TRANSCRIPT OF PROCEEDINGS

IN THE MATTER OF:)
)
STAKEHOLDERS MEETING)
CENTER FOR FOOD SAFETY)
)

Pages: 1 through 51

Place: Riverdale, Maryland

Date: February 26, 2004

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IN THE UNITED STATES DEPARTMENT OF AGRICULTURE

IN THE MATTER OF:)
)
STAKEHOLDERS MEETING)
CENTER FOR FOOD SAFETY)
)

Training Room 1
4700 River Road
Riverdale, Maryland

Thursday,
February 26, 2004

The parties met, pursuant to the notice, at 9:36 a.m.

BEFORE: CINDY SMITH
Deputy Administrator

APPEARANCES:

USDA, APHIS and BRS:

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

For the Center for Food Safety:

PETER JENKINS, Attorney/Political Analyst
JOE MENDELSON, III, Legal Director
DOUG GURIAN-SHERMAN, Senior Scientist

APPEARANCES (CONT.):

Participants:

LEVIS HANDLEY
CRAIG ROSELAND
MICHAEL BLANCHETTE

P R O C E E D I N G S

(9:36 a.m.)

MS. SMITH: Good morning and welcome to our Stakeholder discussion series on our upcoming environmental impact statement and our revised plant biotechnology regulation. We want to thank you for taking time from your busy schedules to participate in this meeting and to share your thoughts with us.

The purpose of these briefings is two-fold. First, to share information regarding our plans to move forward in developing an EIS and amending our plant biotechnology regulations. And secondly, our intention is to gather diverse and informative input which will support thoughtful and effective decision making as we move forward in the completion of an environmental impact statement as well as our new regulations.

We have here from BRS most of our management team, as well as several members of our staff and, when available, other agency personnel involved in supporting BRS in this effort will be sitting in on meetings, as well.

I also want to point out two key individuals who have now been dedicated to providing full time management of our work to complete both the EIS and

our revised regulations. First, John Turner, whom you likely know, a very important member of our leadership team here in BRS. I'm very pleased to say John is leading this effort on a full time basis.

And a second individual, likely a new face with whom you are not familiar yet, is Michael Wach. Michael Wach is a recent new hire here in BRS, as an environmental protection specialist within our environmental and ecological analysis unit that Susan Koehler heads up. In addition to possessing a Ph.D. and an Environmental J.D., Michael brings research experience in plant pathology and weed science, as well as legal experience working on cases involving NEPA, the Clean Water Act, the Clean Air Act and other environmental laws.

As you likely know, we recently participated in inter-agency discussions with FDA, EPA and the White House which, while concluding that the coordinated framework provides an appropriate science and risk based regulatory approach for biotechnology regulation, that the Plant Protection Act of 2000 provides a unique opportunity for APHIS to revise its regulations to potentially expand our authority, while leveraging the experience through the history of our regulation, to enhance our regulatory framework,

particularly to position us well for future advancements of the technology.

We also concluded those discussions with the general agreement on how our biotechnology regulatory approach would evolve. Still, there is much opportunity for public and stakeholder input as we move forward to develop the specifics of our regulatory enhancements. Given this, what we would like to do in these meetings is to have an opportunity to fully hear your thoughts. We have a unique opportunity to listen to all input at this point in the process, since we're not yet in the formal rule making stage of our process.

Our discussion will be professionally transcribed for two reasons. First, an accurate record of our discussions will facilitate our ability to capture and refer to your input. And secondly, in the interest of transparency and fairness to all stakeholders, we will be making available as part of the public record and potentially on our website, documentation on all of our stakeholder discussions that we're holding. That way, each stakeholder group has the benefit of the information shared with each of the stakeholders.

I should acknowledge that we are in

litigation with your group, and as such, that has limited our ability to speak in an informal setting such as this one, without our attorneys. As we considered whether to have this meeting or how to proceed, it was important for us to still have the opportunity to hear fully your thinking and your input and we believe doing it in person is an additionally constructive way than beyond just receiving your input and written comments.

So our objective today will be to have a very productive listening session. We're here to listen fully to your input, to capture it on the record and to have it transcribed so that we may refer very carefully to it. We look forward to considering your input as we move forward, both in the Environmental Impact Statement completion and in writing our new regulations.

Finally, since it will be hard to predict what the final regulations will look like, which will emerge from this process after we've gone through a very intensive public and stakeholder input process, and individuals in the department, such as our Administrator and Undersecretary and Secretary will likely provide us very insightful direction on the direction our regulations will take.

I would like to briefly share with you our overall BRS priority areas of emphasis which we use to set direction and help guide the development and implementation of regulatory and policy strategies and operations. The first is rigorous regulation. Rigorous regulation which thoroughly and appropriately evaluates and ensures safety and is supported by a strong compliance and enforcement.

The second is transparency of the regulatory process and regulatory decision making to stakeholders and the public. We believe this is critical to public confidence.

Third is the scientific based system, ensuring that the best science is used to support regulatory decision making, to assure safety.

The fourth, communication, coordination and collaboration with the full range of stakeholders.

And finally, international leadership, ensuring that the international biotechnology standards are science based, supporting international regulatory capacity building and considering international implications of policy and regulatory decisions.

As we prepare for our discussion, I would let everyone know that for effective transcription, we

all have to speak into the microphones. You don't have to speak directly in, as long as it's on your table, that's close enough. And if the first time you speak, you could say your name for the transcriber and then after that, you won't need to.

With that, I would like to open the floor to hear your comments and input.

MR. JENKINS: Thanks. See, I don't need to speak very loudly into this thing, they just want to be able to hear it. I'm Peter Jenkins. I'm an attorney and policy analyst for the Center for Food Safety and sister organization, the Center for Technology Assessment, here with Joe Mendelson and Doug Gurian-Sherman, also from those groups. And I'll start out and give sort of an overview of the some of the issues.

First of all, I'd like to say thanks again, Cindy, in particular for, you know, the tone that she's taken on this endeavor, you know, very friendly, open and welcome tone to the whole thing. That's very helpful. We will submit written comments that, you know, will spell out in more detail some of the issues that we're probably just going to sort of highlight in the way of questions and highlighting some problems now without going into too much detail.

We can also refer you, I think, to the petitions that our groups and associated groups have filed. One was on genetically engineered turf grasses, which raise some regulatory issues as well. The other on genetically engineered biopharmeceutical and industrial crops, which we had a great deal of discussion about some of these regulatory issues. Another petition we filed is on genetically engineered wheat and Joe may mention some other petitions, too.

MR. MENDELSON: Yes.

MR. JENKINS: Okay, we'll go on from there. On the programmatic EIS process generally, this is something that we've sort of generally asked for, saying there should be a programmatic EIS. But it was in the context of the biopharmaceutical petition that we filed and a programmatic EIS, you're going to find, I think, is going to be a challenge in this area. I think you probably already found it a challenge to sort of identify what the proposal is in detail and what's some reasonable alternatives are to the proposal, besides the no action alternative. You know, it sounds like, Michael, you've got an interesting new job to sort of bring NEPA into this APHIS regulatory process in its full glory. The USDA Forest Service does great NEPA, so you can go to the

Forest Service, generally, and see a good model.

We've been critical of the way APHIS has done NEPA in the past and we've, you know, looked to see it brought up to a really high standard of really complying word by word with the CEQ guidelines on how to do NEPA. SO it's a challenge with the programmatic EIS, because you've got to lay out the proposed action in detail. It can't be all fuzzy and nebulous. And then you've got to lay out some alternative actions that are sort of equivalent in scope and sort of coverage, that really are alternatives to the proposed action, or different approaches.

So we haven't seen that yet in the announcement you sort of laid out with a whole grab bag of ideas as a proposed action, more in the way of questions that you might take these actions, but haven't sort of laid out some alternatives.

So I think that's going to need some more fleshing out. I mean, as it is stated now, it's not clear what the sort of impact topics would be. You've got to talk about impact on the soil and the water and the human health and animal health and so on. But how are those really going to be analyzed in the scope of what you're proposing now, you know, in that context?

I think it's going to be helpful to think,

you know, beyond the box a little bit, outside the box, and think of some other programmatic type alternatives that you could take. We had suggested, I think, in our biopharm petition, that you look, that one approach to regulated biopharm crops is your current approach and the other would be to restrict biopharm crops to very restricted confinement conditions. Say, greenhouses are underground. That would be an alternative with real world impacts that you could assess.

Another alternative would be to restrict the crops to being grown only in very limited geographical areas. And you all had to wrestle with this in defining, well, is a mile a good confinement boundary for biopharm crops? And what does that do to growing in the corn belt and has all sorts of policy considerations, etc., etc.

So, you know that game with biopharm crops and corn. But throughout this whole proposal, you need to really think creatively, what are some alternative actions that really can be analyzed and might have some real world different impacts? You know, besides the no action alternative.

So that's sort of the general NEPA concern. But let's do top notch NEPA. We're an environmental

group, generally. We really rely on NEPA and this is what we focus on a lot, as well as the Endangered Species Act. So if you can show word by word compliance with the CEQ guidelines on NEPA you're probably not going to get sued by us as much or whatever. Same with ESA.

Now in some of the substantive areas, sort of going through some of the things in the order that they were raised in the announcement. I immediately spotted the issue about federal noxious weeds and listing approach -- well, let me rephrase that. I would just say that our groups would oppose an attempt to limit the ability of citizens groups to petition for federal noxious weed listing of a particular variety, just because it happens to be a genetically engineered variety.

An example is with the turf grasses, we petitioned that GE creeping bent grass and GE glyphosate-resistant Kentucky bluegrass be listed as noxious weeds through a fairly familiar and clear noxious weed listing process. And we don't want to see that taken away, that opportunity. It seemed to me that that issue was raised in that part of the announcement and so we would be opposed to that.

One reason to not take it away from the

wheat specialists within APHIS is because you'll get more diverse input if it first has to go through the weed folks, the petition. Of course you guys are going to talk and work together, but let's not cut the weed groups out entirely.

Again, on the turf grass issue, one of the things that came up in your announcement is what sort of maybe post-approval conditions could be imposed? Is that something that you're trying to get at with your new regulatory approach? You sort of hinting that you want to avoid the situation of just deregulating and then losing all control over the variety. Might there be a need to have some follow up monitoring or conditions that you can impose and the turf grass issue sort of raises that, I think, in two areas and you've got a petition before that I can talk about. But it doesn't have to be just about this one petition.

But that is, how do we do things like monitor whether the company is really doing what it said it was going to do in terms of quality control, resistance management, not marketing the product to markets that they state right up front they're not going to market to? You know, what if a year after you deregulate, they're doing all those things that

they said they weren't going to do and you have no authority to enforce, really? Wouldn't it be better to be able to impose conditions consistent with what the applicant has been saying they're going to do?

So in the context of the creeping bent grass, the applicants have clearly said they're only going to market to the golf course industry. And they make a lot of sort of statements about their product, based on the assumption that it will be only sold to the golf course industry. So are their conditions you can impose by way of new regulation that will make that stick, some follow up conditions?

Glyphosate-resistance management, I think, is going to be a challenge for the turf grass issue and do you need regulations to make that stick, as well? I would think so.

And on the biopharm crops, another topic you've raised about, you know, how do we regulate them is, I think, I've raised this in other forums, which is, I think there is a conundrum with biopharm crops. They all have to be grown under permit, they're never going to be deregulated, so people are growing them under permit but they don't have to go through any our middle assessments, because everything is being categorically excluded in the way of field tests.

Yet some people are growing a commercial quantity of the product under this field test regime. ProdiGene, in particular, has been commercializing products under the field test regime. Was that intended, was that result intended by your regulations? I'm not sure.

They could theoretically never sell the corn that they're growing, the product, into other people, so they wouldn't be commercializing the corn, just the product that's grown inside the corn is being commercialized, but it's being commercialized under a field test regime. And don't we need a different sort of approach, something that's sort of equivalent to deregulating the crop without actually deregulating the crop.

Because if we don't have it, then we have this conundrum. IF the field tests are all categorically excluded and there's no deregulation petition, there's never any need for compliance at all. ProdiGene has never had to publicly produce a single NEPA -- you know, you guys have never had to do NEPA on a ProdiGene field test, at least not since 1998.

And so maybe you need to define "commercialization" in that context better, and maybe

you need to impose a presumption that there shouldn't be categorical exclusions for field tests for biopharmaceutical and industrial crops. That should be the presumption. The presumption should be that they get an environmental assessment for all field tests at least, maybe in EIF, but at least an EA. You know, that will get us part of the way along the NEPA road, as would a programmatic EIS get us along the NEPA road for biopharmaceuticals.

And maybe you need to set a threshold where if you're repeatedly growing field tests and you've got 150 acres of field tests out there and you're known to be selling the product for the field test, you're no longer in the field test regime. You're in a different sort of regulatory regime. So these are the sorts of things I hope you're thinking about and I think maybe you are thinking about and would even encourage you to think about.

So those are the two main substantive areas that sort of are in line with what I'm going to address in line with your announcement. But there are a couple of other areas. Your announcement was fairly open ended. It said, well, if there's other issues that come up, raise them, so let me jump in. Some of these are related.

There's confusion, I think, if you try to read APHIS' categorical exclusion regulation in its NEPA regulations. It is very confusing. What is confined, what is environmental release, what is unconfined? And how, you know, the bottom line is that we probably wouldn't be suing you on the biopharm stuff, frankly, I don't know, maybe we would be, but what really dropped this on was the fact that you were able to classify those biopharm field tests as categorically excluded from NEPA compliance. And, you know, this was the same time the National Academy of Science and others were saying, we can't even predict what the environmental effects of biopharm crops would be at all. We just don't have enough experience. Yet they were able to be categorically excluded.

Somehow, under the convoluted language in your categorical exclusion regulation as, you know, confined field releases, it's very confusing. And it needs to be straightened out. You know, most people think of confined as in a greenhouse or, you know, really confined. But you've got this mix of language all through your history of calling it environmental release at the same time you call it confined environmental release. And it just doesn't work, the language is so confused throughout that stuff. So you

could really clear that up and, I think, in the process, help clear up the problem of, you know, not allowing some of the categorical exclusions underneath it.

The other area you talked about transparency. It raises CBI policy. You've got a policy that's from 1985 on biotechnology. In 1985, people weren't thinking about all this stuff we're thinking about now. They were barely even aware of what was going to happen. But your policy is outmoded. You look at EPA's policy with PIPS, the Plant Incorporate -- whatever that is, one of the sillier acronyms of all time.

But their CBI policy is rigorous. You have to, if you want to claim CBI for PIPS field tests under the regulation, you have to state it right upfront. You get one chance to state it and you have to justify it when you claim it. If you don't do that, you waive it.

That is so different from APHIS' policy, which is they seem to be giving a chance repeatedly to claim CBI, they don't have to justify it, at least the justification is not made clear to the public, and the CBI claims are allowed to live on forever, even after the stuff is -- so, you know, four main CBI pitfalls

we've got lined up in our petition, I think. I've stated them before in other contexts.

The four CBI pitfalls are steel claims, stuff that was CBI perhaps at one time, but the company has already released the information publicly, yet your database still says it's CBI. And when we get FOIA or litigation responses back, the thing is still classified as CBI, even though it may have already been publicized. And I think there's a couple of specific cases of that.

Again, the repeated opportunities to claim CBI, giving the companies repeated chances to go back, I don't think that has to be done. You can make them do it once or they waive it. And, you know, maybe you can have a hard, special hard case exemption, where the can claim it a second time if they show that there was something horrible that happened.

And a lack of an emergency exception. I think CBI should allow it to be released. It is in other contexts, at EPA, for example. If there's a chemical release or, you know, a toxic substance release that threatens potentially public health and the environment, the agency is allowed to release that publicly. Your '85 CBI policy does not allow that and so in the ProdiGene case, which maybe it wasn't, you

know, a major threat to public health, but it was very clear right from the start, you were even going to tell people what the compound was. It was a secret.

I asked Cindy once what the compound was. She said, well, go to the ProdiGene website and find out. I said, you know, that's not an adequate answer, really, because these were the guys that were hiding all the stuff in the first place. So the other policy, the fourth pitfall with CBI is the field test location issue. It needs to be clarified, because my understanding is that the field test location was not considered CBI. There is a fairly clear policy that field test location could not be claimed as CBI, up until about 2000 when people got really concerned about this vandalism issue. And there seemed to be a directive, maybe I'm wrong on this. I don't know the whole history, but there seemed to be an internal memo saying that they could claim field test location as CBI because of the vandalism issue.

Well, vandalism may be a real concern, but it's not CBI. Just because you're scared somebody's going to come in and rip up your crops doesn't mean that it's confidential business information. That's a different set of policy concerns and it should be addressed under a different policy. If you're going

to have a policy of vandalism, let's see it. But, you know, don't hide it under CBI.

And we'll debate those policy issues separately. But we don't think that all field test locations should be classified as CBI. And, of course, it frustrates any ability to find out what's really going on. So the bottom line is, we have a hard time seeing the fuel test regime, what's really happening, because we don't know where. We often don't know what and often we don't even know the size of the test.

So two other issues, then I'll turn it over to my colleagues here. It seems to us that you set the stage for doing separate regulations with respect to GE trees and maybe with respect to GE turf grasses. I mean, we went through those workshops, seemed like very useful, probably, workshops on both those topics. In particular, we suggested that the GE trees present such a unique set of circumstances that they should have their own separate regulatory process. I can't spell out to you all those reasons right now, but I think you know them better than I. It takes so long to find out what's going on with trees. They have wild relatives all over the place and the gene flow and pollen flow issues are just very distinct from the

fuel crops, obviously.

So I guess I would encourage you to just lay out some separate regulations for the trees and for the turf grasses, because we've had these workshops, we've heard a lot of expert input. You've got different guidelines that may be appropriate for them compared to the field crops. And so it seems like a reasonable thing to do. And that would allow more public discussion, more opportunity for formal input into whether those. I know with the trees, there's a lot of emerging interest in the trees and it's an emotional issue for a lot of people. So you might be well advised to try to get ahead of that issue and really do something formal and separate, where you get lots of input from lots of expert groups and do something formal on the trees.

So with that, I will turn it over to Joe. Thanks.

MR. MENDELSON: Thank you. Joe Mendelson, I'm the legal director for both the Center for Food Safety and International Center for Technology Assessment. Like Peter, I'd like to thank Cindy and everyone for this meeting. IN fact, I was so excited that I left my sport coat on the back of the door racing out the door this morning.

MS. SMITH: That's okay, we won't hold it against you.

MR. MENDELSON: I think Peter covered a great deal of the topics that I had written down and I'll, in the spirit of openness, be that we're just still formulating our thoughts on this, obviously. And you posed a lot of questions and we've got questions about what your questions mean. And just sitting here, having Peter talk, things are going through my mind.

What I'd like to do is just go through, you mentioned you've got your 11 questions and some of which Peter covered and some that he hasn't. But the first one as far as broadening the roles, I think Peter talked about the noxious weed issues, but he did talk about the biological control issue. And Peter did mention, we did have a petition on insects and it obviously raises, like the trees issues, I mean, certainly insects, that might be a subset of some biological controls, raises probably a need for a separate regulatory regime for those as well.

Given the mobility of the species, given that the Agency is interested in having, or it appears to be having some type of post-commercialization control, I'm not sure how you do that in the realm of

insects. And I think that just needs to be explored and it goes into the alternatives that should be addressed and flushed out further.

Certainly in the field trial sense, you're going to want totally different types of containment mechanisms and things like that. Again, that should be spelled out. And I think some of the things we did present in our petition, it's also not clear and I know you mentioned it in the notice concerning some biological control, which I assume would be like BT and other things that are under other agencies' jurisdictions.

But this distinction between insects that are vectors of animal disease and insects that are vectors of human disease and insects that are both, so that you know, part of our petition was to sort of clarify the authority on those type of organisms. And I think that's one you're going to have to do is figure out what, you know, if you are going to cover biological controls, how do you have someone who's applying for field tests delineate that? How do you, how does the Agency define, you know, what's actually under its control. And frankly, to get into an interagency discussion on how things that are going to be outside of your control, you know, tell the

agencies that they're going to be outside your control and that they better get on board in developing regulations, particularly NIH.

Peter mentioned the noxious weed issues. Number two, talk about specific categories of risk or exemptions for low risk. I think our organization is generally in the position that specifically speaking for plants, each event is an event that requires thorough review, that there's not a tier approach at this point, given the possibility of unintended effects from each particular event.

Certainly that's something we're looking at further. That's one of the reasons Doug is aboard, to help us work through our science on it, but at this point, I think we're reticent to endorse a separate tiered system on the plants. That's not to say that there may be special categories where you, like biopharmaceutical or industrial plants that have different elements, but as far as non-biopharmaceutical, straight, whatever you want to call it, genetically engineered crop at this point, I don't think we support the tiered approach.

Number three, you speak of commercializing with and allowing some type of minor risks. And again, I think we'd be in the position that if it's

identified upfront as some type of minor risk, that it should be, that risk should be fully characterized and assessed prior to commercialization. That's not to say that risk may happen after commercialization that need to be addressed, and I think that's something that I think your notice initially points out and Peter mentioned. I think it's a very positive step that the Agency is trying to at least grapple with ideas how it maintains authority over deregulation. You all are changing deregulation, so that it has some type of authority post-approval. I think that should be the case for every type of approval or deregulation you do, you know, that that is a situation where there may not be risks. And even though you've got the authority, you just don't have to exercise it and that's great. But at least you maintain it over everything in case something unexpected happens.

Let's see. Number four is specific to biopharmaceutical crops. It certainly has been our position that at this time, I don't believe no food crops should be grown, so we used to grow biopharmaceutical or industrial products. And, we view that akin to a split registration, essentially, that led to the Starlink. Starlink was just about registration, obviously, and if we know what the

ProdiGene soybean and corn examples, there's problems in maintaining, even if you set up rigorous guidelines, problems maintaining essentially the sanctity of the food supply.

So I won't repeat, but basically we have a zero tolerance policy in foods, that's our policy now. As Peter mentioned, you know, that's not to say when you put something out, you shouldn't consider different confined methods, greenhouses, underground, and let that be discussed.

Number five, and this is a question I'll put back to you. You speak about the noxious weeds, but you talk about the regulation of non-viable material. And he and I have kind of racked our brains and tried to figure out what exactly you mean by that, I mean, and how would a non-viable material fit within the definition of a noxious weed if it's non-viable. So is there a thinking that we haven't figured out on that or is there something that --

MS. SMITH: I just refer you to, if you look at the definition of noxious weed and get some insight into that.

MR. MENDELSON: This is bad, because I've looked at it. Okay, well, we'll do a little homework, I guess, on that one. But I guess it's safe

to say that when you come out with your next notice or characterization of this, that would be helpful to clarify that, I think, at least even for people who are not, we're close to this, but people may want to comment or might not understand it.

As far as the, you talk about a mechanism where USDA would continue oversight rather than an unconfined release on biopharms. And again, I think it's not, to me, that seems to be the process you have right now, as Peter mentioned, because you do have these field trials under permanent and they're not, you know, unconfined in the sense that they're out commercialized.

So obviously we're taking the position that there shouldn't be any food crops, they always should be, they shouldn't be grown, but if they are grown, they should be confined. But it seems to me that this proposal is seeking out some type of further government involvement or cooperation in the commercial growth of these things, which seems to me creates some type of liability issues to USDA. I mean, it seems to me that there's, in the back of my mind, this piece stems from the need from the commercial producers to want to have some added protection from the government based on how much

regulating. And so that raises concerns for me and I think it should raise concerns for you. I mean, I don't think the Agency wants to be in the position where it's having to create a regulatory regime that's designed essentially to shelter problems that could go wrong when something is commercialized or gets out.

Seven is the issue of adventitious presence. Certainly we would not accept the adventitious presence of any type of crop that has not gone through any type of safety review. You know, I mean, low level occurrence or intermittent occurrence or intermittent presence to us, you know, the issues, it can take, you know, very little something that can go wrong. So, I mean, to say that, you know, .3 percent of one product is somehow low level and won't create a problem, well, .3 of another one could. So, again, our position is that we just don't accept, we don't feel that that's a prudent policy.

Eight, again, talks about the tier process, I think I mentioned that. Nine speaks about, it seems to be contemplating a more narrow research exemption. And we'd have to be, you know, we'd like to see more discussion of that, I think. Certainly, I think, we suggested that if you're creating an exemption, that it shouldn't, it would be limited to non-food entities

and so I think we'd consider a way to insure that research is properly happening and flowing. But I don't think, you know, we want to see an exemption that's created that could cause food based products to be moved without any type of oversight, even if they're only being used for research.

Ten talked about relieving the regulatory requirements on low level risk and we mentioned our tier position. And also, given that we've been in a position of being critical of other regulatory burden at this point, I don't think relieving it is a way we would, you know, relieving the regulatory burden is a way that we would characterize anything. We obviously think that the burden should be greater and hasn't been strong enough.

Eleven, I'm not sure what 11 is talking about. Is it talking about the containers of how you ship these things between states or how you move things? It's not clear to me what the container, you know, what you're trying to get at between having a prescriptive versus performance based container requirement. Again, maybe that's something we need to do more homework, but I would appreciate any direction you can give us on that to help us study through that.

Then as far as other issues, Peter mentioned

some, I think, and he certainly mentioned the issue CBI, which plays into the roles of the states. You know, I know we can't directly comment on an ongoing engagement, but certainly out in Hawaii we've had issues that have come up on how that state entity was monitoring or what its role is or how clear its role was in overseeing field trials or at least being able to discuss matters or release documents to not only us, but also the systems in the state.

So I think as a subset or in conjunction with some of the things Peter mentioned in CBI, like location and what are the claims, you know, I think at this point, it's worth APHIS going back and revamping how and thinking about how it can engage citizens in particular field trial locations and how it can get their comments and their input onto the scope, the method and how field trials were happening in the location. Or certainly at least make the flow of information much more transparent and give the state biotechnology officers more leeway in releasing documents.

Because as we've experienced, it's taken me an awful long time and after the fact to get documentation that folks in Hawaii should have or should be able to get, probably even before the field

trials happen.

Peter mentioned the more immediate need to clarify some of the environmental issues like non-target organisms and that type of review. As you got through this EIS process, I think another issue is how the Agency does its ESA consultations. I know in past discussions, people on staff have alluded to that there is some type of framework that APHIS has, but we've never seen it and I think it would be helpful if it's outlined and made part of the formal regulatory process, or at least in the regulations.

The third is and this goes back to the low level adventitious issues, I don't know if any folks here have seen the recent report by Union of Concerned Scientists, but certainly I would ask you to take a look at it. It outlines a lot of testing that they have done as far as the seed supply of non-genetically engineered seeds. And it's clear that there is a problem with contamination or adventitious presence in the seeds. And while we may debate on the impact of that, it certainly impacts consumers as far as their ability to have a choice as far as non GMO and GMO crops or foods.

So I think there needs to be a further fleshing out of what it means when research is going

on to protect existing non-GMO germ plasm and how the entities that do that, particularly when it's happening in the university systems, how they maintain purity of their germ plasm.

I think that's all I have. Doug?

MR. GURIAN-SHERMAN: Doug Gurian-Sherman. I'm a senior scientist for Center for Food Safety and ICTA and I also want to thank USDA for inviting us. It's very encouraging to have these kind of open forums to discuss issues. And I also want to commend you for your recent changes and additions in staff and changes in your structure. I think you're moving in a strong direction in terms of the science and that's encouraging. I think you've brought on some excellent folks and they'll be a big help to you.

What time are we going to? That would help me in terms of --

MS. SMITH: We should probably try to wrap up within 15 minutes or so at the most.

MR. GURIAN-SHERMAN: All right. I don't really have prepared comments. I'm just going to kind of give a couple of general points that I think need to be considered that are pertinent to or threads that run through the whole FR notice. And for some of you that already heard some of these comments, Robyn and

Susan, I know, for sure, on gene flow issues and confinement issues, I apologize to both of you for having to sit through some of this again. We went over some of these issues recently with EPA.

The issue of containment or confinement comes up in a lot of these issues, you know, adventitious flow, risk assessment in terms of impact on wild relatives. Crops that can become ferile, that are not well domesticate, you know, many of the tree crops and certain others that can escape. So I think it's a threat that runs through this. I want to spend a couple of minutes kind of generally addressing that issue.

The conundrum is, I think, and I think it is a conundrum, that especially at the field trial stage, you don't have all the information you'd like to have in terms of potential risk of the crop. And I think there's either an explicit or tacit assumption, I know certainly with EUPs and EPA and I think based on the kind of regulations you do through notification and even through permitting, that there's an assumption built into this that because of the small scale, limited duration of field trials, that the impact, the assessment does not have to rise quite to the level that you would need for commercial release. And there

is certainly some sense to that.

But I think the caution is especially in these areas where you have crops, again, either that become ferile or not well domesticated or where you have wild relatives, whether they're indigenous or introduced, that you can get, in a sense, an amplification of those genes when they escape. And that pretty much throws a kibosh on the assumptions of limited exposure that are so important in risk assessments.

And I think that needs to be understood in the context of the recent National Academy's report, where I think there are lots of cautions about what the state of confinement and containment is, technically, in terms of human capacity at this point. And the bottom line, of course, was that they have a lot of concerns about good our methods of confinement or containment are.

Certainly, the bigger the field trial, the bigger the scope, the longer the duration, the potential risk increases. But there was, I think, an important quote in that report, that even a single release of a gene that will confer fitness on a wild relative, and I think you could make the same case for non-domesticated crops, if they escape, have the

potential for increasing. And population genetics says that pretty clearly.

Now clearly, if it's a very rare event, you know, there's starcastic influences, you know, random influences, that the escaped gene may just die even if it does confer increased fitness. But there is certainly a finite possibility of increase in frequency of those genes.

So once you have escaped, you know, kind of all bets are off in terms of the assumptions of field trials. So I think in those circumstances, you need to be especially important and I think again NAS report is helpful, not so much in providing solutions, more in terms of cautions or warnings. But they did say a few things that I think really need to be considered in any of these situations where that may be pertinent, which is you need redundancy at all potential vectors of gene flow. So, for instance, if it's a crop that can propagate vegetatively, stolons, rhizomes, whatever, you have to have that covered, as well as pollen flow if it's a non-sterile crop, you know, etc., etc. So you have to have redundancy at all of those levels.

And certainly in certain cases, you have to, even at a field trial level, unless you're going to be

really stringent about it, you have to consider even the possibility of not approving, even at the field trial level, some of these. If you had, I think researchers have done this on their own to some extent, but certainly, you know, one case would be sorghum and johnson's grass.

But the point is that you have to be very careful in those cases. So that's a general caution that I think goes to several of these points that you bring up.

Another that Joe mentioned is the tier approach and certainly, I think, we can say that there are and will be differences in the risk, intrinsic risk in some of these crops. The problem is, I think, that we don't know where to draw those lines at this point. Some of my, you know, scientists, colleagues, Steve Strauss, has been very vocal in this, kind of tried to make a case that with domestication genes, the risk is very low.

But again, as Joe pointed out, we don't have a good sense of where unintended effects fit into this. Again, we have a National Academy's report that may be out soon that may shed some light on this, and I hope it does, how that would impact environmental assessments, because unintended effects in an

environmental assessments have not gotten a tremendous amount of attention.

But even when you're talking about the primary gene of interest, we don't know where to draw the lines yet. So, for instance, non-shattering seed heads have long been discussed as a domesticating trait that reduces the fitness of a crop. And if you included that into a new, genetically engineered crop, there's probably pretty wide agreement that if that got out, it would reduce the fitness of a wild relative.

But there's other traits that are not so clear and some of the scientists, Steve, in particular, has mentioned dwarfing traits. Well, dwarfing traits are very complex. There's different, you know, cascades of genes that are involved in dwarfing. And we certainly know that different eco-types of wild plants that fit in different environments, adapted to different niches -- I've never been clear on what the term is -- have different stature.

So you can look at Alpine eco-types of certain brassicaceous plants and they're very short. You can look at the same eco-types that grow in a valley and you can even look at this with the

Arabidopsis and they're much taller. And that brings up the point that ecological fitness is always a function of the organism and the environment, as well as the gene.

So I think we're just premature in laying, except in maybe some rare cases, in functionally laying out a tiered system. I think, you know, it has merit for several reasons. If it can be done, you know, in a scientifically sound way, which is that, you know, you encourage the developers to build in safety if they can upfront. And one of the incentives of that would be to go through a tiered system where, you know, it wouldn't have to necessarily go to upper tiers. That may encourage them to build in some of those safety measures.

I think there just needs to be a lot of groundwork done from the scientific community to where you can draw those lines. And one of them, I think, clearly could be domesticated versus non-domesticated, while relative to that whole situation. We wouldn't want to see at this point saying that, let's say where there's no wild relative, that you have a diminimus kind of assessment. But there could be differences in the level of assessment. But again, I think it's a concept that needs to be explored further and has some

merit.

I want to just go through just quickly on a couple of the specific issues here. On the first issue, and I'm going to just kind of jump around, do other biological control agents need to be considered? I think there's certainly one category at least that, and I'm sure there's others, that seem to be falling through the cracks, historically falling through the cracks between EPA and you folks, which is nematodes. Somebody has got to pick that up at some point. I mean, there are some nematodes like Steinernema and others that can be important in biological control. They're incredibly important. I think they have the biggest biomass in the soil, nematodes. And it's a real problem to continue to be overlooking those. I think you need to get together with your counterparts at EPA and come to some agreement about who is going to regulate that. Somebody needs to do it.

And especially when you consider some of the insect pathogenic nematodes. People are already working on the genes from the symbiotic bacteria like Photorabdis as PIPs. And so, you know, clearly there's interest in these organisms, whether you're talking about the whole nematode or the symbionts or the proteins from the symbionts. They could be used

in any combination. You could potentially increase the effectiveness or expression of those proteins in the symbionts and still use the nematode as a vector to get a good soil. So I think you really need to start thinking about that.

Going to number three, I think one way that we would look at this is we wouldn't be so much looking at it as a way to allow commercialization with minimal risk. I think the idea, as Joe said, of you all having a handle, post-commercialization is critical. And scientists have said over and over again that you're never going to get a complete risk assessment at a field trial level. EPA has these conditional registrations, of course. I think it would be very helpful if you could have a handle on post-commercialization crops because of the scientific basis of not always being able to have a complete risk assessment at the field trial level.

What I would actually want to see is that you have no evidence of risk at those levels, but then have a handle if risk shows up post-commercialization, rather than trying to find a level of minimal risk, you know, before you commercialize. But the other question would be what kind of handle would you have, of course, on a regulatory basis, what kind of

enforcement actions could you take? And you know, we would, of course, want to see at least your ability, if there was some significant risk demonstrated afterwards of actually revoking that whatever you would be. I mean, I guess you wouldn't call it deregulation, but that would be, we'd want to see some teeth in that approach.

In terms of pharmaceutical crops, I think environmental risks that have to be considered are in the context, again, of the biological use of pharmaceutical crops. You know, they're intended mostly for, you know, obviously for mammalian drug treatment. And so they're going to be hopefully, for the producers, very bioactive in mammals, potentially birds, other, you know, higher vertebrates, especially, so we can expect that. So I think, you know, it cannot be neglected what the impact of that may be.

Not only in terms of food crops should there be extreme caution with pharmaceutical, industrial crops, but again, even if it's not a food crop, if their wild relatives, what would be the impact if you had escape of a pharmaceutical transgene into a crop on herbivores, especially higher vertebrate herbivores? And especially if it did increase the

fitness or the frequency of the gene increased significantly in the population of the wild relative.

And as far as the food safety end, I think from our perspective, the FDA system is, frankly, completely inadequate at this point. It's a voluntary system. You don't get an assessment of the safety. So I'm not even sure how you would build a current food safety assessment into the situation right now, unless you went through the non-GRAS drug assessment process, because FDA does not come out with an approval of the safety, the food safety of the crops under CFSAN's jurisdiction. So I don't think that process we would consider to be adequate to allow you to take that into consideration at this point. If that situation changed at FDA, that may be a different matter. I don't think that's going to happen in the near future, so it may be a moot point for now.

Also, in terms of relieving regulatory burden, I think I've covered this, but I would just want, number ten is again, the emphasis should be on making sure the risk assessment is adequate. And we're not at a point, I don't want to beat this dead horse any further or much further, but with enough work on the part of the regulatory agencies, you might be able to get to that.

I also want to say that I think this might be a good forum to say it, just briefly, is I've been doing some research on USDA field trial trends since 1990 and frankly, I cannot find any evidence, I know USDA has made statements that there is a regulatory burden that may be impacting the number of field trials and applications. Some scientists have said that, as well.

But if you actually look at the trends, both for minor crops, public institution fuel trial numbers, large institution field trial numbers, almost any breakout that you look at from 1990, have gone up exponentially until the late 1990s. And wherever it's not going up exponentially, there doesn't seem to be any correlation with changes in the U.S. regulatory system. And that suggests to me pretty strongly that there is no regulatory burden at this point on field trials that is significantly impacting the number of field trials or who is doing it.

So again, if you look at, you know, academic institutions, they've gone up exponentially in the 90s. There's many fewer of them than for large private institutions. And at some point, I hope to release that data but it's not quite ready at this point. But you can do the analysis yourself and I'm

sure you'll find the same thing.

So I think you have to start relieving regulatory burden, you know. It can be laudable if there's a purpose to it. If there's benefits to the crops, for instance, it is a real public benefit. But if there's not a significant regulatory burden in terms of the actual impact, then it's not clear what the relief needs to be.

And again, at this stage of the development of genetically engineered crops, the emphasis, you know, we think needs to be on making sure they're safe. And I would urge you to look very carefully at the idea that there is a substantial regulatory burden that's actually having an impact.

I was involved in some of the first, the first release of the genetically engineered organism. Maybe some of you remember, called the ice-minus bacteria. I was one of the researchers on that. And we had to go out there in moon suits with huge detectors in areas of fallow ground and etc. It was a burden. I think it was warranted. It drove my PI nuts at the time, Steve Lindow, I was a graduate student. But it was warranted, given the state of our understanding of things.

That's not the case with notifications or

permits anymore. And so I think there needs to be come real care in terms of accepting the argument. And I have to tell you, one of the USDA documents makes that argument. I talked to the people that were the authors of that and they basically were, they had no, by their own admission, support for that contention. It was in the report, but they had said to me in discussions that, as a matter of fact, somebody said it was something that industry contended, which I don't think is necessarily the most reliable source for that kind of information. There was nothing and in that report, I can dig it up and get it to you, there is no documentation of references to regulatory burden in the report. It's just a statement.

Oh, there is just one other issue to briefly touch on in terms of international standards. I think that right now they're in a pretty primitive state. Obviously, there's a lot going on with Cartenga and Codex and etc., etc. But we need to make sure first that the compliance is up to U.S. standards and the regulations are up to U.S. standards before we accept import based on standards in other countries.

So, that's it. Thanks.

MS. SMITH: Go ahead.

MR. JENKINS: Okay, I've got just a few more little notes that Doug spurred my thoughts on and I hate to lose this chance, as long as we've got you all here, to talk about sort of the transparency issue related to the field tests and how they're registered and how they're disclosed and what information you can gather from the data base that's been publicly available, the Virginia Tech data base. Which is a very helpful data base in some ways and very, very frustrating in others. I think we've stressed that to you in other contexts, but some comments or thoughts on that.

I think the policy is now pretty clear that you can't renew the same field test for several years, at least my gathering is that that's now changed, but I think that needs to be spelled out more clearly, just so we understand what's going on with the field test. You know, that one permit number does not go on for years and years under renewals that aren't clear from the data base. We hope that, you know, in the future, when we look for field test records, we can see, you know, what year it's good for. And the other big problem, I think, with the data base entries and the field tests is in some, they're up to 14 different compounds or even more in some cases, I think, being

tested under the same field test permit. Several claimed, often the notification, but several claimed as CBI and unclear entries about what relates to what. And it's just not a very helpful situation when you've got a lot of stuff being tested under the same permit number.

And one other comment on the field test is this relates to one specific field test, which is the one going on in Oregon with Scotts and Monsanto growing the creeping bentgrass. Something like a 400 acre field test and from what we can gather, really are wrapping up the commercial production. Isn't that a different threshold? Should that be allowed to happen under the "field" test regime? I mean, you've got other field tests where they're basically testing one line and one small row of one compound and maybe 25 plants. And that's being treated, you know, maybe very appropriately, as a categorical exclusion. The only thing is we've got a 400 acre field test in Oregon of something that is clearly being grown in commercial quantities and is treated exactly the same under the same regulatory regime, same NEPA compliance.

So, you know, I think maybe you need a threshold of how big a field test can be and whether

it can really be part of a commercial production system. Other comments? Joe?

MR. MENDELSON: No.

MR. JENKINS: Did you not want to answer questions from us about some of these specific things?

MS. SMITH: On the advice of our lawyers, we're not going to be able to.

MR. JENKINS: Okay, we will submit further comments. Thanks again for the opportunity.

MS. SMITH: Well, this has been extraordinarily important that you guys came with a lot of good information. This really has been a very informative session, so we really appreciate your time and willingness to come and share your information with us. And we look forward to seeing your comments. It sounds like your comments are going to be really quite informative and very useful.

MR. MENDELSON: Can I ask, what is the process that goes forward from here? Do you have a time line on where you're going with this, at this point? I mean, you didn't have when we did our briefing over the phone, but --

MS. SMITH: It's hard to know exactly. We're eager to move forward. Our intention is to try to complete our EIS this year. At the same time while

EIS is a priority, we're going to bring a lot of resources to bear to get it done, we're not going to rush it so much that we compromise the integrity of the document. So it's a priority, we're going to go as quickly as we can, but it's hard to say right now, particularly until we get all the comments and get a good sense of the range of things that we need to address in the EIS.

MR. MENDELSON: You're going to wait to complete the proposal that the EIS or the proposal --

MS. SMITH: The intention is to have the draft EIS, the EIS process inform the rulemaking process. And so our intention is to issue the EIS before the proposed rule.

MR. MENDELSON: Okay. Thanks.

MS. SMITH: Well, thanks a lot for coming in. We really appreciate your comments.

MR. GURIAN-SHERMAN: Thanks a lot.

(Whereupon, at 10:44 a.m., the meeting was adjourned.)

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REPORTER'S CERTIFICATE

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I hereby certify that the proceedings and evidence are contained fully and accurately on the tapes and notes reported by me at the hearing in the above case before the United States Department of Agriculture.

Date: February 26, 2004

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