the kind of respect and engagement and
22 patience that all of you had. So thank you.

1 JERRY COURSEY: Thanks, Eva. This will be a
2 short version, just a reminder of a couple important
3 things, and I want to echo what Eva said. Thanks for
4 your interaction yesterday, your dialogue, and your
5 listening and sometimes the debate that went on at the
6 tables. We really appreciated that.

7 If you can continue to identify yourself today
8 in the plenary sessions, that's very helpful for
9 everybody, especially the court reporter here. Please
10 continue to do that.

11 BRS staff again today will be circulating at
12 the tables. There will be one BRS staff person again,
13 and they can answer clarifying questions but not get
14 wholly involved in the dialogue.

15 Now at the tables, ideally we'd like to have
16 five members of the public, one BRS staff. So look
17 around. If you've got more than six or more than five,
18 we have some new tables in the back. Does anyone have
19 more than five? Let's see.

20 [Pause.]

21 JERRY COURSEY: Four? Okay. We can use one
22 more over here. That'd be great. Mike, you can sit

1 right here. That'd be great. Thank you.

2 Okay. Once we have the presentations by the
3 BRS staff on this issue, we'll get the flip charts back
4 out to you. On the flip charts, again thanks for all
5 the presenters, thanks for the reporters who did a lot
6 of work yesterday. Please continue to do that work
7 today and the table groups, I'd like you to help the
8 recorder out. That's kind of a hard job. Both
9 listening for the points and then putting them up on
10 the board.

11 If you see that the recorder has missed a key
12 point that someone has raised, please bring that to
13 their attention so they can go back and add it. So
14 just table groups help the recorder get all the key
15 issues up on the flip chart. That'd be great.

16 And last but not least, please put your
17 Blackberrys on vibrate. That would be very helpful for
18 everybody, and I think that's it.

19 All right. Jane?

20 JANE BERKOW: Okay. We're actually going to
21 have John.

22 EVA RING: We're flipping here. Jane

1 correctly, I think, said that it would be easier if
2 John makes his little presentation first and then
3 she'll review where we were yesterday and we can go
4 right into the exercise.

5 JOHN TURNER: Okay. Thanks, Eva. Good
6 morning, everyone.

7 So I have a very short presentation just as
8 background on plants genetically engineered to produce
9 pharmaceutical or industrial substances, sometimes, of
10 course, called pharma crops.

11 So, first, to talk about our current policy
12 for regulating these, if you read the regulations to
13 see how we regulate pharmaceutical plants, you really
14 won't find any guidance there. Our regulations have
15 enough flexibility so that on a case-by-case basis we
16 can do whatever is needed.

17 I think the only mention of pharmaceutical in
18 our current regulations is to say that you can't get
19 authorization for a pharmaceutical crop in the
20 notification procedure. You have to use a permit.

21 However, to clarify how we regulate these
22 types of crops, what we did was, in 2003, issued a policy

1 statement where we laid out very strict confinement
2 measures and stated that the agency would provide
3 intense oversight activities for all GE crops that are
4 engineered to produce pharmaceutical and industrial
5 substances.

6 So some of these strict confinement measures
7 include things like dedicated equipment, land use
8 restrictions in years after pharmaceutical or
9 industrial plants are grown, and, of course, multiple
10 inspections at key points during the growing season on
11 APHIS' part.

12 And the bottom bullet there is important. It
13 does not expressly prohibit the use of plants
14 ordinarily used for food and feed production to be
15 engineered for production of pharmaceutical and
16 industrial crops. They just simply must be kept
17 separate.

18 Our intent, as we wrote the proposed
19 regulations, was to regulate these using a risk-based
20 permitting system. Under this system, GE plants would
21 be regulated based on the risk that they posed due to
22 the plant used and the trait, not their intended use.

1 It features issuance of permits for
2 environmental release of GE plants that are engineered
3 for pharmaceutical or industrial substances, if APHIS
4 can determine that the release of would not be likely
5 to disseminate a plant, pest or noxious weed, and,
6 finally, confinement measures would be determined on a
7 case-by-case basis based on the risk posed by the
8 environmental release.

9 We certainly want to recognize and acknowledge
10 that pharmaceutical plants, use of plants to produce
11 pharmaceutical compounds, has been a hot issue and it is
12 something that many of the stakeholders care deeply
13 about.

14 We received more comments on this aspect of
15 the proposed rule than any other aspect. The same was
16 true for the EIS, which we published in 2007. It was
17 also the number one issue.

18 If you get into the specific comments,
19 probably the number one was the use of food and feed
20 crops for production of pharmaceutical and industrial
21 compounds. Certainly some commenters were opposed to
22 any outdoor testing, any outdoor growing of any crop

1 that produced pharmaceutical and industrial, but
2 certainly food and feed crop was a concern.

3 There were also specific concerns about public
4 health, about environmental consequences, and,
5 importantly, market disruptions that may occur if these
6 were to get out.

7 Our current position in the proposed rule is
8 to use environmental release permits so that we will
9 issue these for crop species, including those used for
10 food and feed that produce pharmaceutical and
11 industrial substances, if it can be done in such a way
12 which would not disseminate noxious weeds or plant
13 pests, and we would apply very strict confinement
14 measures in order to accomplish this, and again the
15 bottom bullet to remind us that the PPA includes a
16 broad number of concerns and risks that the
17 stakeholders have. The PPA-authorized regulation is
18 only for the purpose of preventing the dissemination of
19 plant pests and noxious weeds.

20 So that's what I have for background.

21 JANE BERKOW: Okay. So as Eva said, your next
22 exercise, your next discussion is going to be built

1 around work we did yesterday, and I did my best to put
2 some themes but I may have misplaced some things, so
3 you can correct that, but at any rate, it looked like
4 some of these -- these were the big issues that were
5 coming up out of yesterday's discussion.

6 First of all, starting out with contamination
7 concerns, particularly worries about contaminating the
8 food supply and what that might be and then how do you
9 control, you know, energy flow, persistence in the
10 environment, things like that.

11 Then the other -- another concern or group of
12 concerns would be grouped around unintended use or
13 commercial risk, so what would be unintended use of
14 these products and then really needing some intense
15 scrutiny for this and things like that.

16 And then there was some mention of the
17 liability concerns, so that if there was a breach of
18 containment or what have you, then what would be the
19 liability and how would that get handled in terms of
20 the statutes covering that and/or insurance concerns
21 with that.

22 Another area of concern was around safety and

1 mostly around human health safety concerns and how that
2 gets managed and the importance of coordinating with
3 FDA and managing the safety issues, and then a lot
4 about containment and the importance of that, and then
5 the ability to enforce it and how do you -- including
6 the transportation of these products and how you make
7 sure that they're safe and those concerns.

8 Then there was sort of a whole group, I call
9 them regulatory options, that may not be the right
10 title, but at any rate, it just seemed like there was a
11 whole grouping of things that you were saying -- a
12 message that you were trying to communicate which is
13 the importance of -- that you felt that pharma products
14 really needed to be scrutinized under a high set of
15 standards and criteria that's very clear, and then the
16 importance of getting clear guidance from APHIS and how
17 to handle these things.

18 The need to establish tolerance for what's
19 okay and how that gets handled and then an interest in
20 terms of, okay, it just sort of depends on what the
21 pharma product is and how these get -- need to be
22 treated individually and considered individually as

1 opposed to one size fits all approach. And then there
2 was a group that came up with questions that need to be
3 considered as the regulation is getting formed and sort
4 of really being clear about scope of the authority--
5 where does it begin, where does it end--and also
6 mention of the importance of this being mandatory, not
7 voluntary; things like that, science-based.

8 And then what I thought was an interesting
9 one, the last comment that came out of one group where
10 they felt BRS has a good track record so far on the
11 safety front and need to recognize that.

12 So those were the groupings and then Eva can
13 then direct you in terms of your next set of exercises
14 because you're going to be sort of thinking about these
15 things in your next discussion.

16 EVA RING: Was there anything else that we may
17 have missed that was really important to anyone here?

18 [No response.]

19 EVA RING: All right. Right now you're being
20 -- every table should receive copies of the issue paper
21 that was written up on plants that can produce
22 pharmaceutical and industrial compounds--the BRS's

1 current thinking, summary of the comments that have
2 been received on that, and what we want you to do,
3 based on what you did yesterday, based on what Jane
4 just presented, and the issue, is to talk at your
5 tables about two questions.

6 Given the authorities that we learned about
7 yesterday, do you feel there are ways within these
8 authorities to mitigate these risks as well as are
9 there ways that you see in there, I think I would add
10 to that if you think there are ways.

11 The second one is are there other mechanisms
12 or processes outside of these authorities that might
13 merit further discussion, you know, even after today
14 and in what appropriate venues could that discussion
15 take place?

16 I'd like to just piggyback on what the
17 Secretary said. We may only make one step forward
18 today, but I think you can -- you know, we're asking
19 you here to suggest some ways that you think the
20 dialogue needs to continue and who should be involved
21 in it and how might you like to be involved.

22 Thank you.

1 Oh, I think for this one we're allowing about
2 20 minutes. So about 5 of.

3 [Pause.]

4 EVA RING: We're going to take just a couple
5 more minutes. Thank you.

6 [Pause.]

7 EVA RING: We're going to start. Even if you
8 haven't quite finished, I'll let you finish that
9 discussion in the next round. I don't want to stifle
10 any ideas.

11 Why don't we go question by question? If you
12 don't mind, I'd like to get a sense of what answers the
13 groups have for the first question, which was are there
14 ways, given the current authorities, to mitigate these
15 risks?

16 Who would like to begin with what you talked
17 about on that question?

18 KEITH REDING: Keith Reding with Monsanto. We
19 kind of took the first approach related to combined
20 field trials and we said APHIS has authority to place
21 any condition on a permit to address any concerns. So
22 we felt there is a way, but we could not identify any

1 means to prohibit use in food crops based on the Plant
2 Protection Act and we fear it would require legislative
3 solution at the state or federal level because
4 authority given to them under the PPA is to address
5 plant pest or noxious weed risk and not whether
6 something is a -- a crop is in food or not.

7 EVA RING: Any questions or clarification?

8 [No response.]

9 EVA RING: All right.

10 RACHEL LATTIMORE: I guess personally I had
11 questions about sort of the assumptions in the question
12 about the risks and one of the things that we talked
13 about was that the concerns about what we've defined
14 here as pharma crops are really the same kinds of
15 concerns that go across any kind of biotech crop, that
16 you've got the safety profile, the regulatory status,
17 you know, how the protein may be expressed in the
18 plants. Those drive so many of these concerns, whether
19 it's liability, you know, across the whole risk of
20 things, and so, you know, those are addressed by the
21 PPA in the same way that they're addressed for other
22 types of crops.

1 EVA RING: Any questions about that, their
2 interpretation?

3 [No response.]

4 EVA RING: Thank you. Who else had an answer
5 to Question 1? Back here. What do you think the
6 current authority has that can address --

7 WENDELYN JONES: Wendelyn Jones. We also
8 discussed the fact that under the PPA, APHIS has the
9 ability to set restrictions with pharma so that
10 they could do business.

11 EVA RING: Thank you. A question?

12 GREG JAFFE: I think in our group, we were --
13 I think we questioned whether APHIS did have the
14 authority under the Plant Protection Act to cover all
15 of the potential risks and concerns that stakeholders
16 and others have about pharma crops.

17 I think there was a thought that maybe a broad
18 reading of the noxious weed provisions could do that,
19 but we had a lot of concerns that if we did do that,
20 that that would also be that same broad reading for the
21 more conventional genetically-engineered crops, that
22 APHIS would be required to do that same reading for

1 those crops, and we didn't feel that that necessarily
2 was the best way to go.

3 EVA RING: Thank you for clarifying. Did you
4 have a question back here?

5 [No response.]

6 EVA RING: Anyone else have an idea about the
7 authorities?

8 MIKE WACH: This is Mike Wach. We had the
9 same discussion our neighboring table had about whether
10 or not there was sufficient authority, but I think
11 something there was agreement on was that that's
12 probably not the first question.

13 The first question is what are the risks, what
14 are the identifiable risks that we need to manage?
15 Then you ask if you have the authority to manage them,
16 and I think there was some feeling around the table
17 that some of the risks are known and managed well and
18 some of the risks are not known and therefore you don't
19 know if you're managing them or not, if you have the
20 authority to manage them.

21 EVA RING: So did you feel that you could
22 manage the ones that were identified as known in your

1 first session yesterday or not?

2 MIKE WACH: Not the consensus among the table.

3 EVA RING: And you definitely feel like how

4 can we say we can manage what's unknown? Is that what

5 I hear you saying?

6 MIKE WACH: I'm sorry?

7 EVA RING: The second part was if something's

8 unknown at this point, you're not sure whether the

9 authority can really manage that?

10 MIKE WACH: Yes.

11 EVA RING: Thank you. Why don't we move to

12 the second question then because I heard a lot of good

13 discussion going on with some ideas around perhaps some

14 other mechanisms or processes outside of the confines

15 of the authority as it was described that might merit

16 discussion, a lot of appropriate venues for those

17 discussions take place, who should be involved.

18 Anybody want to start with what you talked

19 about on that?

20 RACHEL LATTIMORE: We moved pretty quickly, I

21 think, into this question and talked about again, to

22 the extent that, you know, we had discussed that the

1 safety, the regulatory status, et cetera, may not
2 depend on, you know, that this is being used for
3 therapeutic purposes, this is being used for a biofuels
4 purpose, the safety could differ widely. That
5 information needs to be given to the public in a
6 better, more transparent way, and we talked about the
7 importance of communication of real versus perceived
8 risks with the public and ways that that could be
9 accomplished through, we discussed, independent
10 published safety data, you know, having academics out
11 there looking at data, developing data.

12 We talked about the involvement of FDA,
13 particularly for the regulatory status, that some of
14 the issues of concern, be it safety or regulatory
15 status, may be that FDA hasn't weighed in on some of
16 these things and ways that we could encourage that
17 through something like the early food safety assessment
18 or through the NEPA process that may go along with some
19 of the early permitting of these products.

20 And we also talked about that, as the
21 Secretary mentioned, the emphasis in the Administration
22 on biofuels and the importance of new technologies for

1 biofuels may provide the attention and resources to
2 allow for BRS to work more closely with agencies like
3 FDA to make that happen.

4 EVA RING: Thank you very much. Another
5 group, other ideas?

6 KEITH MENCHEY: We had a lengthy discussion
7 about the role of FDA and safety determinations there.
8 We got into discussion about their authorities and what
9 they can and they cannot do, but I think we finally
10 came to an agreement that there should be some FDA
11 involvement to make some safety determinations before
12 things go to the field, so that in the case that a
13 potential event does happen, that we're prepared
14 quickly to go to the public and say there is not a
15 health concern.

16 Steve brought up the case of the rice and how
17 FDA's statement seemed to have saved the day.

18 So then, of course, we talked about the
19 planting could be contingent upon such a safety
20 determination. And then, finally, as Gregg said earlier,
21 some concern about the breadth of the noxious weed
22 authority and it is very broad, encompasses some

1 economic market concerns that we're not so certain that
2 APHIS is either qualified to deal with or should be
3 dealt with in other places, and that if we open the
4 door just for pharmaceutical there, then we're going to
5 have to open that door for pretty much everything else.

6 EVA RING: Thank you. Back here. Anybody
7 else?

8 UNIDENTIFIED MALE: I'll add a little bit to
9 it. They're turning it over to me.

10 We had a conversation very similar to what
11 Rachel's and Pete's were regarding the role of FDA and
12 having an early evaluation and I think we took a little
13 bit different tack.

14 We wanted to see this described a little bit
15 more formally in that there would be some form of
16 interagency coordination defined perhaps in the
17 proposed rule that would spell out how this interaction
18 would be promoted between FDA and APHIS, something like
19 a memorandum of understanding or something like having
20 OSTP as the oversight agency to make this formal
21 interaction occur, where it would be involved in the
22 decision-making process by providing safety information

1 ahead of time.

2 So that's our addition to what was already

3 said.

4 EVA RING: Thank you.

5 UNIDENTIFIED MALE: That just falls in the

6 general category of how to mitigate the risks and we

7 thought that certainly as we read the proposed rules so

8 far, it seems to fall in the scope of the use of risk

9 analysis involving very good risk assessment and risk

10 assessment informing the risk management approach, risk

11 management including safety which is primarily what

12 we're talking about here, but also environmental safety

13 and commercial aspects of the application, and should

14 have some indication of how this addresses liability.

15 So we think the general structure is there and

16 we just want to tighten it up a little bit.

17 EVA RING: Thank you.

18 MIKE WACH: One of the primary parts of our

19 discussion about the second question was that not every

20 stakeholder has been given a place at the decision-

21 making table about this particular issue and that

22 including those who may incur costs from system failure

1 and that kind of drove the rest of our discussion.

2 A key challenge for the agency remains public
3 perception, in spite of assurances that the regulations
4 are science-based. There are certain -- you know, they
5 call it the “yuck” factor, but there are certain hurdles,
6 public perception hurdles that you have to address,
7 regardless of how firmly grounded in science the
8 regulations are.

9 A key other approach or additional approach is
10 to support new research. We find that most research is
11 quite old. We’re realizing that this is not sexy
12 research or easily-published research and because of
13 those two things, it’s probably actually going to take
14 some enabling support from the government to get those
15 studies done and get the data out there.

16 And then one of the things we talked about was
17 to enable people who want to actually pursue this
18 technology to make a business decision with all costs
19 and considerations in front of them. And to have some
20 sort of -- we talked a lot about tiers, but to have a
21 tiered system within just pharmaceutical crops so that
22 the tiers take into account the crop you choose, the

1 trait you choose, and that there is increasing rigor,
2 depending on the crop that you've selected and with all
3 those considerations in place you can intelligently
4 make the decision to grow the particular crop, the
5 particular trade, and not have surprises at the end.
6 You can work all these risks -- all these management
7 costs into your business plan so you're not doing this
8 blindly.

9 JIM BAIR: Jim Bair from the Millers
10 Association. My only addition would be that when APHIS
11 reviews and approves the production of a
12 biopharmaceutical crop, you are in essence a partner.
13 You have -- you approved it. You're in essence a
14 partner with the tech provider and like everything in
15 life, it's all about the money, right?

16 Well, the reason the food companies are
17 nervous about technology is how will it impact my
18 business? You have -- it has the potential to cause
19 real damage to my brand and I could lose my company.
20 So if APHIS is going to be a partner with the tech
21 provider in approving this biotech crop, then there's,
22 my view, should be a plan for indemnification or

1 somehow assuming a liability for any containment
2 failure.

3 We honor biotechnology and if you can build a
4 better mousetrap, you might get wealthy doing it, but
5 you don't have the right to put my business at risk,
6 and if the government is going to be a part of that
7 plan that fails and costs me my company, then I need to
8 be indemnified for that loss.

9 Another way to look at it, if I'm not
10 participating in any potential profits that result from
11 the production of that crop, then don't ask me to take
12 -- to assume the damage or to clean up the mess when
13 there is a failure.

14 MIKE GREGOIRE: Mike, I'm going to ask if you
15 can just go back to the other -- I had a question on
16 one of -- the top item on the next page -- the previous
17 page about participation in the process.

18 I just wanted to ask you to expand on that a
19 little bit.

20 MIKE WACH: The two?

21 MIKE GREGOIRE: Yeah. How not every
22 stakeholder gets a place. Could you just explain more

1 about what that discussion entailed and --

2 MIKE WACH: I thought I just did that. I'll
3 take another whack at it, but it was largely if I come
4 to you and complain about a permit, let's say, you
5 might respond and say, well, it's all on our website
6 and that's probably -- I'm sure that's true, but is it
7 my responsibility either as a consumer or as a food
8 manufacturer who's concerned about -- is it my job to
9 spend an hour a day on the APHIS website just checking
10 to see if anything new, any new permits have been
11 dropped in the hopper?

12 I think my point was APHIS needs to do more,
13 and it's gotten better, don't get me wrong, I think
14 it's gotten better, I'm saying it could be made even
15 stronger. The information needs to be pushed out of
16 the agency as opposed to, well, we put it on our
17 website and if you're interested, just go find it.

18 You know, that puts responsibility on me to go
19 find it. I don't want that responsibility. I want the
20 responsibility on you to go out to all stakeholders and
21 say -- and I don't know what that -- you know, how does
22 -- what form would that take. Listservs or somehow a

1 more active dissemination of information as opposed to
2 the very passive process of just putting it on the
3 website and anybody that cares, it's their job to go
4 find it.

5 MIKE GREGOIRE: I understand.

6 MIKE WACH: I mean, you can spend six hours a
7 day just poking around the APHIS website, if you wanted
8 to, and I don't want to do that. Sorry.

9 LARRY ZEPH: Now for the other side of the
10 story. The issue I have with that is there are laws
11 out there and there are procedures to do exactly what
12 you want to do. It's not the Plant Pest Act. There
13 are legal mechanisms in place to accomplish those
14 things.

15 So I'm very puzzled why another regulatory
16 system would be brought in to do something that it's
17 not covered to do. It's set up specifically to cover
18 these plant pest activities in the field trials and
19 commercialization of biotech crops. It's apples and
20 oranges in my view. Yeah. I'm talking about
21 liability.

22 EVA RING: I would remind people to identify

1 yourselves when you speak. Thank you. Who were the
2 two folks that were talking?

3 JIM BAIR: Jim Bair from Millers.

4 EVA RING: And?

5 LARRY ZEPH: Larry Zeph, Syngenta.

6 JIM BAIR: Yesterday, one of the tables had on
7 their flip chart, I don't remember to which question
8 they were responding, but it was something along the
9 lines of that APHIS had the responsibility to promote
10 biotechnology and I'm not sure that I agree with that.

11 I think you're a regulator. You're not, let's
12 say, the Ag Marketing Service whose job it is to
13 promote standards and quality and facilitate the
14 marketing of fruits and vegetables.

15 I would argue that APHIS is a regulator and I
16 think that that may be part of the discomfort that a
17 lot of consumers have, is that they have a perception
18 that maybe you've been too cozy with the biotech
19 companies over the years, and they just want to know
20 that somebody's worrying about this stuff.

21 So I would probably quarrel with the notion
22 that APHIS should be a promoter of biotech. How about

1 -- you know, so if you're the promoter of biotech, then
2 who is looking out for the consumer? You could say,
3 well, FDA supposedly, but that gets to the bullet which
4 appears on about 50 different flip charts over the last
5 24 hours which is there's a lack of real coordination
6 between the three agencies on that very topic, on that
7 bullet, which is giving people information that calms
8 and reassures them about the safety of biotechnology.

9 EVA RING: That's a specific suggestion. I'm
10 going to add it to your chart.

11 KEITH REDING: Just one clarification. I
12 think that bullet point on the chart yesterday was to
13 promote and protect agriculture, not biotechnology.

14 WENDELYN JONES: APHIS's mission statement,
15 and you all who work for APHIS can correct me on this,
16 is promote and protect American agriculture.

17 MIKE GREGOIRE: The mission of APHIS is to
18 protect the health and value of U.S. agriculture and
19 natural resources.

20 JIM BAIR: I would argue as a food company that if my
21 commodity gets devalued because of containment failure,
22 you have failed your mission. You haven't protected

1 U.S. agriculture.

2 EVA RING: Thank you for your views.

3 MIKE SCHECHTMAN: Mike Schechtman, USDA. I

4 just had a question for the people at Keith's table and

5 Jeff's table over here and that is a question about the

6 FDA consultation, and I wanted to get a little more

7 information about what you actually thought that FDA

8 was -- would be able to deliver.

9 Some of these products might get some kind of

10 safety evaluation and some kind of result. Are you

11 suggesting that if it didn't get that result from FDA,

12 that APHIS would say no, you can't plant them for some

13 reason or what actually were you saying in terms of the

14 hand-off between FDA and APHIS?

15 GREG JAFFE: This is Gregg Jaffe from the

16 Center for Science in the Public Interest. I don't

17 think we talked about this as though it would be an

18 interaction between the FDA and USDA or APHIS on this

19 point.

20 Our point was that we wanted an FDA safety

21 determination on a pharma crop which included a food or

22 feed crop and if they weren't -- whatever that standard

1 was, if they didn't make that safety determination, I
2 think that we felt that that crop therefore shouldn't
3 be grown. We didn't say that APHIS necessarily had the
4 authority to stop that growing or that. So we didn't
5 -- we were talking -- answering the question of sort of
6 what other agencies should be involved and what should
7 they be doing in that involvement. We didn't get into
8 the details of therefore FDA should be stopping that
9 planting or APHIS should be stopping that planting or
10 how did the BRS regulatory process interact with that
11 FDA process.

12 We were talking more theoretical about what we
13 want to see happen to ensure that the risks that we
14 talked about yesterday with these pharma crops were
15 addressed by the Federal Government. We thought FDA
16 was a place to do that, but we didn't talk about what
17 they had the authority or not.

18 We did have some discussion about whether they
19 had the authority and things like that, but we didn't
20 come to the conclusion. We were talking more about the
21 principles.

22 RACHEL LATTIMORE: We discussed this, as well,

1 and I think it goes back to getting beyond, ooh, pharma
2 crops are scary. So there's automatically liability
3 and there's automatically concern and going back to
4 what is the basis of those concerns. Is it a safety
5 issue? Is it regulatory status? Is it people don't
6 like it?

7 And I think we've got to recognize what the
8 government can and can't do and again how it can go
9 about doing that. "I don't like it" may be best
10 addressed by communication and education. You know,
11 safety is certainly addressed in some respects by, you
12 know, within the authority of the Plant Protection Act
13 by APHIS and FDA has a role to play with regards to
14 food safety and they also can have a role to play with
15 regards to regulatory status, that, you know, whether
16 it's some kind of LLP something, you know, but some
17 type of role to play.

18 And again, we didn't get into the details of
19 what -- how broadly their authority lies, but, you
20 know, as I think this table discussed, you know, when
21 FDA steps in and makes a statement regarding safety,
22 regarding, you know, is this allowed to be in the food

1 supply, that goes a long way towards the concerns both
2 of the public and of the liability of other
3 stakeholders.

4 EVA RING: Did we get to this table over here
5 for the second question?

6 KEITH REDING: We're done.

7 EVA RING: Okay. Anyone else have any
8 discussion you wanted to share around this second
9 question?

10 [No response.]

11 EVA RING: Thank you. I appreciate people
12 asking for clarification and explaining things further
13 because sometimes just a simple statement isn't clear.

14 What we're going to do now is Andrea Huberty,
15 who is the Branch Chief of the Regulatory and
16 Environmental Analysis Branch, is going to give you a
17 presentation on the proposed permitting process in the
18 reg and then a little bit about the background on the
19 notification and the permitting process.

20 ANDREA HUBERTY: Thank you, Eva. Okay.
21 Now I have to follow that discussion.

22 So we're completely switching gears here.

1 Before, we were talking yesterday and a little bit more
2 this morning about more conceptual issues. We were
3 talking about regulatory authority, what we can and may
4 not be able to do under the PPA.

5 Now we're going to switch a little bit more
6 into talking about more implementation, what we propose
7 in the rule regarding notification and permitting.

8 So, currently under our current system, we
9 have a two-tiered system, permitting system. We have
10 our regular permits as well as our notifications and
11 our notification system is an expedited system for
12 GE plants that meet our eligibility criteria in the
13 regulations and that APHIS considers lower risk and has
14 extensive experience regulating.

15 The changes in the proposed rule have the goal
16 of providing more flexible risk-appropriate oversight,
17 better regulatory enforcement, and improved
18 transparency.

19 The current notification procedure does not
20 provide such flexibility. When John was talking
21 earlier about permitting and allowing the flexibility
22 to establish permit conditions, those really are just

1 for our permit procedures. Notifications don't have
2 that flexibility because their performance standards
3 are built into the regulations and, additionally, the
4 other problem, perceived problem with performance
5 standards is that they're sometimes difficult to
6 interpret as well as enforce.

7 And so, additionally, APHIS considers that the
8 use of the permitting procedure itself, instead of
9 notifications, will give the agency a way to address
10 the recommendations from the USDA Office of Inspector
11 General and also certain provisions of the 2008 Farm
12 Bill. Some of those OIG recommendations called on APHIS to
13 require additional reports during the course of the
14 environmental releases that we regulate as well as the
15 2008 Farm Bill recommended additions to the current
16 recordkeeping and reporting requirements.

17 Such recommendations can be implemented under
18 the permitting procedure by imposing records or
19 reporting as permit conditions and again as it stands
20 for notifications, we're not allowed to add conditions
21 to notifications, and thus to achieve the goal of a
22 more flexible risk-appropriate system with better

1 regulatory oversight and improved transparency, APHIS
2 is proposing to authorize all of our importations,
3 interstate movements, and environmental releases under
4 the permitting procedure, eliminating the notification
5 procedure, thereby again providing APHIS flexibility to
6 establish permit conditions, when needed.

7 So as with all of these issues, we have
8 significant comments. Some commenters supported the
9 proposal, believing that eliminating the notifications
10 actually could increase APHIS oversight by requiring
11 APHIS involvement and tailoring specific conditions for
12 every environmental release.

13 Other commenters had substantial problems with
14 the proposal, citing longer time frames for APHIS
15 action on applications, a lack of clarity about the
16 information needed in particular applications, and
17 vague descriptions of increased demands for reporting
18 and recordkeeping.

19 Some commenters suggested that the increased
20 regulatory burden does not correspond to the low risk
21 nature of the GE plants that APHIS typically had
22 authorized under the notification procedure, and in

1 particular academic researchers commented that APHIS
2 should make the existing notification procedure more
3 streamlined with fewer regulatory requirements in
4 circumstances where APHIS has already seen similar
5 genetically-engineered plants that pose no or little or
6 no risk of plant pest or noxious weeds.

7 And finally, some commenters were concerned
8 that the categories of permits were not adequately
9 based on risk as well as the risk assessment procedure
10 used by APHIS for permitting was not described
11 adequately in the proposed rule.

12 So this is our current thinking. APHIS
13 considers that the goal of a more flexible risk-
14 appropriate oversight with better regulatory
15 enforcement and improved transparency can best be
16 achieved by eliminating the notification procedure and
17 revising the permitting procedure in a way to provide
18 oversight that is commensurate with the risk of
19 introduction or dissemination of plant pest or noxious
20 weed.

21 However, APHIS does acknowledge and recognize
22 the concern of many commenters that the proposed

1 regulations need a clearer description regarding
2 categories, permit conditions, and other requirements
3 associated with those categories.

4 APHIS also acknowledges the concern that the
5 proposed regulations need to take into account how
6 timely the system operates. Based on experience, APHIS
7 considers that the time frames needed for issuing a
8 given permit will be based on the degree of APHIS
9 familiarity with similar genetically-engineered plants.
10 For example, familiar crops and traits will be reviewed
11 in a similar time frame as current notifications, and
12 other crops and traits will be reviewed in a similar
13 time frame as our current permitting procedures.

14 APHIS is still considering whether and to what
15 extent such time frames will be captured in the
16 regulations.

17 And finally, APHIS considers in certain cases
18 proposed recordkeeping and reporting requirements could
19 be substantially increased for some permit holders and
20 APHIS is attempting to balance these burdens with the
21 need to have information available to verify
22 compliance.

1 So before we move on into talking about the
2 implementation of these procedures, are there any
3 questions?

4 [No response.]

5 ANDREA HUBERTY: Then I will pass it on to
6 Eva.

7 EVA RING: Thank you. We're going to pass
8 around now the issue paper that covers what Andie just
9 went over. There's a lot of information.

10 So I'm just going to ask you to talk about one
11 thing for about 15 or 20 minutes. What do you see
12 after you've heard what she was talking about as
13 APHIS's intention to do? What are the potential
14 impacts of the proposed permitting procedures that you
15 see?

16 RAY DOBERT: Just a clarification. As
17 proposed in November?

18 EVA RING: Yes. Thank you.

19 [Pause.]

20 EVA RING: Excuse me. I'm really sorry to
21 interrupt. I just wanted to call your attention that
22 in the interest of time, I'm throwing out the questions

1 that are going to be in the next session because I
2 think some of you are already starting to get into not
3 only identifying the question about, you know, what are
4 the impacts but what other approaches might work or
5 some things, some reasons why you think.

6 So I'm going to -- if you get to this, that
7 would be great, too. If you can include not only what
8 are the impacts of the proposed procedures but what
9 other things might work, we could do it all in one
10 report-out session. So putting those up there. Sorry
11 to interrupt.

12 [Pause.]

13 EVA RING: I just wanted everybody to know
14 that the lunch is back there. So if you're done, you
15 can -- we're going to reconvene at 1 and I'll give you
16 a little bit of time just to finish up, if you haven't
17 finished capturing everything, but you can get your
18 lunch now. The sandwiches are in the back and the
19 cafeteria, as I said, is up the hall to the left, if
20 anyone wants to go there.

21 [Pause.]

22 EVA RING: All right. We're going to have our

1 first report-out on what you discussed with the
2 permitting. Could everyone please take a seat?
3 Just to refresh for one minute the questions
4 that were on the table were what are the potential
5 impacts of the proposed permitting procedures in the
6 proposed reg; specifically, what was important to you
7 and what approaches did you think might work better, if
8 you felt that the permitting process as it was outlined
9 wouldn't work for some of your needs?

10 I'm going to start with this group over here.

11 Thank you very much. Annie, you're first.

12 ANNIE GUTSCHE: Annie Gutsche from DuPont.

13 This group talked a lot about the specific items that
14 we thought would be helpful in defining more clearly
15 the permitting procedures and we talked a lot about the
16 need for a little more guidance to be helpful in
17 clarifying the uncertainties that we need for
18 developers.

19 For example, it would be useful to have
20 guidance or case studies to flesh out the different
21 categories to make it more clear what category an article
22 might fall under.

1 We did recognize, of course, that the rule
2 needs to balance regulatory flexibility and this is
3 needed by agencies and regulators to deal with the new
4 science coming up, but developers also have to have
5 certainty and predictability for our timely needs. So
6 that's a difficult balance but something that both
7 sides felt was very important.

8 Then another important item in the permitting
9 process was the efficiency of the review and the group
10 felt that the current timings were appropriate and one
11 way to look at the different categories is by
12 streamlining, depending upon the category of risk.

13 So I'm going to jump to the last point and the
14 idea there is the data requirements should be
15 appropriate to the risk and not as it currently is in
16 the proposed rule, sort of a one size fits all type of
17 system.

18 So one example that was brought up was perhaps
19 one way to streamline is to agree to a set of
20 conditions upfront for the lowest-risk category and
21 that way all of these conditions are reviewed, they're
22 binding, and people who are reviewing them within the

1 agency don't need to look at it over and over again and
2 do it case-by-case.

3 And the final item we talked about was the
4 need to have implementation time for the new rules and
5 that is largely due to IT types of constraints because
6 we have IT systems in place to -- that are currently
7 adjusted to the e-Permits that BRS has in place and so
8 if recordkeeping and permit conditions change, we need
9 to adjust our systems, as well, and that doesn't happen
10 very quickly. So that was something that was also very
11 important to this group.

12 EVA RING: Thank you. Any questions for what
13 she said?

14 DAVID HERON: Just a quick follow-up.
15 When you said the timing, by that you mean the timing
16 of the current regulation or the timing in the proposed?

17 ANNIE GUTSCHE: Current, the timing of the
18 current. The timing of the proposed is unknown. We
19 would like specific timing.

20 WENDELYN JONES: Wendelyn Jones, Syngenta.
21 One of the first areas of true consensus we had at our
22 table was the need for case studies, both relating to

1 this section of the proposed rule and the entirety of
2 the proposed rule to help add clarity to it.

3 We thought, in considering the various
4 proposed changes to the permit requirements, science
5 was of key importance. We discussed the timeliness by
6 which permits can be issued and concern over that they
7 may not be processed in a timely manner.

8 We thought it was important to have
9 transparency of actual permit conditions, and we
10 thought that the factors considered in setting the
11 permit conditions needed to be emphasized because there
12 was going to be need for coexistence between say
13 biotech and organic, et cetera.

14 We were a little worried about the lack of
15 clarity around record keeping and want to emphasize the
16 need to have the goals of the record keeping match the
17 actual risks of the products. And lastly, we thought
18 with the proposed reg that perhaps APHIS wasn't giving
19 itself enough credit with regards to their own
20 experience with the history of field trials going on in
21 this country. The old system was working. So would you
22 all like to add anything? Okay.

1 EVA RING: Any questions of this group? If
2 not, I have one question. I notice that you mentioned
3 case studies, and you mentioned case studies, and I
4 guess I find myself wondering what are you seeing, what
5 are you picturing when you talk about a case study?

6 WENDELYN JONES: I personally was using the
7 word “case study” as opposed to guidance, because case
8 study I’m envisioning as something the agency might be
9 able to deliver more quickly to help with the clarity
10 as opposed to guidance, which can be higher level sign-
11 off before it can be issued.

12 EVA RING: Thank you.

13 RAY DOBERT: In previous -- when APHIS has
14 implemented new regulations, they came out with what
15 was called guidance, but inside the guidance a lot of
16 times were specific descriptions. I’m sorry – with
17 Monsanto. They would give specific examples of a
18 particular crop or a situation and they would give an
19 example of how one would apply the performance
20 standards for a particular crop. So in some respect,
21 that is -- that could be envisioned as a case study,
22 where you take a particular situation and you describe

1 how would you go about meeting the performance
2 standards or meeting the confinement conditions, so
3 that kind -- that's a kind of example that one could
4 use.

5 WENDELYN JONES: Thank you, were you also
6 going to -- thank you so much.

7 EVA RING: Would anyone else like to share? I
8 think it's -- I can tell there were very good
9 discussions going on in all the groups around this
10 question, so who would like to -- this table.

11 GREG JAFFE: Greg Jaffe with Center for
12 Science and Public Interest. Our group has gotten
13 smaller since this morning, so there's just three of us
14 left. And I think we first talked about the proposed
15 changes for the permitting and notification process, and I
16 think, you know, in our perspective, we thought the
17 proposal had merits, there was a simplification to it,
18 it was better for the public in terms of understanding.
19 We viewed the process of the changes of getting rid of
20 notification and just one permit process, more of a
21 process change and not a substance change. We thought
22 that most of the products that had gone through

1 notification and this process still have the same kind
2 of time period and things like that, and we thought
3 that they just need to more explicitly spell those
4 kinds of things out, give people -- I would call them
5 case studies, examples. There are, you know, 15,000
6 field trials that they've approved over the years, and
7 a lot of those have been approved in a notification,
8 how will they now be taken? Actual real examples and say,
9 okay, this BT corn that went under notification, this
10 is how it's going -- under the new system, this is how
11 it's to be processed, this is the data it would need,
12 things like that, so I call them examples.

13 But you compare to things you've done in the past.
14 That gives the regulated community and the
15 stakeholders a real opportunity to see is there any
16 substantive change or is there a process change or what
17 are the changes by the new system. But I think the view
18 was that the proposal we thought had merit, and
19 especially when it came to things like explaining the
20 system internationally, notification was very difficult
21 to understand, and everybody else does permitting, we
22 thought there were benefits to that. But as I said, I

1 think our thing was we need a better explanation about
2 how the new system would operate and practice with
3 examples. To us, that was -- a lot of what might be
4 concern about the system is that people don't
5 understand or are unclear about how it would really
6 operate in practice, and so the more examples one can
7 give, I think about where it's going to be the same as
8 the current system and where it's going to be different
9 from the current system. That would be beneficial to
10 all stakeholders.

11 When we talked about one of the other
12 questions, which was sort of, well, what alternative or
13 other options or other ways that one might go with
14 this, and this was more my idea than the other two in
15 my group, is that to consider both field trial and
16 commercial permits, to eliminate deregulation, but to
17 have just a permitting system within that system, field
18 trail permits and commercial permits as a way to,
19 again, I think a way to eliminate a confusing thing
20 about deregulation when it comes internationally and
21 otherwise, as well as being able to deal with some of
22 the other concerns that we did talk about as a group,

1 which was -- there was some concern that one of the
2 problems with the current permitting system, it doesn't
3 always acknowledge as a commercial product actually
4 being produced in a planting -- a GM planting, so
5 whereas in most cases when you have a commercial
6 planting, things are deregulated, but especially in the
7 case of pharma crops, for example, they're done under
8 permitting.

9 They may be actually producing a commercial
10 product, but nobody knows about that. One, the permit
11 system is not as transparent and participatory as the
12 deregulatory process, but also they're not necessarily
13 -- APHIS isn't always looking at the intent of the use.
14 They don't even know sometimes whether there -- there's
15 a product that's actually being commercialized through
16 that planting.

17 And Steve mentioned in particular rice and
18 concerns about the U.S. government or his industry
19 needing to certify that there are no GM rice --
20 commercial GM rice being grown in the U.S. when, in
21 fact, there were some GM rice being grown in the U.S.
22 under permitting, but nobody knew about it, didn't

1 know that the product was actually being produced. And
2 you get into the question of what's commercial and
3 what's a commercial product. But also, there was also
4 a talk of one of the reasons not having commercial
5 permits might also work. One would be that you know
6 the product; and two, there was some issues, I think we
7 all agreed, at least a couple of us agreed that it
8 might be good to have some oversight after a commercial
9 product -- after deregulation, but the system right now
10 really doesn't allow for that, but there are some
11 benefits to having some oversight or the potential to
12 have oversight after a product is commercialized.

13 And then the last issue we talked about was
14 imports. And one of the things we brought up was, you
15 know, again, more explanation by APHIS in the proposal
16 about how they're really going to deal with import
17 permits, and in particular import permits for things
18 that might not necessarily be grown in the U.S., but it
19 might be used for food, feed, or processing, but might
20 be viable plant material that might be imported, and
21 exactly how are they going to deal with that.

22 There was talk about reciprocity and whether

1 we deal with worries about market issues and access to
2 where we're exporting things, importing things, are
3 they being treated the same by other countries in terms
4 of their regulatory system and their permitting system.
5 So they covered a bunch of issues. I think they
6 covered the questions more or less.

7 EVA RING: A lot of policy issues here --

8 MICHAEL WACH: Thank you. Michael Wach again.

9 Let's see, one of the primary reactions we had before
10 category system is that it's unlikely the staff will be
11 able to handle the work load generated if things that
12 were currently managed under a streamline system
13 suddenly turned into a permit, but you have much longer
14 time frames and much more actual work to send through
15 the processing system.

16 And so we turn back to a system where at
17 least one of those categories that have to encompass
18 the time frames currently represented by notification.
19 The, you know, not only for the people at the table who
20 would feel that the time frames and the record keeping
21 requirement and so forth would slow down their
22 operations; we also identified other populations such

1 as university researchers who often have to have a
2 permit in hand before they can apply for a grant, and
3 if that permit takes six months to get, you may just
4 never get a chance to apply successfully for a grant.
5 Chances are, theirs would be material that would
6 typically go out under notification.

7 It also generally lacked the recognition of
8 the agency experience and the science that underlies
9 the safety of these materials and treat them all as --
10 as other groups have pointed out, treat them all the
11 same in terms of record keeping and compliance.

12 Also, the sort of -- and others may at the
13 table may need to articulate this for me, but felt that
14 changing -- the change may strain cooperation between
15 USDA and EPA because of a sudden shift in how certain
16 things are handle may cause friction.

17 One of the proposals, because that was going
18 to be one of the questions was something that was
19 proposed in the EIS, but did not remain part of the
20 proposal for the actual rule was, I believe,
21 improvement or putting burdens on movement of low risk
22 materials, some sort of electronic record keeping

1 system that would enable things to be moved if
2 ordinarily they would be moved under notification.
3 And, again, that is better allocation of resources,
4 letting the staff focus on other things that --
5 underlying message that is not really part of the rules
6 themselves are the coordination of e-Permits with the
7 rule, as much as staff have to adjust philosophically to
8 the rule system, the e-Permits the entire -- upon which
9 everyone in this room technically is relying upon, as
10 well as the staff, would have to coordinate with that
11 if there would be a crash of the system.

12 And the more we talk about what we'd like to
13 see, if we took PMP's out of the picture, was a
14 two tiered system, where tier one was notifications --
15 permit type one, and everything else under a permit
16 type two. That system enables the flexibility that we
17 have now and it basically lets the staff focus their
18 time on things with the highest risk. Any questions?

19 EVA RING: Thank you.

20 RACHEL LATTIMORE: We went over some of the
21 same issues that have been discussed by other groups.
22 We sort of phrased it in terms of things that we felt

1 were lacking in the current proposal that would be
2 needed to improve that proposal moving forward. The
3 first has been discussed, deadlines. We also
4 characterized the different permit categories as
5 needing risk based data requirements. Right now the
6 data requirements for a permit application for each of
7 the four categories appears to be pretty similar, if
8 not identical, and we think that the data that is
9 required should be commensurate to the risk that's
10 posed.

11 Predictability regarding the permit category
12 that a particular crop would go into has been discussed
13 earlier, as well as the conditions of that permit, and
14 we agreed that case studies or examples would be very
15 helpful.

16 We also discussed a need for risk-based record
17 keeping-- that record keeping for its own sake, was not
18 helpful; it added to the burden on both the agency and
19 industry, but that that should be tailored more closely
20 to the actual risks involved.

21 And in -- we wanted to make sure that while
22 some of this may have been the intent of the agency in

1 the original proposal, the regulatory language itself
2 doesn't always reflect that intention, and so we would
3 encourage the agency to more carefully craft the
4 regulatory language to conform to the agency's intent
5 in some of these areas.

6 EVA RING: Any questions? Thank you. I do
7 want you to ask questions.

8 DAVID HERON: I'm just wondering if you
9 could give us an example for this last one where you
10 thought the regulatory language could more clearly
11 reflect the intention.

12 RACHEL LATTIMORE: I think there were
13 situations where the -- there may have been language in
14 a preamble that this would -- data requirements, for
15 example, could be tailored to individual permit
16 categories, but the language itself may say something
17 like data to be included in the application shall
18 include the following, and, you know, for the regulated
19 community, shall means must, and so preamble language
20 saying this may be discretionary is somewhat at odds
21 with the mandatory language of the regulation itself.
22 So if the agency intended to be discretionary -- shall

1 might need to be changed, should be changed to may; is
2 that clear?

3 EVA RING: Any other questions or comments for
4 any of the group?

5 CAROL DISALVO: You had mentioned that APHIS
6 might review -- have oversight after a product was
7 commercialized but could you explain what parameters
8 you'd be speaking about? My name is Carol DiSalvo with
9 National Park Services.

10 GREG JAFFE: Greg Jaffe again; I don't know if
11 we had come up with specific conditions that might be
12 in a commercial permit or a commercial license. I know
13 that Steve could maybe talk about it a little but, but
14 he has concerns that LibertyLink was a deregulated
15 product, and yet there were concerns about how that was
16 captured and got released and there were major
17 problems.

18 And from my perspective, I know that one thing
19 you might have in that after oversight or after
20 deregulation is a lot of timed risk assessments that
21 are done or EIS was done based on certain kinds of
22 hypothesis or certain assumptions about how behavior

1 will be. And the one thing after oversight might be
2 collection of some data by the developer to see if, in
3 fact, the use of the product was the same as was
4 anticipated under the assumptions of the risk
5 assessment, for example, that kind of thing. So I
6 don't think we had said, oh, you know, these specific
7 things, but we did see some merit in keeping a
8 commercial product that has no risk still within the
9 regulatory system and having some ability necessarily,
10 not necessarily saying everyone had to have oversight,
11 but having the ability to have some sort of oversight,
12 it might be data collection might be just record
13 keeping type thing.

14 I think that we thought in most cases those –
15 if they had some sort of condition, it would be minimal
16 and very generic, but we could also proceed in specific
17 examples with far more things like that that you
18 could have significant oversight.

19 And I think even in the proposal, the idea of
20 a conditional exemption or the proposal talks about a
21 situation where a product is commercialized, but there
22 still are some outstanding questions on the EIS and

1 they're allowed to go forward and those kind of things
2 that can allow the collection of that data or the
3 analysis of that data while the product was being used
4 by farmers.

5 EVA RING: Any other questions? We've given
6 the group a lot to think about and a lot of good ideas
7 and feedback on what was in there. John Turner, at
8 this point, was going to present a little information
9 on the LLP thinking about the low level presence issue,
10 and I think there's also a paper about that that will
11 be passed out.

12 JOHN TURNER: Glad you're all still here.
13 It might be a low level presence for the -- I think
14 it's been very useful to us so far. Low level
15 presence, our sort of working concept is this
16 unintended mixing of small amounts of regulated GE
17 materials that may sometimes occur in commercial grain
18 or seed.

19 So a lot of people have a lot of different
20 ideas about low level presence, whether it's GM in
21 non-GM and organic, and those are important concerns.
22 But when we talk about it, we're talking about

1 regulated materials occurring in commerce.

2 The goal of the LLP policy in the new regs was
3 to establish in the regulations an effective and
4 transparent policy that describes the criteria APHIS
5 will use when determining that an LLP will or will not
6 require remediation. In other words, for certain
7 things that meet certain criteria, remediation may not
8 be required. The LLP policy in the proposed rule is a
9 safety-based policy, it describes -- and it also is
10 based on the fact that remediation will not always be
11 required. And it's modeled on our current LLP policy,
12 which was published in 2007, but also incorporates some
13 key components of the noxious weed authority which is
14 being used in the new regulations.

15 The heart of the policy isn't a new policy -- it's
16 these criteria, and it's going to use pest and noxious weed
17 based criteria for determining when the agency will
18 need to take remedial action. Next slide, please.

19 So, again, it's based on plant pest and noxious
20 weed events, and described to when remedial action will
21 take place. And the agency retains discretion on the
22 need for remedial action, so there's flexibility built

1 in for that. It does not feature a specific threshold
2 level for remedial action, and so these would be
3 determined if needed on a case-by-case basis.

4 And remedial action is separate from
5 compliance and enforcement actions. This is a very
6 important concept. The agency could reach a finding of
7 safety and recommend no remedial action. But if anyone
8 has violated the regulations, and there's evidence of
9 that, enforcement actions would still take place. I
10 apologize, too much on this slide, but this gets into
11 some of the comments that we received on the LLP policy
12 and rule, and I'll read these if you can't see them.
13 Many people were generally opposed to the policy, and
14 some of the comments that came out were along the lines
15 of, there should be a zero tolerance for LLP. Simply do
16 not allow it.

17 APHIS should consider the economic impacts of
18 LLP to organic or conventional farmers. APHIS should
19 be aware of certain consumer market sensitivities to
20 LLP, and field tests should be designed to achieve
21 strict containment of GE material.

22 Others were not opposed to us having this type

1 of policy, but recommended some changes. One such
2 comment was, there's no need to incorporate LLP policy
3 changes into the regulations, the agency simply needs
4 to update the 2007 LLP policy, which isn't a
5 regulation, by the way, update that to reflect the
6 addition of the noxious weed criteria.

7 The LLP regulatory policy criteria in the
8 proposed rule focus on safety of the gene and protein
9 and do not adequately take into account environmental
10 effects for gene flow resulting from GE material mixing
11 with commercial commodity or seeds. Some agree that it
12 should be incorporated into the rule, in the LLP
13 policy, that is, and that violators would not be
14 absolved from causing LLP incidents thought that agency
15 should develop regulatory guidance that would prevent
16 LLP from occurring. And another comment was that APHIS
17 should establish a tolerance level for LLP.

18 Other comments on the policy, I think I've
19 already hit the first one, there's no need to
20 incorporate LLP into the regulations, and LLP does not
21 adequately take into account environmental effects for
22 gene flow. Actually, these appear to be redundant with

1 the last.

2 We should develop guidance for preventing LLP
3 from occurring, but incorporate the policy into the
4 rule, and we should establish tolerances.

5 Our current position is that it's prudent for
6 us to establish a science-based LLP policy into the
7 regulations, as we've done, that describes when
8 remedial action will be needed, and I think that's all.

9 EVA RING: Any questions for John? Right over
10 here.

11 JEFF BARACH: Could you describe generally
12 remedial action?

13 JOHN TURNER: Remedial action has to do
14 with whether we're going to have to maybe recall
15 something, have things destroyed, put a hold on seeds,
16 and again, gather them up and make sure they're
17 destroyed or disposed of in some sort of way. So the
18 flip side, no remedial action might mean that things
19 were allowed to continue to move in commerce even
20 though there was this very low level of regulated
21 material mixed in.

22 EVA RING: Any other questions? Thank you,

1 John.

2 BRS wants to know what you think about
3 their current thinking if they would incorporate policy
4 into the regulation; do you think it should be, why or
5 why not? And I'm trying to get clear what the criteria
6 are. I know they're in the proposed reg, are they in
7 this paper that's being handed out. The second
8 question was whether you think the criteria should be
9 revised to better accomplish APHIS's goal of deciding
10 when to require remedial measures.

11 Oh, they're in the actual -- okay. So
12 they have reference on the table of the regulatory
13 language, it has the criteria. So do you think it should
14 be in the regs, and how could they be revised to be
15 clear about when to require remedial measures? Thank
16 you. If you could address that for about 20 minutes,
17 thank you.

18 DAVID HERON: Some people are asking about
19 where the documents are, so if you want to see the
20 existing policy, the LLP policy, that was in your
21 registration packet that you have, and the proposed is
22 in the proposed rule itself. We're doing a --

1 EVA RING: This is what's current.

2 DAVID HERON: And this is just – the LLP
3 FR notice from 2002 about low level presence that's in
4 the back of the package that has the proposed rule, so
5 it's the binder on the table, so there's one copy on
6 the table. If you need extra copies, we can get you
7 extra copies.

8 EVA RING: If anyone can't find the material
9 you need, let us know and we'll make sure you have
10 them.

11 All right. We're going to be having them
12 present out in one minute. Okay. Once again, I'm
13 going to ask for a volunteer table. Did I see a hand?

14 MICHAEL WACH: So the consensus was that
15 having an approach is good, having an approach in the
16 regulations is better, it's harder to ignore. The
17 criteria should be -- are used to make these decisions
18 should be clear, predictive, and well communicated to
19 stakeholders so that everybody knows how decisions are
20 made and that there are no surprises when these issues
21 come up.

22 Decisions under the LLP rule must be

1 definitive, there shouldn't be any doubt about where
2 the agency -- where the
3 department stands. If they say we're not doing --
4 we're not requiring mitigation, that has to be made
5 clearly and precisely so that everyone knows, everyone
6 who might be affected by a decision.

7 And the infrastructure, interagency processes
8 must be in place; interagency engagement is
9 necessary. So it's nice when the government says, you
10 know, everything is okay, it's safe, and don't worry
11 about it, but in the event that they say that we are
12 going to do some sort of mitigation, processes should
13 be in place, interagency communication should already
14 be in place so that it's done efficiently and -- and if
15 anyone else at the table has any comments.

16 EVA RING: Any questions for this group? I'll
17 tell you what, I'm going to let you pass it on to the
18 next group. You can choose who goes next.

19 (Pause)

20 RACHEL LATTIMORE: We vote yes, too.

21 EVA RING: Yes.

22 RACHEL LATTIMORE: And we think that that

1 provides, you know, certainly it's harder to ignore it
2 and provides greater credibility both internationally
3 and domestically as to, you know, the action that the
4 agency is taking. And we would encourage set formats
5 some other aspects that are communication regarding the
6 -- to make sure that, you know, for folks who may have
7 concerns about what this means, that it's not a license
8 to be sloppy, and very clearly communicate the agency's
9 commitment to take, you know, all necessary remedial
10 action when safety warrants that and make sure that
11 that's an important part of the message. With regard
12 to the question about environmental aspects, we talked
13 about this, that the low level part of LLP is to -- is
14 environmental mitigation, that we were talking about
15 the import of, you know, certain ornamental seeds from
16 New Zealand, and if they're in a, I don't know how it
17 comes in, but, you know, in a big bag full of seed,
18 there may be, you know, one off type that assuming that
19 the regulatory structure which was field tested, that
20 they weren't -- it wasn't a noxious weed to begin with,
21 it doesn't have those qualities that the one seed will
22 have weediness characteristics and take over the

1 world.

2 The fact that there's one means that this is a
3 type of environmental mitigation. So the concern about
4 the LLP policy not addressing environmental concerns, I
5 think it is addressed by the simple matter of being at
6 a low level.

7 With regard to the criteria and more
8 specificity around some of the criteria, we talked
9 about trying to align with FDA's position that protein
10 safety does not need to be species specific, and also
11 making sure that the term "new" as it's applied is --
12 takes into consideration the continuing advancement of
13 science and if there is -- putting some clarity around
14 what that means.

15 EVA RING: Any questions for this group, what
16 they presented? Thank you.

17 BILL WENZEL: Bill Wenzel with the Farmer to
18 Farmer Campaign on genetic engineering. We didn't have
19 any consensus on this particular issue. There was
20 quite a variance and disagreement. We argued, at least
21 from a farmer perspective, that this is not a good
22 public policy.

1 Our goal should be 100 percent containment,
2 whether that is realistic or not, and largely due to
3 the message it sends to our trading partners, both
4 domestic and international.

5 As part of the certification process for our
6 exported commodities, there is a GIPSA
7 requirement that products being shipped are certified
8 as GE-free. And the feedback that we've gotten from
9 our producers and the regulators in this regard is that
10 a policy like this would not allow them to make that
11 certification, and that would have a definite effect on
12 our ability to market American products overseas.
13 Another basic tenant of where we're coming from
14 problematically is that it is in conflict with co-
15 existence.

16 If we are moving toward a philosophy of co-
17 existence, our belief is that there has to be kind of
18 integrity of our own space and our own property. And
19 once we allow low level presence come into play, it's
20 warranting a contamination of that integrity.

21 And so we believe that it's conflicting with
22 our movement toward coexistence, if that is, in fact,

1 where we're going. So our sense is that, regardless of
2 whether or not low level presence is an issue, we
3 should maintain our policy of 100 percent containment
4 and move toward those goals.

5 WENDELYN JONES: Wendelyn Jones; the other
6 side of the table has a slightly different view point.
7 We actually thought the LLP provisions put in the regs
8 would be a good thing, and we actually thought that it
9 would, in fact, enable trade, because it could
10 recognize science. I can just repeat everything that
11 some others said, but I'll just stop it there.

12 ISABELLE COATS: I'm Isabelle Coats from Bayer
13 Crop Science. We also, I guess, took a vote and it was
14 unanimous on our table that, yes, incorporate the LLP
15 policy into the regs. It would increase transparency
16 and certainty. Incorporating it into the regs also
17 would help facilitate public understanding, clarity,
18 and maybe increase confidence where there is concern
19 now.

20 It would prevent APHIS from having to take
21 regulatory action, such as the recall that is not
22 necessarily science-based. Much like other groups have

1 said, you know, it defines what can be done leading to
2 the criteria.

3 It allows the agency to have, much like the
4 decision between -- that can lead to science-based
5 decisions. We also wanted to mention that developers
6 have such practices in place that already help to
7 minimize low level presence to the greatest extent
8 possible. And that we should -- interagency
9 coordination should continue wherever is applicable
10 also, again, in going -- continuing on or adding to the
11 point from our neighboring table. And something we
12 didn't put on here, but we would like to add that the
13 zero tolerance or zero percent presence is
14 realistically not feasible. In any other crop or
15 product, there's mixing of, you know, rocks and bugs,
16 and, you know, no seed is technically 100 percent pure,
17 whether it's conventional, organic, or by technology.

18 Any questions?

19 EVA RING: Thank you.

20 STEVE HENSLEY: Steve Hensley with USA Rice
21 Federation. We decided that it would probably be best
22 to have LLP presence or LLP policy stated in the

1 regulations for certainty and predictability as well as
2 other reasons. One situation which was primarily -- my
3 discussion was expanding LLP beyond purely regulated
4 material to a deregulated material. And as we
5 discussed in an earlier situation where there might be
6 something like a commercial permit or a permit with a
7 regulatory authority which follows past deregulation as
8 it stands now, then you might be able to have LLP
9 follow that product after its deregulated. And this
10 would help in the event that a material finds itself in
11 a food crop and that material is still not acceptable
12 to some markets. Having LLP follow something even
13 after its deregulated might help in that instance.

14 EVA RING: Does anybody need any
15 clarification on that?

16 BEVERLY SIMMONS: Steve, just so I
17 understand, when we're talking about LLP -- I'm over
18 here -- LLP and a commercial permit. So you're saying
19 LLP in a situation where a product that was say
20 presumably being produced under commercial permit ended
21 up in a use that it was not intended to be used? I
22 guess I'm just trying to figure out what circumstance

1 for LLP would be on something that would be permitted
2 to be produced?

3 STEVE HENSLEY: That -- that would be --
4 that would be one way, yes. Another -- another thought
5 is, is that you have approved a product, that product
6 is deregulated. That product is not necessarily yet in
7 commercial production. It may not be for a variety of
8 reasons, including that it may not yet be acceptable to
9 consumers. Yet that -- that event, that trait find
10 itself in the commercial food supply. And whether or
11 not, yes, I realize the whole science-based argument
12 versus economic. The real world is, there are terrible
13 economic repercussions from that and -- but once it's
14 been deregulated, other -- other countries can say,
15 well we're sorry, your LLP system -- we can claim that
16 this is a low-level presence, but other countries can
17 say, sorry, your LLP system only applies to products
18 that are still being regulated. This is a deregulated
19 product. So therefore, you would be -- the industry
20 that is producing the crop, which is now mixed with an
21 approved product, yet an unacceptable product finds
22 that USDA can say sorry, we've approved the product.

1 This is no longer in our purview. The developer can
2 say, sorry this product is approved, nothing we can do
3 about it. And we can't even -- even if it -- with the
4 numbers showing that it's low-level presence, we can't
5 say, this is a low-level presence as defined by USDA.
6 Because it's an approved deregulated product, LLP does
7 not apply. It would be helpful I think in future trade
8 if LLP could apply past deregulation in those
9 instances.

10 MICHAEL SCHECHTMAN: Michael Schechtman
11 of USDA. Steve, if I could follow up on that just a
12 little bit further to get us into what you mean by LLP
13 would apply. Do you mean that just a definition would
14 apply so that you could say, yes, in fact, this is LLP
15 in some broader definition? Or is APHIS supposed to be
16 able to then come up with some sort of course of action
17 even if they've said that it's safe?

18 STEVE HENSLEY: Assuming that you were
19 dealing with another country or system that has some
20 sort of acceptance of the USDA system here, you could -
21 - we could at least state that under our system, this
22 is a low-level presence and hopefully that would reduce

1 the amount of barriers in another country if they say,
2 okay, the United States feels that this is not only an
3 approved product, but there's also low-level presence
4 of that product. We think that that would be very
5 helpful.

6 Now, we wouldn't be adverse either to USDA being
7 able to help that industry along, using the LLP in any
8 way they saw fit.

9 EVA RING: Thank you. I think all that
10 clarification was useful for everyone, so thank you for
11 that clarification. Any other comments overall on this
12 topic?

13 Our final topic -- I think we're going to receive
14 one more presentation of information here on the
15 opportunities for the public to participate in the
16 development and implementation of this regulation.

17 Clint Nesbitt.

18 CLINT NESBITT: So I apologize as I begin
19 on this. This isn't a presentation as much as just
20 sort of an introduction to the next topic for
21 discussion.

22 As you know, one of the themes that's been

1 recurrent throughout this meeting, but also the meeting
2 we've had previously on this subject, has been the idea
3 of making opportunities for public participation in
4 APHIS process -- processes, whether it be rule-making
5 or issuing permits or deregulation and so forth.

6 So we wanted to kind of come back to this theme
7 since we're here in the public meeting, using the
8 public participation process, to kind of come back to
9 the subject and talk about not only where are the
10 opportunities for public participation built into the
11 proposed rule but just sort of about how APHIS uses
12 public participation in general.

13 So in terms of the proposed rule, the proposed
14 rule is actually very similar to the current rule in
15 terms of formal opportunities for public comment that
16 are built into the rule. Currently, the rules include
17 a 60-day comment period on petitions and that's --
18 that's built into the rule. So the new proposed rule
19 actually retains that similar 60-day comment period on
20 petitions but also adds a 60-day comment period to that
21 new parallel process that we've created for extending
22 new exemptions to certain things that are still under

1 regulation.

2 So using that analogous new petition process in
3 the rules -- they're both petition processes -- they
4 both will have that sort of analogous 60-day comment
5 period on -- on the petition.

6 But besides those two opportunities, those are
7 really the only places in the rules where we're
8 formally putting in some you know, sort of permanent
9 opportunity for public comment.

10 But if you move on to -- thank you. Besides what's
11 in the actual rules for the biotech regulations, there
12 are routinely other opportunities for public comment
13 and public participation in APHIS process.

14 One of them derives from NEPA, the National
15 Environmental Policy Act, and that typically includes
16 things like commenting on draft EA's and draft EIS's,
17 which we routinely do for actions that are not
18 categorically excluded under our NEPA-implementing
19 regulations.

20 So that usually includes all of our petition
21 actions, granting them non-regulated status, and it
22 includes a lot of our environmental release permits;

1 some but not all.

2 And then another opportunity for public
3 participation is in the rule-making process. And this
4 is a part of notice and comment rule-making under the
5 APA. And it is a part of why we're here today, that
6 everybody has the opportunity to comment on our
7 proposals and we respond and so forth.

8 So really, that in a nutshell, covers all
9 the different types of public participation that --
10 that we either use or that are formally built into the
11 regulation. But we wanted to start with that.

12 And I don't know if you maybe just even want to switch
13 to the discussion questions. Because we wanted
14 to end with this opportunity, really just start a
15 discussion about how APHIS views this public
16 participation and are there other things that we could
17 add to the rules to stress more opportunities for
18 public participation. This is a topic that came up in
19 our -- in our last public meeting. I think maybe even
20 Greg was one of the ones that talked about
21 that.

22 But not just in the rule-making process and not

1 just necessarily formally built into our rules, but
2 also just in general. Are there different ways that
3 APHIS can use public participation in its everyday
4 activities or in its rule-making process. So I guess
5 I'll turn this over to Eva.

6 EVA RING: You've done my job.

7 CLINT NESBITT: I've done your job?

8 Okay. So I guess now I'll pretend --

9 EVA RING: How much time --

10 CLINT NESBITT: -- like I'm Eva. How
11 much time do you want --

12 EVA RING: -- how much time do --

13 CLINT NESBITT: -- to them to have?

14 EVA RING: -- want to give them?

15 CLINT NESBITT: I -- I don't -- don't
16 give me those kinds of decisions.

17 EVA RING: Maybe about 20 minutes then.

18 CLINT NESBITT: About 20 minutes?

19 Okay so I think we're going to formally discuss the
20 questions that are up here and then we'll have a little
21 report out on notes at the end. Does anybody else have
22 any clarifying questions for me before I drop the

1 mic? No? Okay then let's move back into the
2 discussion.

3 [CROSS TALK]

4 EVA RING: All right, we're going to
5 start our report out. One minute if everyone could
6 take a seat please, thank you.

7 [CROSS TALK]

8 EVA RING: Jeff, would you like to do the
9 honors?

10 JEFF: I think Jane is going to help us
11 out to get us started here.

12 EVA RING: Okay, okay, good. All right,
13 we're starting with this table over here.

14 JANE RISSLER: I'm Jane Rissler from the
15 Union of Concerned Scientists. I know my colleagues at
16 the table will make it clear when I've said something
17 that doesn't represent their point of view.

18 The -- the emphasis on participation that APHIS
19 has --

20 EVA RING: Jane, if you could use the
21 microphone.

22 JANE RISSLER: The emphasis on

1 participation that APHIS has articulated, brings with
2 it an obligation and that is to respond to
3 participation.

4 The -- so far we have not seen a response to
5 comments on the draft EIS, that is the basis of this
6 proposed rule. We should see a -- a response to the
7 draft EIS before the end of -- well before the end of
8 any comment period on the proposed rule.

9 My point of view, which is not a consensus view, is
10 that in fact the draft EIS was not done according to
11 NEPA and that it did not provide an evaluation of the
12 environmental consequences of regulatory options and
13 that another EIS should be done according to NEPA to
14 take public comments, to respond to those comments with
15 any proposed rule.

16 The consensus was that there is a request for the
17 final EIS before the end of the comment period on the
18 proposed rule. And that in fact, there has been --
19 there have been so many comments on the inadequacy of
20 this proposed rule from both industry and the public
21 interest community that an appropriate response to that
22 participation would be to offer a new proposed rule.

1 The second point, which is not represented here,
2 which I would like to raise based on our experience
3 working with APHIS over the past 15 to 20 years is, has
4 to do with a sub-point that this -- the APHIS speaker
5 made that the importance of participation in
6 environmental release permits and in other petitions.
7 We have participated a lot in the last few years on
8 pharma-crop permit applications.

9 The day before yesterday, I received a response
10 from APHIS to a 2004 Freedom of Information Act request
11 for information so that we could participate in the
12 deliberations about a pharma-crop product. This was,
13 according to APHIS, an initial partial reaction of
14 response to a 2004 FOIA request. I would like to see
15 if -- that -- that APHIS provide information so that
16 the public can participate in these permit
17 deliberations. It can't be done with FOIA requests
18 that are five years old.

19 I have 22 more FOIA requests and some about that
20 age; some a little younger. But all not answered in a
21 timely way for us to have participated in the permit
22 review.

1 So I think that perhaps APHIS is waiting for the
2 Attorney General to put out guidelines under President
3 Obama's directive on the Freedom of Information Act,
4 but I certainly hope to see under the new
5 Administration, a -- a -- a real honest effort to
6 respond to Freedom of Information Act requests so that
7 members of the public can have more information to
8 participate in reviews.

9 Are there any -- any other comments from the
10 table?

11 EVA RING: Any other comments?

12 KEITH REDING: This is Keith Reding,
13 Monsanto. We agree with Rissler's table on the
14 first point that following this current 60-day public
15 comment period that we would like to see the revised
16 rule published for public comment.

17 Regarding the other APHIS processes for petitions,
18 we wanted to see APHIS seek a 30-day public comment
19 period early in the process in order to allow for
20 proper scoping underneath to identify the issues
21 already in the process.

22 As far as general issues for things that could be

1 done, revise the Web site, making it easier to find
2 information; something at this table's -- table's view.
3 And another suggestion was to create a mailing list for
4 regulatory actions, similar to the current -- what you
5 do for the stakeholder mailing list. But basically
6 expand that to cover other items people are interested
7 in.

8 EVA RING: Any questions for this group?

9 MIKE GREGOIRE: (Off mic) Go back, I --
10 the -- say more about the --

11 COURT REPORTER: I'm sorry, I cannot hear
12 you.

13 MIKE GREGOIRE: Your second point for
14 petitions, seek public comment, 30-day on the
15 petitions. Say a little bit more about that second
16 bullet, please.

17 KEITH REDING: Okay, what we were
18 thinking -- I guess right now, the current process is
19 when a draft EA comes out, you seek public comment at
20 that point. Go back the way it was done many years
21 ago. You announce receipt of the petition and invite
22 public comment at that point. Then the process changed

1 a few years ago.

2 So as part of the new petition process, we discuss
3 round table to see public comment early in the process,
4 after receipt of the petition, maybe a 30-day comment
5 period, to allow the public to give input on the issues
6 they feel are associated with that particular
7 regulatory request.

8 Then following that, maybe a second 30-day public
9 comment period on a draft EA or if it goes to an EIS.

10 MIKE GREGOIRE: Thank you.

11 MICHAEL WACH: Okay, Mike Wach again. I
12 think we pretty much agree with the table just prior to
13 ours, for those at the table who have experienced
14 dealing with the other agencies, they felt that
15 generally that transparency was better than the other
16 two. The -- again, the stakeholder list server is
17 great idea and it does provide a lot of information,
18 but it could maybe offer more -- this dialog, maybe
19 some of the people here and other stakeholders
20 incorporate more information that could be pushed out
21 as -- as the information that Jim was talking about
22 earlier.

1 The Web site is difficult to maneuver through,
2 although there are valuable online tools and tables on
3 the Web site, it would be probably useful for BRS to
4 re-examine those, perhaps provide guidance and
5 instructions, sample searches and so forth. So people
6 who're only occasional users don't have to call the Agency
7 every time they want to figure out how to use the
8 Virginia Tech Web site, which is a powerful tool, but
9 it -- you forget how to use it unless you use it all
10 the time.

11 EVA RING: Any reaction, questions?

12 GREG JAFFE: I'm Greg Jaffe with the
13 Center for Science and Public Interest. Our major
14 discussion revolved around public participation for
15 permits for commercial products and we felt that there
16 sort of a loophole in the system that there usually is
17 or almost always is public comment when a product is
18 deregulated, but that for some products they might be
19 commercialized under a permit situation, particularly
20 the pharma-crops although we also talked about
21 something like the corn amaylase, where you could decide
22 to just get a permit for a grower district or a -- a

1 select number of sites to grow a product.
2 But we all felt I think, that when you are
3 commercializing a product like a pharma-crop that there
4 is a public interest in knowing about that and then
5 having an opportunity to comment before that permit is
6 issued and right now the Agency's position is that
7 they're not going to deregulate pharma-crops. They're
8 always going to go under permit, but they'll be
9 commercialized under permit.

10 And so we thought a trigger should be that if you
11 are commercializing a genetically engineered plant,
12 then you should -- there should be public opportunity
13 to comment before that -- that process occurs, whether
14 it's under deregulation or under permitting. There
15 shouldn't be a -- there shouldn't be a distinction
16 there and only -- only allowing them to deregulation as
17 the proposed rule suggests.

18 We also thought under public participation that we
19 thought so far that the -- for the -- for this rule-
20 making, that the process has been very good in terms of
21 getting public participation and we didn't have any
22 suggestions about other ways to increase public

1 participation for this rule. We think there've been a
2 lot of public comment and we think that's been great.
3 The only other thing we did talk about similar to
4 the other groups about the idea of alerting the public
5 more on decisions that there was a few that -- that the
6 list serves and -- have been good to tell people about
7 stakeholder meetings and press conferences and things
8 like that. But -- but there should also be a way of
9 alerting the public to the decisions BRS makes. That's
10 it.

11 EVA RING: Any questions? Yes?

12 RACHEL LATTIMORE: We, I guess, are too old
13 to think about fancy new technology like the Internet
14 and Web sites, so we -- we didn't write that down, but
15 we were then mumbling amongst ourselves that gee,
16 that's a great idea. But we were talking about public
17 meetings you know, I think a general theme of our
18 discussions throughout today has been increased
19 communication with the public. And the idea of public
20 meetings for the next proposed rule, which is an idea
21 that's been suggested by -- by others here.

22 We had talked about the guidance that maybe there

1 should be public meetings associated with that so there
2 could be question and answers between the Agency and
3 the public on the meaning of guidance documents. And
4 we -- we also talked about ways to announce things like
5 new scientific developments so that the public could be
6 better educated about what's -- what's coming down the
7 -- the pike, some of the product pipeline, maybe get
8 some of the academics in to talk about some of their
9 activities so that they're -- you know the -- the
10 Agency is involved in educating the public about the
11 technology and -- and what's going on.

12 We also mentioned, you know, increased
13 communications about the BQMS project as examples of
14 some of the things that could be the subject of public
15 meetings or the fancy Internet site.

16 EVA RING: Other questions? After
17 hearing all these ideas, anyone have anything else they
18 want to add?

19 JANE RISSLER: Yes, might I? Thank you.
20 I was thinking about public meetings and in the new
21 era. I'm old too, so I don't know how to do those
22 things. But I think having a -- a meeting here is

1 quite limiting in terms of a lot of stakeholders who
2 haven't the resources to come here, particularly in the
3 nonprofit community.

4 So I think it -- it in some ways limits or -- or
5 affects the composition of the group here and I'm
6 wondering if there's some way to explore online for
7 public meetings so that there are no financial or
8 geographic types of limitations to stakeholders
9 participating?

10 I suspect that could be complicated and not as
11 pleasant as seeing people face-to-face, but I wonder if
12 it wouldn't increase the number of more poverty-
13 stricken stakeholders to participate in -- in these
14 types of discussions.

15 EVA RING: Thank you. Any -- any other
16 comments or reactions or experience with that? All
17 right, well that was very helpful. I -- I know BRS
18 appreciates very much all the suggestions that you made
19 and will -- they also have others that they've been
20 talking about too, similar.

21 So what I wanted to ask a favor of you to do now
22 is I did have a -- a -- we had just a couple questions

1 as with yesterday and instead of waiting to the end to
2 ask you to fill them out, I was thinking if you could
3 reflect a little bit, answering these questions now for
4 about 10 minutes and at the same time, Mike Gregoire
5 wants to again recap for you and [inaudible]
6 what they've heard from you today and during the whole
7 course of this meeting so you can be -- he wants to
8 prepare for that. At the same time, you could reflect
9 a little with these questions and we all have a -- a
10 talk, the idea is to finalize the meeting in about 10
11 minutes. Thank you.

12 [CROSS TALK]

13 EVA RING: All right, before Mike closes
14 the meeting and gives some final remarks from BRS, is
15 there anything that any of you wanted to share, last
16 thoughts for the public record, whatever? I want to
17 thank you one more time, because --

18 JANE RISSLER: I have a question. Is
19 APHIS willing to make dramatic changes as a result of
20 public comment? I'm not -- this is not asking you what
21 you're going to do, but are you -- is there direction -
22 - can there be direction that you can make major

1 changes in proposed rules?

2 MIKE GREGOIRE: I'll go ahead and answer
3 that question now and then touch on this too in my
4 final --

5 JANE RISSLER: Thank you.

6 MIKE GREGOIRE: -- remarks. Jane, you
7 missed the Secretary's presentation this morning and
8 one of the things -- well I'd say a couple of things.
9 One is that he didn't have any preconceived ideas about
10 what the final rule should look like and that he was
11 open to a number of different ideas about what the
12 final rule should look like.

13 And he also said that he was very committed to
14 transparent public and participatory process to get the
15 input to work through the issues that have been raised
16 about this rule and he talked about the importance of
17 what was going on here yesterday and today and in terms
18 of how that will inform the decisions he will be making
19 on this rule.

20 So I think the answer to your question is yes.

21 JANE RISSLER: Good.

22 NEHRA NARENDER: Yeah, just a simple one.

1 I'm Nehra Narender with ArborGen. I was wondering all
2 these questions that we addressed or we -- we dealt
3 with, are you going to make those and the summaries
4 available on your Web site?

5 MIKE GREGOIRE: The -- the transcript for
6 the meetings these two days will be published on the
7 APHIS web site and on regulations.gov. As will the
8 supporting materials, the issue papers that were handed
9 out today. So all that information will be available
10 for all of you as well as members of the public who
11 were not able to attend so they can read about what
12 happened. They can look at the documents that were
13 used and that they can provide comments on those.

14 And again, the comment period will remain open for
15 60 days from today until June 29th.

16 EVA RING: Any other comments or
17 questions, final remarks? All right, Beverly Simmons
18 is going to -- oh. Where are you? You moved.

19 BEVERLY SIMMONS: I just wanted to
20 comment on a couple kind of broad areas that I've heard
21 over the past two days and actually some new areas that
22 I think were emphasized today.

1 I think the most important thing that really
2 resonated with me is this whole idea of communication.
3 And I think it was very informative I think for all of
4 us here at BRS to hear your concerns and comments about
5 how we can engaged collectively, not only just in the
6 rule-making process but on an ongoing basis about how
7 we're making our decisions and making sure that that
8 information is proactively provided to you.

9 So that is something that I think we're going to
10 have to give some thought as to how we can move forward
11 in that area. Again I heard yesterday and again
12 reiterated today the need for interagency
13 coordination. And again, as I've repeated, said
14 yesterday, I think this goes along with communication.
15 We might need to be giving some more opportunities for
16 sharing with you what kinds of engagement is already
17 occurring. Maybe that's not so evident.

18 That's not to say that there aren't areas where we
19 can improve our coordination and I think that's
20 something we'll need to -- to focus on. Transparency
21 again was something that was -- came up again and again
22 yesterday and today. Certainly it was an area that the

1 Secretary and Deputy Secretary emphasized this morning
2 that we need to find ways to be more transparent in how
3 we deliberate and make our decisions.

4 Some new things that I heard today and I didn't
5 hear yesterday but I'm glad I -- people did bring this
6 up was the notion that as we move forward on this rule,
7 we need to be talking about practicality and how we can
8 look at ways to move forward on the rules and not only
9 in what we put in the rule, but how we implement and
10 how we provide guidance on how we implement it. So
11 that it's practical and it provides an opportunity for
12 those who need to comply with the rule to be able to do
13 it in a fashion that is not overly burdensome.

14 I heard today for the first time the word imports.
15 I don't think I heard that yesterday. That is an area
16 some of you may know that our own OIG has emphasized is
17 something that we need to be looking at. So I was glad
18 to hear that that's also on your radar screen and I
19 think that's something that we need to work
20 collectively on.

21 The other topic that got raised repeatedly today
22 and I didn't hear yesterday was the whole notion of

1 coexistence. We heard loud and clear this morning from
2 the Secretary that is -- simply an area that he
3 thinks we need to be attentive to and need to find
4 practical ways that the various areas of agriculture
5 can coexist.

6 So those are kind of the takeaways that I heard
7 yesterday and today. I know Mike has some more
8 detailed comments on things that he thinks need some
9 attention from us.

10 MIKE GREGOIRE: Thanks, Bev. And I
11 probably will be repeating some of the things that --
12 that Bev said. I'm going to kind of work in
13 chronological order.

14 Starting with my kind of take-home messages from
15 what the Secretary said this morning that have caught
16 my attention. He said that technology is here to stay
17 and our job is to find ways for biotech to coexist with
18 other forms of agriculture. He acknowledged how
19 challenging and complex that issue is and he said that
20 he didn't have any preconceived ideas about the
21 particulars of this rule, but that he was committed to
22 a transparent, collaborative and participative process

1 to move those issues forward. And he saw this
2 gathering as a very important step in that -- in that
3 process.

4 And I think some of the discussions we had today
5 around some of the issues like the LLP policy
6 demonstrate how complex these issues are and the
7 variety of views that there are around issues like
8 that.

9 On the pharma issue, some of the key things that I
10 summarized, generally I got a sense that stronger
11 measures are needed beyond what was in the proposed
12 rule. We need much greater engagement with other
13 agencies, in particular, the FDA on this. There needs
14 to be more public awareness, more guidance, direction,
15 restrictions, particularly for new developers in this
16 area and perhaps more research to fill the scientific
17 gaps that exist.

18 With respect to the whole permit discussion, I
19 sort of have -- I think there were sort of two levels
20 of discussion there. I heard a lot of practical
21 suggestions about what we might do as an alternative to
22 what we proposed to achieve some of the objectives that

1 we had to be able to add conditions and reporting
2 requirements and so on without necessarily blowing up
3 the current system entirely.

4 But I also heard a lot of different policy
5 recommendations that were made in this discussion about
6 things like commercial permits, more transparency about
7 commercialization of products that are being done
8 basically under permit. And post-market monitoring,
9 which came up several times yesterday as well.

10 The LLP, again, that just sort of illustrated for
11 me, the challenge of finding the right balance on this
12 coexistence issue that the Secretary talked about.

13 The public participation discussion I thought was
14 very helpful. First in terms of outside of this rule,
15 per se, a number of really good ideas about what we
16 might do to make our information easier to find, more
17 people like making our Web site easier to navigate,
18 pushing information out to people, having public
19 meetings like this just to provide people general
20 information about what's new in terms of the science
21 and what products are coming onto the scene and what
22 new developments are occurring in the program, like

1 BQMS and stuff like that, a number of really good ideas
2 about how we can improve our communication strategies
3 that aren't really dependent on getting a rule
4 finalized and so on.

5 With respect to the rule and the -- and the public
6 participation process in the development of this rule,
7 I heard a lot of people say we should simply re-propose
8 the rule, we should re-publish an environmental impact
9 statement while the rule is opened. What I'll say
10 about the process is this; when we published the
11 proposed rule, we did have a section in the proposed
12 rule that made reference to the draft programmatic EIS
13 that was published last year. And our statement in the
14 preamble said that the proposed rule was consistent
15 with the draft EIS that we published, but we did invite
16 comments from the public on the adequacy of the EIS and
17 in fact, we've gotten many comments on the adequacy of
18 the EIS and many calls for a new document to be
19 published while the rule is out there.

20 And in the proposed rule, we also indicated that
21 our legal obligation is to publish a final EIS in
22 conjunction with the final rule. The comment period on

1 this rule again is open until June 29th. At the end of
2 that time, we will be evaluating all the comments that
3 we received and there will be a lot of deliberations
4 that will need to take place within the Department here
5 about not only what the substance of the rule should
6 look like, but what process we will need to undertake
7 to move forward.

8 And that may involve re-proposing some or all
9 parts of the rule. It may involve putting out a
10 supplemental EIS. But those decisions will be made in
11 conjunction with the Secretary's Office once we have
12 evaluated the comments at the end of the comment
13 period.

14 FOIA. Jane, I'm sorry and I'm happy that you got
15 your 2004 FOIA request. I'm sorry that it took five
16 years and Greg told me he got a call from somebody in
17 the FOIA Office asking him if he still wanted the
18 answer to his 2006 FOIA request. So --

19 JANE RISSLER: I've had several of those
20 also.

21 MIKE GREGOIRE: I'm -- no, I'm sorry and
22 happy about that too and the reason I say I'm -- I'm

1 sorry because it took so long, but I'm happy that you
2 got that and that you got that call, because we've
3 recently sent one of our people to the FOIA Office for
4 six months, full-time to work on backlog. So that
5 tells me they're making some progress because their
6 first priority is to clear up the oldest ones that we
7 have. We're also trying to improve the turnaround time
8 on the ones as they come in. And we're also looking at
9 things we could more routinely publish on the Web site
10 so that people could have access to those without
11 having to go through the -- the FOIA process.

12 And we are being so encouraged to do so by the new
13 Administration who's paying very, very close attention
14 to this whole FOIA issue and believe me, our
15 Administrator's Office is as well. So I wanted to --
16 to mention that.

17 Just some other interesting ideas that I heard
18 around -- additional -- alternative way of dealing with
19 petitions, maybe having an additional initial scoping
20 period was an interesting concept. So anyway, I just
21 thought there were a lot of practical suggestions that
22 we got from people in that particular segment; both

1 with respect to this rule, but things that we could do
2 that -- well don't have to tie those to the rule per
3 se.

4 So those are the key things that -- that I heard
5 today and -- pardon?

6 EVA RING: I'm going to let you say the
7 final remarks.

8 MIKE GREGOIRE: Oh, okay. So anyway, I
9 just want to conclude by again thanking everybody for
10 your participation. I know it's been a long two days.
11 This is a tiring process I think for maybe some of us
12 more than others. But I appreciate everyone really
13 sticking with it and -- and really engaging and giving
14 us your thoughts, ideas and suggestions.

15 So I feel good with how it turned out and I thank
16 you very much. I think we're adjourned.

17 [APPLAUSE]

18 (Whereupon the meeting was concluded.)

19

20

21

22