

**Day 1 Closing Remarks by BRS Deputy Administrator Mike Gregoire and
Associate Deputy Administrator Beverly Simmons**

(Extracted from transcripts.)

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.