

# TRANSCRIPT OF PROCEEDINGS

IN THE MATTER OF: )  
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STAKEHOLDERS MEETING WITH )  
FRIENDS OF THE EARTH )  
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## **HERITAGE REPORTING CORPORATION**

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UNITED STATES DEPARTMENT OF AGRICULTURE

IN THE MATTER OF: )  
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 STAKEHOLDERS MEETING WITH )  
 FRIENDS OF THE EARTH )  
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Training Room 1  
 4700 River Road  
 Riverdale, MD

Friday  
 February 27, 2004

The parties met, pursuant to the notice, at  
 8:12 a.m.

BEFORE: MS. CINDY SMITH  
 Deputy Administrator

APPEARANCES:

For the U.S. DEPARTMENT OF AGRICULTURE:

REBECCA BECH, Assistant Deputy Administrator  
 JOHN TURNER  
 NEIL HOFFMAN  
 MICHAEL WACH  
 SUSAN KOEHLER

Meeting with: Friends of the Earth  
 BILL FREESE, Research Analyst

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P R O C E E D I N G S

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(8:12 a.m.)

MS. SMITH: Well, good morning and welcome.  
We will start first by introducing everyone and then  
we will give our background information.

MS. BECK: Good morning. I am Rebecca Bech  
and I am the Associate Deputy Administrator.

MS. SMITH: I'm Cindy Smith, the Deputy  
Administrator.

MR. TURNER: I'm John Turner. In the past,  
I was a biotechnologist here; and then, for awhile, I  
was acting in Jim White's position, which is now under  
Neil's umbrella, so I came from the regulatory side  
over. I am Director of Policy Coordination.

MR. HOFFMAN: Neil Hoffman, Director of  
Regulatory Programs.

MR. WACH: I'm Mike Wach. I am the  
Environmental Protection Specialist.

MR. ITANDLEY: I'm Lee Itandley, a  
biotechnologist on the staff. I started in December.

MS. SMITH: Robyn?

MR. ROSE: This is Robyn Rose.

MS. SMITH: And Christian?

MS. ZAKARKA: Chris Zakarka.

MS. SMITH: Okay. Welcome to our

1 Stakeholders' Discussion Series on our upcoming  
2 environmental impact statement (EIS) and our revised  
3 plant biotechnology regulation. We appreciate you  
4 taking time to spend with us today, as well as  
5 bringing lots of great information for us to factor  
6 into our upcoming decisions.

7           The purpose of this briefing is twofold.  
8 First, we want to provide an opportunity to share  
9 information about our plans to go forward with the  
10 development of EIS, as well as revisions to our  
11 planned biotechnology regulations. And secondly, our  
12 intention is to gather diverse and informative input  
13 for us to use to support effective decision making in  
14 the development of both our EIS and our biotechnology  
15 plant regulation provisions.

16           We have here from BRS members of our  
17 management team as well as additional staff, when  
18 available, and other key Agency personnel such as  
19 Chris, who are supporting us in this effort. I wanted  
20 to point out two individuals who are dedicated to this  
21 effort on a full-time basis. First, John Turner, who  
22 you know. John is providing overall leadership for  
23 both the completion of the EIS as well as the new  
24 plant biotechnology regulation provisions.

25           And Dr. Michael Wach, who introduced himself

1 as a newly-hired environmental protection specialist  
2 with ERS. He is with our new Environmental and  
3 Ecological Analysis Unit that is headed up by Susan  
4 Koehler. Michael brings both a Ph.D. and a J.D., as  
5 well as research experience in plant pathology and  
6 science and legal experience in cases involving NEPA,  
7 the Clean Water Act, the Clean Air Act and other  
8 environmental statutes.

9           As you likely know, we recently participated  
10 in inter-agency discussions with EPA, FDA and the  
11 White House, which, while including the coordinated  
12 framework, provides an appropriate science interspaced  
13 right between the search for biotechnology and we  
14 included with that the Plant Protection Act of 2000,  
15 which provides a unique opportunity for APHIS to  
16 revise its regulations; and potentially to  
17 substantially expand our authority while leveraging  
18 the experience gained through our history of  
19 regulation to enhance our regulatory framework,  
20 particularly with an eye towards future advancements  
21 of this technology.

22           We also concluded these discussions with the  
23 general agreement on how you will be proceeding in  
24 terms of enhancing our biotechnology, the biotech-  
25 regulatory approach for plants. Still, there is much

1 opportunity for public and stakeholder input in the  
2 process that we are undertaking as we look to  
3 developing the specifics of our regulatory  
4 enhancements.

5           Given this, what we would like to do in  
6 these meetings is have an opportunity to hear your  
7 thoughts. We are in a unique position to have very  
8 open input into our process, as we are not in the  
9 formal rule-making stage of our regulation  
10 development.

11           Our discussion will be professionally  
12 transcribed today for two reasons. First, we want an  
13 accurate record of your discussions, one that  
14 facilitates our ability to capture and refer to your  
15 input all through the rest of this process. And  
16 secondly, in the interest of transparency and fairness  
17 to all stakeholders, we will be making available, as  
18 part of the public record and potentially on our Web  
19 site, documentation of all these gatherings, so that  
20 each stakeholder will have the benefit of the  
21 information shared with each of the others at this  
22 conference.

23           I need to acknowledge that we are in  
24 litigation with you; and, as such, that has limited  
25 somewhat our ability to speak to important segments

1 such as this without our lawyers. However, your input  
2 is very valuable to us. So what we look forward to  
3 doing today is having a very productive listening  
4 session. We are here to listen to your input, to  
5 capture it on the record; and have it for you to refer  
6 to.

7           Finally, since it will be hard to predict  
8 what the final regulation will look like that will  
9 emerge from this process, I would like to briefly  
10 share with you our overall ERS-priority areas of  
11 emphasis, which we use to set direction and help ride  
12 the development and implementation of regulatory  
13 policy strategies and operations.

14           First, Rigorous Regulation: Rigorous  
15 regulation, which thoroughly and appropriately  
16 evaluates and insures safety and is supported by  
17 strong appliance and enforcement. Secondly,  
18 Transparency: Transparency of the regulatory process  
19 and regulatory decision making to stakeholders and the  
20 public. We feel this is critical to public  
21 confidence. Third, a science-based system insuring  
22 the best science issues to support regulatory  
23 decision-making to assure safety.

24           Fourth, communication, coordination and  
25 collaboration for the full range of stakeholders. And

1 finally, international leadership: assuring that  
2 international biotechnology standards are science  
3 based; supporting international regulatory capacity  
4 building; and considering international implications  
5 in policy in regulatory decisions.

6           As we enter the discussion, I would just let  
7 you know that the first time you speak, if you can  
8 precede your first comment with your name for the  
9 purposes of the transcriber; and to remind you that we  
10 will all be speaking into microphones for the purpose  
11 of recording this for the public record.

12           With that, I will open the floor to use this  
13 time in any way that you would like, and to share as  
14 much information as you would like to. You don't have  
15 to speak right into it. It is on the table.

16           MR. FREESE: Yes. My name is Errol Freese.  
17 In my presentation, I peppered it with a number of  
18 questions from verification of certain terms from the  
19 *Federal Registrar* notice. But I will just have to  
20 assume that I understand what those terms are at a  
21 later time.

22           MS. SMITH: Actually, the way that the  
23 Center for Food Safety handled that was they just  
24 stated what the questions were and kept going, and  
25 then we can kind of make a note of those.

1 MR. FREESE: Okay, all of them.

2 MS. SMITH: Just go ahead and mention what  
3 they are. At least you have questions about what kind  
4 of track and see the schedule and clarification, too.

5 MR. FREESE: Okay. Just to calculate into  
6 this, I guess on the first section, I was wondering  
7 about including the noxious weeds in the definition  
8 under the category of what APHIS regulates here. I  
9 was just wondering what you were thinking of? If  
10 there would be, for instance, herbicide-resistant  
11 volunteers that could become passers such as the  
12 resistant canola in Canada, I guess would be an  
13 example.

14 And then, related to Question 5, I guess you  
15 were including the plant products, the non-viable  
16 plant material under the definition of noxious weeds.  
17 I would make a clarification on that.

18 Then I am wondering where would weedy  
19 relatives, that might be endowed with beneficially  
20 engineered traits, where would they fit into the  
21 regulatory framework? Again, an example here, might  
22 be that you have herbicide-tolerant rice, which may  
23 perhaps be the herbicide-tolerance traits that could  
24 get into a related wheat species. If that would somehow  
25 fit into any of your categories for regulation?

1           Then, on biological-control organism, I want  
2 to have a clarification on that as well. The one that  
3 came to mind perhaps was the genetically engineered  
4 insect, engineered for sterility here versus something  
5 along those lines?

6           MS. SMITH: I guess on my comments, I would  
7 like to start with Section 7 because that is one of  
8 the ones that raises the most concern for Friends of  
9 the Earth: an adventitious presence. The proposal  
10 here seems to be APHIS's attempt to implement the  
11 August 2002 OSTP policy directive on adventitious  
12 presence.

13           In that document, you are directed "to  
14 provide criteria under which regulated articles may be  
15 allowable in commercial-seeding commodities, if they  
16 pose no unacceptable environmental risk."

17           I guess to your questions, I would just  
18 state our position: We would not support establishment  
19 of a separate component in the regulatory system to  
20 address adventitious presence; hence, we would urge  
21 you not to exempt adventitious presence, at whatever  
22 level, from APHIS regulation.

23           The rationale for that I think is just  
24 pretty basic. APHIS regulates experimental  
25 genetically engineered crops; and these crops are

1 grown under notification or permit, in part, to  
2 evaluate their potential environmental impacts.

3           So, from the very first, to provide any  
4 tolerance allowance for the presence of experimental  
5 GE plant material in commercial crops: food, feed or  
6 seed, before you have conducted the environmental  
7 assessment that comes at the time that the petitioner  
8 applies for deregulation, it prejudices the outcome of  
9 that environmental assessment.

10           In other words, such a premature tolerance  
11 setting or allowance would be tantamount to a finding  
12 of no significant impact for, again, experimental GE  
13 crops for which all the field-trial data is not in.  
14 This possible scenario, in which an experimental GE  
15 crop containment, exempted from APHIS regulation under  
16 this adventitious presence clause, is later found to  
17 have a significant environmental impact in the  
18 environmental assessment that you conduct when the  
19 crop is considered for deregulation.

20           So, at that point, the trait would be out of  
21 the bag and would be in the environment. And, yet,  
22 you would have found formally, at the time of  
23 deregulation, that this trait does have a significant  
24 impact and shouldn't be out there, but it would be too  
25 late perhaps to do anything about it.

1           In this connection, I think that it is  
2 interesting to look at the fate of genetically  
3 engineered traits in the environment, say a low level  
4 of a certain experimental trait did get out into the  
5 environment to contaminate a conventional crop.

6           I think the conventional wisdom is that:  
7 Unless such traits offer some kind of a damage, some  
8 kind of selective damage, they would eventually  
9 disappear. But it is interesting to have it here, a  
10 presentation by Norman Ellstrand, who is a leading  
11 geneticist. He has a more nuanced view of this and I  
12 think that it is kind of interesting. He looks at two  
13 situations, one where you have a single gene-flow  
14 event; and the other where you have a recurrent gene-  
15 flow. That would, I guess, be the situation where you  
16 have repeated field trials of the same sort of plant.

17           According to him, he has looked at gene  
18 crops to wild gene flow pretty carefully. If the  
19 trait is neutral, it could persist. Okay, with the  
20 single-gene-flow event, a neutral trait could persist.  
21 So I guess the metabolic cost may not be significant  
22 enough to eliminate it from the population. Of  
23 course, if it offers any advantage, it could increase  
24 over time; decrease only if it is detrimental. But if  
25 you have a recurrent gene-flow, which I think is the

1 more interesting situation, it could increase over  
2 time if it is beneficial or if its neutral.

3           So even a neutral trait, that gets out into  
4 a related wheat species say, could increase over time  
5 even if it were neutral. I think that that is a  
6 concern; and it could persist even if it is  
7 detrimental, if you have repeated introductions. So I  
8 think that should be kept in mind when we are talking  
9 about adventitious presence.

10           Now, some other problems we have with this  
11 is just the notion that this intermittent and low-  
12 level assumption, I think, needs to be very carefully  
13 looked at. One of the questions that I would have is:  
14 Are you going to establish numerical tolerances for  
15 adventitious presence? Is it going to be a general  
16 tolerance for all adventitious presence of any traits,  
17 or is this going to be done on a case-by-case basis?  
18 Is there going to be any assessment to establish  
19 whether adventitious presence is allowable for certain  
20 crops, and, if so, at what levels?

21           I know that at the OTSDP meeting that was  
22 called when that directive was first put out in August  
23 2002, and Cindy you were there, I asked James White  
24 about this and the thinking at that time seemed to be  
25 that there would be no limit to the level of

1 contaminant if permit conditions were followed. I  
2 guess the assumption there is that if permit  
3 conditions were followed, there wouldn't be any  
4 adventitious presence.

5           But you get into circular reasoning here. I  
6 think it is clear that just the fact that this  
7 proposal is being put out there is an admission that  
8 adventitious presence does occur. And we would be  
9 strongly against --- well, we don't think adventitious  
10 presence should be allowed and certainly it shouldn't  
11 be allowed to be any level just based on following  
12 permit conditions because I don't think that those  
13 permit conditions have been validated or perhaps even  
14 can be validated under environmental conditions which  
15 vary widely.

16           I guess another comment is: How do you  
17 propose to confirm compliance with permit conditions?  
18 Again, according to James White back at that 2002  
19 meeting, only 10 percent of notification trials were  
20 ever inspected at all, which is a very low level. I  
21 believe that even those that had perhaps one  
22 inspection at the time, the initiation of the trial.

23           So there are two levels here. Permit  
24 conditions are not going to guarantee any certain low  
25 level or intermittent level of contamination. And

1 then, even if they are, how are you going to confirm  
2 compliance with those conditions?

3 MS. SMITH: Bill, I am going to interrupt.

4 MR. FREESE: Okay.

5 MS. SMITH: On any of these questions where  
6 you are kind of asking, are you asking how we are  
7 going to proceed, it is useful for us if you have any  
8 thoughts on how we should be answering those  
9 questions. In other words, how are you going to seek  
10 compliance? You would like to see us inspect 40  
11 percent of notifications three times. On any of  
12 these, please feel free to just give us any of your  
13 thoughts on what you would like to see us do.

14 MR. FREESE: Okay. One way that you might  
15 be able to see how good these permit conditions are  
16 and to test compliance with them is to use strip  
17 tests. I have suggested this before in other comment  
18 notes. Perhaps before field tests take place, the  
19 manufacturer should make available strip tests to test  
20 for the protein to test neighboring crops, or  
21 whatever, to see if you were actually getting in  
22 contamination. I don't believe that has ever been  
23 done from my understanding.

24 I think that that is actually really  
25 necessary, especially given we have the incidents in

1 Hawaii, for instance, where there has been  
2 contamination of neighboring crops. This was under  
3 trials that were both somewhat under EPA jurisdiction  
4 and PIPS that were -- I think one trial was over 10  
5 acres, so that was the EPA; and one was under, so that  
6 USDA. I forget the exact details but that seems to  
7 have been the exception that sort of testing.

8           Then, I would mention also that adventitious  
9 presence in seed contamination is a particular  
10 concern. The Union of Concerned Scientists has put  
11 out a report that perhaps you have seen, which  
12 documents a pretty high and unexpected level of seed  
13 contamination with genetically engineered traits. One  
14 very striking example that we found a number of years  
15 ago was the Starlink. Well, actually, the USDA  
16 discovered this.

17           In order to get rid of the Cry 9C trait from  
18 the commercial seed supply, USDA invited firms to have  
19 testing done. We have those 270 seed companies that  
20 had never dealt with Starlink and this is what I find  
21 interesting: They had never sold Starlink. They had  
22 these tests done and nearly a quarter of those  
23 companies found the Cry 9C trait, at some level, in  
24 some of their commercial seed lines. To me that is  
25 very striking. How did that happen? These are

1 companies that never sold Starlink.

2           So, this raises a lot of concern on a number  
3 of levels because: With contamination at the seed  
4 level, there is nothing you can do. There is nothing  
5 a farmer can do to avoid that. You can talk about  
6 pollen flow and all these other concerns, but if your  
7 seed is contained then what can you do? So confidence  
8 in the seed supply is extremely important I would  
9 think.

10           Then you mentioned international  
11 considerations I believe, Cindy. The economic impacts  
12 of allowing adventitious presence, I think, require a  
13 lot of consideration. You can legislate, you can  
14 legalize adventitious presence, but that is not going  
15 to force markets to accept contaminated seeds or  
16 crops. All right. And we know that export markets  
17 here and in Japan are extremely sensitive to  
18 genetically engineered foods in general, even if they  
19 have been deregulated in the United States. Their  
20 sensitivity is going to be much greater for  
21 experimental traits.

22           So I would, again, strongly urge you not to  
23 allow adventitious presence. I think we need to have  
24 zero tolerance for all of these experimental traits,  
25 for all of reasons that I have mentioned.

1           Then, I guess, next I wanted to move to  
2 Section 2. Some of this applies to Section 10 as well  
3 about the tiered-risk category section. I guess our  
4 Friends of the Earth would urge that the low-risk  
5 categories, so called, are not exempted from  
6 permitting requirements; and that all genetically  
7 engineered crop trials should meet the criteria  
8 proposed for the highest-risk category. That is: the  
9 PMPs and the industrial compounds.

10           I guess the rationale for this is somewhat  
11 similar to the argument for adventitious presence. It  
12 seems that in order to define certain product types as  
13 low risk, moderate risk or high risk, is premature  
14 because, again, these are experimental crops. You  
15 haven't done environmental assessments on them. So to  
16 make a prejudgment as to the level of risk is, again,  
17 premature. You don't have the data.

18           Then I wanted to ask you to give examples of  
19 product types that you were thinking about here. The  
20 one that came to mind perhaps that you might be  
21 thinking of as a low-risk category would perhaps be:  
22 herbicide tolerance. If that were the case, if  
23 herbicide tolerance is a "product type," it would  
24 presumably encompass glyphosate, glufosinate  
25 tolerances well as resistance to 2, 4-D or any other

1 herbicides. I don't know exactly what is in the  
2 works.

3           My point here is: The resistance mechanisms  
4 for each of these different herbicide tolerance traits  
5 are completely different. They vary widely and I just  
6 wonder: What is the scientific justification for  
7 considering this heterogeneous group to pose a similar  
8 degree of risk, I mean if you have completely  
9 different mechanisms? And even if you take a narrower  
10 product type, such as glyphosate tolerance, even there  
11 you have completely different mechanisms: the EPSPS  
12 enzyme, which is insensitive to glyphosate. And on  
13 the other hand, you have the glyphosate oxido-  
14 reductase, which degrades glyphosate.

15           So, again, even within the most narrowly  
16 construed product type, you have very different  
17 mechanisms. I just wondered that if a third mechanism  
18 was developed, if it were completely different, a  
19 completely different mechanism, would this  
20 automatically qualify for this particular product type  
21 and what would be the scientific justification for  
22 doing that?

23           I guess what I am trying to get at here is I  
24 just think again the whole idea of making prejudgments  
25 about the level of risk, without the data from the

1 field trials, is premature. I guess one way that you  
2 might want to define a product type is on a supposed  
3 history of safe use. You could say: Well, glyphosate  
4 resistance is proven low risk in soy beans. In my  
5 view, this has not been demonstrated but you might  
6 make that argument. So, based on that, you might say  
7 that all experimental glyphosate-resistant crops will  
8 be classed as low risk.

9           But, again, here we are dealing with  
10 recombinant DNA techniques. Each genetic  
11 transformation event is unique and has its own set of  
12 unintended affects. Some of them will be quite  
13 subtle, perhaps there won't be so many with signs of  
14 others, but the point is that each event is unique and  
15 cannot -- that prevents you from tracing these crops  
16 in certain product types. I think that's why people  
17 always talk about case-by-case assessment. That  
18 always is what the industry and government have both  
19 said: These crops need to be evaluated on a case-by-  
20 case basis because these techniques are unique and  
21 non-repeatable, each event.

22           So it seems to me that that just invalidates  
23 the whole notion of product type and this prejudgment  
24 as to risk. I think this becomes especially true when  
25 you look at the paucity of data that is collected at

1 the field-trial stage. And with notification trials,  
2 it is very abbreviated; and I don't think that you  
3 collect a whole lot more for the permits.

4 I will just give you one example: The  
5 herbicide-resistant sugar beets that were deregulated.  
6 I forget but I think that this was in the late '90s.  
7 They contain a fusion protein that is expressed by a  
8 stretch of DNA composed of a truncated glyphosate  
9 oxido-reductase, a gene fused to sugar beet DNA.  
10 This, of course, is a result of breakage of the  
11 transformation factor in them, the holistic  
12 transformation process. So, you have a novel protein  
13 expressed. The FDA called it: Protein 34550.

14 This is just an example of how you can get a  
15 completely unexpected event. Now, these sugar beets  
16 were apparently glyphosate resistant but what does  
17 that tell you about the hidden environmental risk of  
18 this novel protein? So, again, I would urge that all  
19 field trials be regulated according to the highest  
20 standards that you are talking about for  
21 pharmaceutical or industrial crops.

22 On Section 3, let's see: Continuing  
23 Regulation in some cases rather than just complete  
24 deregulation. I think this is a good idea. I think  
25 this was suggested by the National Academy of Science

1 Committee that, in some cases, APHIS shouldn't have an  
2 absolute deregulation, but rather, I guess, a  
3 conditional deregulation. Actually, I think that  
4 should be the norm rather than the exception.

5           One case where this might be important is  
6 where regulation should continue beyond the  
7 deregulation stage. Maybe we need other terms here in  
8 this case, but for herbicide-resistant traits, for  
9 instance. In Canada, we have the development of  
10 doubly and triply resistant canola, which, according  
11 to the Royal Society of Canada, is becoming one of the  
12 biggest weed problems in western Canada. That's huge.  
13 They found one, some volunteer canola plants that  
14 were resistant to, I believe it is glyphosate  
15 glufosinate, and imidazolinone, I believe it is.

16           That is unacceptable. I know that in the  
17 case of rice, there is a Libertylink rice, a  
18 glufosinate-resistant rice that has already been  
19 deregulated a number of years ago. I believe in the  
20 deregulation notice, APHIS states that there I believe  
21 two others that are under development. One is  
22 Monsanto's glyphosate-resistant rice. Then, I  
23 believe, a third.

24           Well, first of all, APHIS admits, in this  
25 environmental assessment, that this trait will get

1 into weedy red rice and that people can just use other  
2 registered herbicides if that is to occur. I think  
3 there needs to be a stricter standard here, especially  
4 when you consider that there might be others coming  
5 along, other herbicide resistant traits. Because then  
6 it seems like you are setting yourself up for possibly  
7 a situation as in Canada with the canola.

8           In addition to continuing regulation,  
9 perhaps APHIS should retain the authority to cancel  
10 registration, so that if problems come up, for  
11 instance, this herbicide-resistance problem,  
12 especially double or triple resistance; and then I  
13 believe in the deregulation that the original  
14 transformation event is deregulated along with all of  
15 its progeny. I think that is the standard term.

16           I believe the NAS raised a question as to:  
17 Whether there shouldn't be continued regulation to  
18 look at stability of the integrated DNA after many  
19 generations of breeding into multiple hybrids for  
20 example. So that would be another possible case where  
21 you should use this Section 3 clause.

22           On Section 3, just a couple of questions.  
23 How do you define minor-unresolved risk? I am sure  
24 that you have had that question before.

25           I guess I will jump here to maybe Section 6.

1 Just some clarification questions here. You are  
2 talking about establishing a separate mechanism for  
3 regulating PMPs or IC crops grown under confinement  
4 conditions with governmental oversights, rather than  
5 use the approval process for unconfined releases. I  
6 guess I am a little confused as to terminology. I  
7 thought that all field trials basically -- well, first  
8 of all, there hasn't been an environmental assessment  
9 of a PMP field trial since 1998.

10 My understanding is that the legal basis for  
11 that is that these trials have just been defined as  
12 confined or contained, so exempt from, I believe, it  
13 is NEPA. So I am wondering: What does unconfined mean  
14 here in this context? Perhaps you are using it in a  
15 non-technical sense to mean an open-air trial. Does  
16 that make sense?

17 MR. TURNER: Which number?

18 MR. FREESE: This is No. 6. Because my  
19 first thought when you used the term "under  
20 confinement conditions," I interpreted that to mean  
21 greenhouse or other underground mines or some of the  
22 other mechanisms that have been proposed. So, first  
23 of all, I would like a clarification of that; and then  
24 when you say rather than use the approval process for  
25 unconfined releases, that is why I assumed the

1 proposal referred to true containment in greenhouse or  
2 underground mines. I hope that I am making myself  
3 clear.

4           In any case, I think it is a very good idea  
5 to consult with the states in this case, as well as in  
6 all cases. I think there should be closer  
7 collaboration with the states on all genetically  
8 engineered field trials, especially the high-profile  
9 kind of pharmaceutical and industrial crops. I know  
10 that in a number of states there is growing concern  
11 about what these trials might mean for the state's  
12 agriculture if containment isn't absolutely 100  
13 percent.

14           One recommendation that we would have is  
15 that states should be given -- I am not a lawyer but I  
16 think states should be given explicit authority to  
17 reject disapproved field-trial applications in all  
18 cases of experimental gene-crop trials, especially the  
19 pharmaceutical and industry compound crops.

20           Then, also, I think that some mechanism is  
21 needed to inform and consult with local authorities,  
22 neighboring residents and farmers, or their  
23 representatives, about any experimental GE field  
24 trial, again especially the pharmaceutical or  
25 industrial crops; and that trial should proceed only

1 with the approval of the stakeholders.

2           There is actually precedence for this in the  
3 very first bio-pharmaceutical crop field trial in  
4 1991. It was trichosanthin-producing tobacco. North  
5 Carolina set up a genetic engineering review board to  
6 help review the application. I don't know the details  
7 of that mechanism, but it seems valuable to have true  
8 consultation with the state.

9           Another example is: in Colorado a review  
10 committee has been set up. It is, in my view, much  
11 too narrow. I believe it is three scientists from the  
12 university setting. So maybe this is the state's  
13 responsibility to do it, but APHIS I think should  
14 allow for it at least.

15           Then, Section 8, I guess I have the same  
16 objections to: How do you define low risk without  
17 field-trial data? Also, the idea of regulatory  
18 approval in a foreign country. Should APHIS provide  
19 for expedited review, or exemption from review, of  
20 certain low-risk genetically engineered commodities  
21 intended for invitation that have received all  
22 necessary regulatory approvals in their country of  
23 origin?

24           Again, you have the general problem with:  
25 How do you define low risk? In this case, we don't

1 know anything about really the regulatory approval  
2 process in a foreign country. It could fall far short  
3 of U. S, regulatory standards. I don't think we  
4 should allow that. I think that there should always  
5 be a separate APHIS assessment.

6           Section 4, I guess would be the final  
7 section. The position of Friends of the Earth: We  
8 support a ban on all open-air plantings of all crops  
9 genetically engineered to express pharmaceutical  
10 proteins, industrial compounds or other proteins that  
11 are not intended for the food or feed chain; and  
12 whether these crops are food crops or non-food crops?

13 We believe that most cultivation of non-food crops  
14 engineered to express such proteins should be allowed  
15 under: proving 100-percent containment.

16           Food-safety evaluations are not appropriate  
17 for crops engineered to express these non-food  
18 proteins and should not be used to justify tolerances.  
19 That is the thought in this section about food-safety  
20 evaluation. Zero tolerance is the only acceptable  
21 standard.

22           In referring to Section 4, you ask about:  
23 How should the results of the food-safety evaluation  
24 affect the review permit conditions and other  
25 requirement for these plants? We don't think that

1 these crops should be even evaluated for food safety.

2 They are not meant for food; they have no business in  
3 food meeting the zero-tolerance standard.

4 Now, also, it seems to be more of an FDA  
5 question, so I was kind of puzzled to see it here in  
6 this foreign notice.

7 This raises another question about: How we  
8 define pharmaceutical and industrial crops; and should  
9 there be a category, for instance: non-food proteins?  
10 Because pharmaceutical and industrial proteins do not  
11 cover the universe of these genetically engineered  
12 proteins that are not meant for food use.

13 There is the category: novel protein. I  
14 handed out some recommendations that have come  
15 comments that I submitted back, I believe, March of  
16 last year. The novel-protein phenotype where does  
17 that fall? Are all novel proteins -- again, I am  
18 talking about on the APHIS Web site, the phenotype  
19 novel protein. Are all of those considered industrial  
20 proteins, some but not others?

21 We need to have a consistent system. When  
22 you put a phenotype up on your Web site, we should be  
23 able to know what category that falls into in terms of  
24 your regulatory system? Does that make sense?

25 So, for instance, like a novel protein I

1 found once that laccase, which is an industrial enzyme  
2 that had been classified as a novel protein. That was  
3 one that actually -- you did change after I pointed  
4 that out. There could be many other examples that I  
5 haven't seen, but it seems to me that you need to over  
6 these pheno types and make it clear where they fall.  
7 Are they permitted? Are these permitted pheno types,  
8 or notification pheno types. Are they non-food  
9 proteins or food proteins?

10           This would help with transparency, too, so  
11 that groups like ours can go to your Web site and know  
12 what we are dealing with, I guess. Again, just novel  
13 protein, too, is kind of -- I mean all of these  
14 proteins are novel proteins, right? When you produce  
15 a human or animal, for instance, antibody on a plant,  
16 it is a novel protein and it is going to be a little  
17 different than the original. So it is really a  
18 meaningless category and I urge you to get rid of it.

19           Then the other thing is -- again, these are  
20 comments that you made before but with pharmaceutical  
21 protein. You have two different phenotypes. Okay,  
22 let's take three: pharmaceutical, antibody and  
23 antibiotic. Those are different categories. And yet,  
24 antibodies and antibiotics are obviously  
25 pharmaceutical in nature. So, again, if someone goes

1 to your Web site and clicks pharmaceutical protein,  
2 they are not going to get antibodies; they are not  
3 going to get antibiotics. And there could be others  
4 too.

5           So, again, that is a big transparency  
6 problem because we should be able to go to one place  
7 and get all of the pharmaceutical proteins. That  
8 makes sense.

9           Another example with non-food proteins.  
10 Avidin is a good example. I just handled one of the  
11 case studies from my report back in the summer of  
12 2002. Avidin, I believe was classified as a novel  
13 protein. I am not sure. I don't think that I ever  
14 actually found it on your database. It is being sold  
15 right now by Sigma as a research chemical. It  
16 actually causes Vitamin B deficiency. I don't think  
17 that it would necessarily fall under industrial  
18 compound or pharmaceutical. Yet, it has health  
19 impacts. It kills insects. It has environmental  
20 impacts.

21           What category is this going to be regulated  
22 under? We need to make sure that all compounds that  
23 potentially have these kinds of environmental health  
24 impacts are regulated under the strictest category.  
25 Right now, that seems the pharmaceutical- and

1 industrial-compound category.

2       Aprotininm is another example. In, I believe, it  
3 is the 2002 trial, where aprotinin is first identified  
4 on your Web site. It is listed as pharmaceutical,  
5 which is appropriate. It is a blood-clotting protein.  
6 Yet, I know that from press accounts, field trials  
7 have been going on since 1997 or 1998. It must have  
8 been classified as novel or some other category at  
9 that time, which is totally unacceptable because it  
10 kills insects and has adverse impacts on honey bees.

11           An SAP to the EPA pointed to problems with  
12 ingestion of this class of protein. It is a protease  
13 inhibitor. So these kinds of compounds need to be  
14 strictly regulated.

15           MR. FREESE: There is another issue that  
16 might have been cleared up. I am not certain but I  
17 know that in 2001, APHIS issued a letter to companies  
18 that were doing field trials of pharmaceutical crops.  
19 And, John, we talked about this. They were able to  
20 renew their permits for, I believe, up through the end  
21 of 2003. Hence, those renewed trials were not being  
22 listed on the Web site and I am not sure if that has  
23 been taken care of.

24           But, in the interests of transparency, we  
25 need to know about all field trials. Whether they are

1 being done under renewed or original permits? I guess  
2 one question: I am wondering if APHIS plans to  
3 continue that process. For instance, do permits that  
4 you issued in 2004, can they be renewed for one or two  
5 years without being listed on the field-trial Web  
6 site, so we strongly discourage you from doing that  
7 because we need full records.

8           Then on the whole CBI policy, I know that  
9 orally I have been told that BRS checks -- okay, when  
10 an applicant claims something, a gene, a CBI, that the  
11 standard procedure is: go to the literature, do a  
12 search, and if a company has, in fact, publicized this  
13 gene, then it does not qualify as CBI.

14           In fact, I found several examples in which  
15 that policy doesn't seem to have been followed, in  
16 which genes that have been publicized by the company  
17 are, nevertheless, listed as CBI on the Web site. One  
18 example is trypsin, which was widely publicized by  
19 ProdiGene. It is trypsin corn.

20           Yet, it was -- I asked Gene Light (ph)  
21 several times and I could never find out which trial  
22 this was. and it is not identified on the Web sites.  
23 So I would urge you to really publish all, and be as  
24 transparent as you can under the law. That hasn't  
25 been done up to now. Disclose the acreage for all

1 field-trial permits. I don't think that there is any  
2 reasonable basis for claiming acreage as CBI. I know  
3 the industry says it might indicate how far they are  
4 along in the process, but that just doesn't seem to  
5 hold water to me.

6           Then, the acreage-field trials by state, for  
7 a multi-state permit, would be very helpful to enable  
8 us to know: What is the acreage in various states?

9           Then, I guess expeditious responses to the  
10 Freedom of Information Act requests would be very  
11 helpful. Friends of the Earth filed a FOIA back in  
12 April 2001; and thus far, of the 131 permits that we  
13 were inquiring about, we have gotten information for  
14 two so far and it has been three years.

15           MS. SMITH: What was the subject of that  
16 FOIA request?

17           MR. FREESE: It was on the pharmaceutical  
18 crops. There were actually two responses. One was  
19 two files for permits. We were at the University of  
20 Wisconsin when the CBI was claimed. Then the others,  
21 apparently all had CBI at some level, so they are  
22 going back to the companies to clear the release of  
23 CBI information.

24           MS. SMITH: Could I ask you to send me a  
25 copy of that FOIA request?

1           MR. FREESE: Okay, sure. Finally, the three  
2 case studies I put out, I urge you to take a look at  
3 them. I think they pull together a lot of information  
4 and I think they are valuable to just look at as  
5 examples of problematic crops that perhaps haven't  
6 received the regulatory attention they deserve.

7           I guess that's it. Thank you.

8           MS. SMITH: Do you have any questions?

9           MR. HOFFMAN: I have lots of questions but I  
10 was wondering if I am allowed to ask them? Let's see

11          MS. SMITH: You can raise them now.

12          MR. HOFFMAN: This goes back to the point  
13 about: no open-air tests, pharmaceuticals. I think we  
14 can certainly understand our concern about the food  
15 crops. But I care more about your reasoning for non-  
16 food crops not having open-air tests?

17          MR. FREESE: One reason is, and this  
18 wouldn't cover the universe of non-food crops, but one  
19 of the key studies is trysosantin in tobacco. This  
20 was evaluated a virally vectored case. It was  
21 actually the very first bio-farm field trial back in  
22 1991. It was repeated, I believe, in 1996.

23          Basically, the tobacco-mosaic virus was  
24 altered with the trysosantin gene from a Chinese plant  
25 added to the virus. The virus was used as a vector to

1 infect the tobacco and TMV also infects tomatoes,  
2 peppers, all members of the solanaceous family.

3           So, this is an example for a non-food crop  
4 tobacco that is used to produce a pharmaceutical  
5 protein. You have potential infection of food crops  
6 with this virus. Okay, that is the viral vector.

7           I think there could be environmental  
8 concerns in the case of other non-food crops, even if  
9 there aren't food-safety concerns. I would point to  
10 the very high levels, especially levels that are being  
11 achieved recently. The latest record that I came upon  
12 was an entry where the rice was 45 percent of soluble  
13 protein for their lysozyme lactoferrin. That is a lot  
14 of protein. So with these increasing levels, it seems  
15 like environmental impacts become more of a concern,  
16 too. You have leakage from roots with BT crops.

17           There are studies showing that for hundreds  
18 of days, the BT toxin from a BT plant can leak into  
19 the soil and exist for hundreds of days and retain its  
20 insecticide-level activity. That is just one example  
21 of how a protein can get into the environment and  
22 cause problems.

23           MR. HOFFMAN: So, non-toxic affects.

24           MR. FREESE: Yes, yes. The short answer:  
25 yes. And these are bio-active molecules, so they are

1 probably more concerned than maybe other traits.

2 MS. SMITH: Given the time, I think we need  
3 to wrap up.

4 MR. FREESE: I just thought of a couple of  
5 more points that I could raise. One thing that really  
6 concerns me, especially with the bio-pharm and  
7 industrial crops. Actually, with all of the  
8 experimental crops, there doesn't seem to be any  
9 provisions to stop gene flow by bird or animal. That  
10 seems to be a big gap in the regulatory system.

11 Just as an example of this, I am looking at  
12 an article from the *Sacramento Bee* on Aventis  
13 Bioscience's trials of lactoferrin and lysozyme rice.  
14 This is a quote from the article: "The draft proposal  
15 from Aventis is light on some details, including: How  
16 Aventis will prevent birds from spreading its rice;  
17 what constitutes proper disposal of rice plants; and  
18 whether the company will notify the rice growers?"

19 Just as a side note, I know that Brazil, for  
20 instance, hosted a field trial of Aventis Libertylink  
21 rice some years back. I believe it was in the late  
22 1990s. One of their conditions was actually to have  
23 netting over the field trial to prevent birds from  
24 spreading the rice. I had never heard of that being  
25 even suggested here. Aventis didn't follow that

1 condition and the Brazilians had the field trial  
2 burned, as a matter of fact.

3 I think that is a really serious concern  
4 that hasn't gotten any attention at all, animals as  
5 vectors. Also, with rice, it just strikes me that  
6 small-grain crops like this are especially bad for  
7 bio-pharmaceutical and industrial crop applications  
8 because it is just so hard to control the seed. I  
9 believe that NAS suggested this or Norman Ellstrand  
10 mentioned this once. So that is a real concern. For  
11 instance: How can this bio-pharm rice be kept from  
12 getting beyond the field-trial site and getting into  
13 the environment?

14 MS. SMITH: Anything else? Go ahead.

15 MR. FREESE: No, I think that's it. If I  
16 forgot anything, I will include it in my comments.

17 MS. SMITH: Well, this has been really  
18 informative, lots of really good information.  
19 According to our notes and who else have we here? We  
20 are looking forward to their comments as well.

21 Thanks a lot for coming in today. We  
22 appreciate it.

23 MR. FREESE: Thank you for having me.

24 Whereupon, at 9:07 a.m., the meeting in the  
25 above-entitled matter was concluded.

