

**Day 2 Closing Remarks by BRS Deputy Administrator Mike Gregoire and
Associate Deputy Administrator Beverly Simmons**

(Extracted from transcripts.)

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.