# TRANSCRIPT OF PROCEEDINGS

IN THE MATTER OF: )
)
STAKEHOLDERS MEETING )
COALITION FOR THE ADVANCEMENT )
OF BIOTECHNOLOGY BASED )
PERENNIAL AND SPECIALTY PLANTS)
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1220 L Street, N.W., Suite 600
Washington, D.C. 20005-4018
(202) 628-4888
hrc@concentric.net

IN THE UNITED STATES DEPARTMENT OF AGRICULTURE

IN THE MATTER OF: )
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STAKEHOLDERS MEETING )
COALITION FOR THE ADVANCEMENT )
OF BIOTECHNOLOGY BASED )
PERENNIAL AND SPECIALTY PLANTS)
)
)

Training Room 1
4700 River Road
Riverdale, Maryland

Thursday,
February 26, 2004

The parties met, pursuant to the notice, at 11:16 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

APPEARANCES (CONT.):

For the Coalition for the Advancement
of Biotechnology Based Perennial
and Specialty Planter :

SHARIE FITZPATRICK, Forage Genetics International

Director of Regulatory Affairs and Quality
Assurance for Biotech Traits

DAWN W. PARK, Arbor Gen
Manager, Public and Governmental Affairs

TERRY STONE, Scotts Company
Director, Biotechnology Regulatory Affairs

Participants:

LEVIS HANDLEY
CRAIG ROSELAND
MICHAEL BLANCHETTE

P R O C E E D I N G S

(11:16 a.m.)

MS. FITZPATRICK: Good morning, everyone. We represent the Coalition for the Advancement of Biotechnology Based Perennial and Specialty Based Plants. This morning before you, I'm Sharie Fitzpatrick. I'm with Forage Genetics. This is Terry Stone with the Scotts Company and Dawn Parks with ArborGen.

We'd like to discuss with you this morning the Part 340 regulations and some of our questions, particularly, that we have in formulating a response.

MS. SMITH: Before you get started, we have some background information.

MS. FITZPATRICK: That would be helpful.

MR. STONE: Oh, that's great.

MS. SMITH: Some general information we can give you before you start with your comments, if that's okay. First, of course, we want to welcome you to the Stakeholder Discussion Series on our upcoming EIS and our revisions to our plant biotech regulations. We really thank you for taking time from your busy schedules to join us here today and spend some time with us.

We're looking forward to hearing your input.

We have two purposes for these briefings. The first is to share information about our plans to move forward with the Environmental Impact Statement and EIS, as well as to amend our plant biotechnology regulations. And the second is to gather diverse and informative input, which will support effective decision making on our part in the development of our revised regulations.

We have here from BRS most of our management team, as well as a number of staff. And what available other key agency personnel who are involved in supporting BRS in this effort will be attending meetings, as well.

I also want to mention two key individuals who have now been dedicated to this effort full time. The first is John Turner, whom you likely know, a very important member of our leadership team here in BRS. John will be providing full time leadership to our effort to complete an EIS as well as our new plant biotech regulations.

And a second individual, who may be a new face with whom you are not familiar yet, is Dr. Michael Wach, a recent BRS hire, as an environmental protection specialist within our environmental and ecological analysis unit. In addition to possessing a

Ph.D. and an Environmental Law 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.

At this point, I'm going to turn it over to John Turner and have him share some additional information with you as well, and then we can open it up for your comments and discussion.

MR. TURNER: As you probably know, we've been in interagency discussions with our sister agencies, EPA, FDA and with the White House. And while we concluded that the coordinated framework as it stands has provided a great and appropriate science and risk-based system, we also concluded that the Plant Protection Act of 2000 provides us an opportunity to revise our regulations and potentially expand our authority while leveraging the experience that we've gained through our history of regulation. It is my position as well for future advancements into technology.

And so with those discussions, we have some general direction as to how the regulatory approach is likely to evolve, but still, it's early in the process so there's yet plenty of opportunity for public and

stakeholder input as we look forward with the specifics.

Given this, what we want to do at these meetings is provide an opportunity to hear your thoughts and to have some informal given and take of ideas. And we have a unique opportunity for this discussion, because we're not yet in the formal rulemaking phase of the process. So feel free to speak freely and we'll have an open exchange of ideas.

Our discussion will be transcribed primarily for two reasons. First, we want an accurate record of our discussions that will facilitate our ability to capture and refer to your input later. And secondly, in the interest of transparency and fairness to all stakeholders, we will be making this available as part of the public record, potentially maybe even on our website, so that documentation on all of our stakeholder discussions will be available to everyone, so that they can benefit from the discussions with the other stakeholders. the stakeholders.

I should emphasize that while we're happy to share information on the direction we are likely taking during the process, what we'll be sharing is our current ideas. And this is going to evolve and change over time. We'll have input from the

stakeholders, but also from sources within USDA, including our Administrator, our Undersecretary and, of course, our Office of General Counsel and the Secretary.

So while we value all input, it's important for you to know that our thinking will evolve over time. Finally, since it's hard to predict what the final regulations will look like, one thing that we do know is we can share with you basic priority areas of emphasis. And these will guide us through the system. The first is 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. This is critical to public confidence.

The third is to have a science based system. We want to ensure that the best science is used to support regulatory decision making, to assure safety.

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

And finally, international leadership. We need to ensure that the international biotechnology standards are science based, We want to support

international regulatory capacity building and consider the international implications of policy and regulatory decisions.

As we prepare to begin our discussions, I would let everyone know that for effective transcription of our sessions, that all statements and questions need to be directed into a microphone. You're all fine, this was more appropriate when we had people at tables that didn't have a microphone. But direct those into a microphone and the first time you speak, if you could give your name for the transcriber and then after that, that will be fine.

So with that, then, I think we're ready to start and kick it back over to your side of the table.

MS. FITZPATRICK: Thank you. We have a prepared statement that we'd like to kind of work back and forth a little bit here to guide our discussions. We are here on behalf of the Coalition for the Advancement of Biotechnology Based Perennial and Specialty Plants. The Coalition is a group of six companies whose biotech efforts are focused on developing perennial or specialty plants, that is, small market, agricultural crops or plants used for specialty applications.

The Coalition's goals include assisting

regulators, policy makers or other interested parties in establishing appropriate science based policy, regulatory guidelines and data requirements for biotechnology derived perennial and specialty plants. Our comments address several aspects of APHIS' regulations under 7 C.F.R. Part 340 as they currently exist and as they may be modified under the alternatives described in the Federal Register notice, as well as the possible environmental impacts of such potential changes to the regulations.

We would first note the appropriateness of the effort that USDA has undertaken and state our position that statutory authority given to the USDA under the Plant Protection Act provides a strong, sound statutory basis for continuing the regulatory program of the Part 340 regulations and for carrying out appropriate science-based risk assessments under those regulations.

The Coalition, like many industry groups and other observers, believes that the existing Part 340 regulations and APHIS' implementation of those regulations have provided the basis for the prudent, safe development of the agricultural biotechnology industry in the United States. The regulations have allowed the development and testing of improved crops

and other plants to go forward under a system that provided for a science-based assessment of the potential environmental and plant pest risks. This process helped to assure the public that appropriate federal and state oversight was in place. APHIS should be commended for its stewardship of the program and for its continued willingness to examine the scientific basis for these regulations in response to changing circumstances over the years.

In the nearly two decades since the establishment of the coordinated framework in APHIS' oversight of biotechnology derived plants was first outlined, the Agency has overseen tens of thousands of field releases and deregulated about 60 biotechnology derived plant varieties, representing 13 plant species. Throughout this period, there has not been a single validated instance of harm to the environment, agriculture or non-target organisms arising from the use of plants regulated under Part 340. Furthermore, new weeds have not developed as a result of outcrossing from a biotechnology derived plant to either other plants of the same species or related species with which it can interbreed.

This last point is important to stress. While it is true that there are potential

environmental impacts that are important for a regulatory scheme to assess, it is also true that the hypothetical concerns and disaster scenarios voiced by some observers for the past 20 years have failed to materialize. Biotechnology regulation and public policy must continue to be driven by sound science and the enormous accumulated track record derived from real world uses, rather than from hypothetical fears that experience and science have shown to be exceedingly unlikely.

Furthermore, USDA's environmental impact statement must take into account environmental factors other than risks. Many of the products of plant biotechnology have proven and will continue to prove to be beneficial to the environment and to the general public. These benefits have been realized through significant reductions in the use of agricultural chemicals, an increased opportunity to use more environmentally benign pesticides and improvements to the food supply and, more recently, greener methods of industrial production and the clean up of contaminated soil and water.

As we go forward, products in development at our universities, at the USDA's Agricultural Research Service and private industry will reinforce these

benefits. The current applications of biotechnology will be extended to plants of minor or specialty use and advances in trade development will result in healthier food and plants with greater adaptation to the environment through salt, cold and drought resistance, to name a few.

USDA should also consider the negative environmental impacts that might occur if overly strict regulations were to prevent or slow the development of environmentally beneficial biotechnology products. The Coalition would like to stress the following points regarding the questions APHIS is seeking comment on during the EIS scoping process and review regulations pertaining to biotechnology.

The first point is the authority currently provided under the PPA gives APHIS flexibility to anticipate and keep pace with the evolving array of biotech applications that scientists are discovering and companies are developing for a diversity of annual and perennial plant species.

The second point, APHIS should continue to base their assessment of environmental risk on sound science. Risk assessments should be performed on a case by case basis for a particular trait and a

particular plant of interest. This approach is essential for new traits under new development intended for an application in perennial plant species.

MR. STONE: Excuse me, Terry Stone. The questions we have, we're going to go through these points and we're going to break it up a little bit with questions, so that we're able to keep a dialogue going. But for the first question, we were having a little bit of difficulty understanding completely how environment is actually defined in the documents, so we were hoping that you could provide us with, in your perspective, how are you defining environment? What was in your minds when you were drafting the document?

MS. SMITH: Actually, as I understand it, and part of this drafting came from our environment staff at the Agency uses these in writing and I know as we asked the director of that unit how he was defining environment when we first heard talking about it, all of the kinds of things we could put in this notice, he referred to environment as the full environment, which would include, also, human health issues. So it's not the physical world around us, but it's the full environment, is how it was used.

MR. STONE: Okay, so then having said that,

it kind of leads into what our second question was, then. So the human environment is a part of that, it's not defined differently. Really, you're looking at this very holistically.

MS. SMITH: That's correct.

MR. STONE: Okay, fair enough. Okay. Sharie, do you want to go on?

MS. FITZPATRICK: Point number three, the U.S. and Canadian Bilateral Agreements on Molecular Environmental Characterization data encompass the essential biological and molecular characteristics needed to assess their potential impact on human health or the environment. These same characteristics should continue to form the basis for risk assessments of new plant species and great combinations that take into consideration the unique aspects of these combinations.

USDA APHIS BRS guidance documents for corn and cotton are excellent examples of how data requirements can be flexibly applied on the species and trait. We encourage BRS to encourage similar guidance documents for perennial species using the information received during USDA sponsored workshops held to identify appropriate data requirements.

MS. PARKS: One of the questions that we had

here was we do really believe in the development of guidance documents, especially around as they come from the input that you get from the workshops. We're wondering if there are other mechanisms to be able to provide data as guidance developments, as guidance documents are developed, assuming that guidance documents are going to be developed for each of the new products?

MR. STONE: Yes, similar to the OECD documents or even the Canadian documents where there's input taken from all stakeholder groups, so that there's an opportunity to provide, you know, that kind of an input. First of all, are you considering the development of additional guidance documents? And secondly, in doing so, are you looking at input from all stakeholder groups? We assume that you would.

MS. SMITH: We're certainly open to considering how to approach that and this is a good time for us to kind of hear your specific suggestions on what kind of additional documents. We have talked about developing additional documents, but this is a good time to hear specifically what kind should be priorities for us.

MR. STONE: Well, for companies that are developing new species, I mean, and I think as time

goes on, there's going to be more and more new plant species that are going to be transformed, seeking deregulation.

The flexibility is fantastic, but having a framework is really very valuable. From a perennial standpoint simple things such as the number of years for field trials, number of locations in adapted, non-adapted or transition zones, things like that, are really fundamental, because the biology is going to be, a lot of the biological characteristics that have been evaluated are going to be very consistent. But the actual implementation of getting that data requires that kind of guidance.

So being able to do that as you go forward and when you're thinking about developing the regs, I wouldn't necessarily see it as codifying regulations. You really wouldn't be able to do that, but it would be nice if there was a vehicle that would allow you to continue to develop these guidance documents.

And the workshops have been really nice to be able to, that a lot of the concerns having something come out of those would really be helpful. Then once those documents are drafted, hopefully by APHIS, that you're given the, stakeholders are given the opportunity to provide that input, again similar

to what's done in OECD.

MS. FITZPATRICK: Point number four, if a tiered risk system is to become part of the new regulations, individual products should be assigned a particular level of risk on a case by case basis, using sound scientific evaluation. It is essential that regulations be based on the risk assessment of a particular trait and a particular species.

One question we might have to go a little bit further was, we were wondering if you would please describe for us a hypothetical tiered system that you might be thinking about at this point in time.

MS. SMITH: John, do you want to do that?

MR. TURNER: Yes, in a sense we have a tiered system today. I don't know if you consider it case by case, but they're very specific eligibility criteria that somebody must meet in order to be field tested for notification.

Having at least some of it written down as to what puts it in that tier helps with transparency and is the type of tangible things that we could explore in an EIS. So we were actually looking to build on that and then within permits, we have different levels. We have pharmaceutical permits and other types of permits. So one f the things that

we're doing is we would get rid of the notification classification, but things similar to notification might fall under the low risk tier of the tiered permitting system.

So you might expect similar types of eligibility criteria there. Inasmuch as we need to address AP and there are some human health components, we might additionally add a food safety component in the same way that many have talked about it in the AP proposals. So said things are allowed to be field tested in this way, would need a food safety review at some point.

We have special use categories such as pharmaceutical industrials. They might at least start out in a high risk tier. So those are some examples. They can have a tolerance or not have a tolerance, where really the question, what should these criteria be for the tiers. But those are some ideas that have been kicked around at this point.

MR. STONE: John, let me ask you then, because you said from a PMP standpoint, that in the beginning, they would be a high risk category. Are you looking then, and maybe that will change. Are you looking then at the safety of a particular trait itself or the protein that's being produced and as

more information is known about that protein, maybe it's an antibody. It really has no human health effects necessarily. Would that be part of that assessment, that we move it to a lower degree?

MR. TURNER: As field testing goes on, we are certainly thinking that we would need to start asking more and more questions and find out more data about the proteins themselves.

MR. STONE: So they're actually based on risk or safety rather than category, PMP versus -- okay.

MR. TURNER: The idea that we're thinking about is that it might be able to move from one category to another as the situation comes up.

MR. STONE: Okay, one other question then related to, you know, different categories. For perennials, I mean, we're at the same product and you're smiling, because you probably know where I'm going. I mean, we'll have the same trial for numerous years. And the way it's done now is you have to continue to get a new notification each year.

I've got tot ell you, it's a pain in the neck because we get new notification numbers each year and then from a compliance standpoint and from a record keeping standpoint, it's difficult to keep

track of. You guys are doing a great job from an inspection standpoint, but I think for everybody's sake, it would be wonderful if that could be simplified, where maybe an acknowledgement or a notification back to the Agency each year saying, nothing is changing. We're doing the same trial or maybe we're using the same construct but we've added a couple other lines or events. But it's going to be at the same place, performance standards are going to be the same, nothing is changing, can we just get a sign off for renewal so that that number stays the same. That's where we're at, you guys.

MR. HOFFMAN: I was just wondering how keeping the number the same is beneficial to you?

MR. STONE: Oh, my gosh, I'll tell you, it's really important. Because what happens is, from a compliance standpoint, when you have a number of different cooperators, you're sending out compliance packages to each one of them. And they're all told, you do not plant until you have acknowledgement.

Well, the notification number goes to them and then they're waiting to hear from us. You tell them that it's been acknowledged and everything after that, the file, the data that's collected, all the monitoring forms, is all based on that notification

number, okay, for us. Each company does it differently to some extent. And then the next year, we get a new notification number. Well, it's not a different file, it's a new notification. From a record keeping standpoint, it sounds simple, but if the numbers can stay the same, then you're using the same file from one year to the next and everything is staying together.

What happens if you have new people coming in, into that mid-stream, say you're at a university and they have a technician that's taking the monitoring data. One year he's there and the next year, you know, they have somebody else come in, they may have a tendency to start another file. And it gets very confusing in trying to get information back.

I mean, you can imagine if you're a stockbroker and you've got a client and you're dealing with, you know, their transactions and then she gets married and changes her name. And then where does that information go and how does that continue to move on?

So in some respects, it's similar to that. And for our company or as a coalition, I think, this has been something that we've been concerned about and certainly we'd love to see changed. Sharie, did you

want to say something?

MS. FITZPATRICK: We would do things a little bit differently, where we use the new notification number. However, then, when inspected, you need to say, well, yes, our planting date is before the effective date of that --

MR. STONE: Right, right.

MS. FITZPATRICK: So we're effective, say, February 1, but it was up 2004, but it was in the ground. So actually, our trial predates the effective period.

And you say, but we established it under a previous notification. It's just a matter of you have to just connect all the dots. And if things change in your number of locations per year, it's a web. And it is not straightforward and even though we're working under -- I mean, we are being compliant. There are aspects of that that could be misinterpreted or it's just more difficult to show your full compliance in a very clear way. And so adding clarification, one way to add clarification and transparency would be able to keep the same. Even if we had to renew every year, if we could still have a permit of record that you guys would always reference and we're always looking at the same file, not three or four or five.

One of the other challenges comes when we need to apply for new permits before the other one expires. That works real well most of the time, but if it's been in process for six weeks, seven weeks, two months, we haven't heard back, there's been instances where a day before it expires, you take the plot of it and you tear it out, just to be sure that you're not out of compliance. And that's not useful.

So we want to avoid those situations as much as possible. One other point I might just bring forward for consideration for multiyear and for, I think of it when you do your taxes, the paperwork reduction sort of idea. If there were, very often I believe, and I could be wrong on this, that biotechnology laboratories are inspected and then they can work with organisms within that confined or defined area. And they have a permit or a license. I'm not sure if licensure is the right term, but having a site permit to work as opposed to individual permits for individual trials, I think that especially if you're working with, and again, we can predefine that and do a notification and, you know, define and stay within our limits on genes released or, you know, the elements that go into that. But given a certain list, laundry list of what we're working with, then be

available to work with that on site as needed in following -- as long as the performance standards are homogenous across that set. So in other words, you weren't mixing permits and notifications through that example. So you'd have a site permit and I think that would be very useful for primary research stations. It may not work for all instances, but I think it might reduce your paperwork, would reduce numbers in the system and still aid the compliance. Thank you.

A little further on point four, the Coalition believes that some product types represent a low risk to the environment and some product types may be perceived to have additional risk associated with them, due to the degree of scientific experience by APHIS with the product, trade or species.

As APHIS updates its regulations, it should not be a move towards broadly defining or categorizing the risk associated with new traits, species or products. Rather, APHIS should continue to address risk on a trait by species basis, incorporating information available from the scientific community at large for products that have not previously been through the regulatory process.

It is through this process that APHIS can identify the risk posed by a specific product, trait

or species and whether it should be considered of low risk or in need of additional considerations.

MR. STONE: Well, actually, I think the comments you provided us, John, which you are thinking or which you all are thinking about the way it's going to be structured, I think that covers where we are at, actually. Glad to hear there's that kind of flexibility involved. I think that makes an awful lot of sense.

MS. FITZPATRICK: I have one question. With regard to the tiered system for field release, would that at all impact, can you give us some guidance on how you might feel that would influence time for deregulation or review of a submission?

MR. TURNER: You're to a level of detail, certainly, that's not resolved. I don't think the tieing directly impacts the deregulation decision in terms of length of time.

MS. FITZPATRICK: Okay, there was a note, something regarding expedited review at another point and I was wondering if that would at all apply to, if you could foresee that things of low risk may get something like an expedited review?

MR. TURNER: It's something that's under consideration and we would love to hear your comments

on what the types of things would be appropriate for that.

MS. FITZPATRICK: Point number five --

MR. STONE: We'll come back to that.

MS. FITZPATRICK: Okay. In the past ten years, APHIS has deregulated more than 60 plants under the Part 340 regulations without the need for additional conditions to address minor unresolved risks. Among these are plants with a wide diversity of traits, including those conferring disease and insect resistance, herbicide tolerance, male sterility and quality enhancements.

Both annual and perennial plants were evaluated, including several having the ability to outcross to related species. Many of these plants provide substantial environmental benefits are being sold today if there has not been a single confirmed case of these plants posing a risk or becoming a weed. Given this track record, it will be the rare case that would require additional conditions to address unresolved risks for the product to be commercialized.

APHIS should continue to review each product on a case by case basis and base their decisions on sound science. We support APHIS having the ability to impose restrictions that will permit commercialization

to occur while insuring the safety of the environment, agriculture, humans and other non-target organisms. This is consistent with APHIS' ability to approve products of biotechnology in whole or in part, under 7 C.F.R., Part 340.6(d)(3)(i) and to reach a finding of no significant impact through the risk assessment by identifying alternate measures under 7 C.F.R. Part 372.5(c) to address potentially unresolved risks.

MR. STONE: One of the questions we've got is almost fundamental, really. IT's that when you look at the risk equation that's hazard time exposure, so exposure, if you, just to use as an example, pollen flow. You can calculate the frequency that pollen might flow different distances, so you have an idea what the frequency is. But the hazard is a differing question and to really understand what minor unresolved risks are, it's really valuable to understand what the real hazard is, what the hazard is that's being, you know, evaluated.

So we were hoping that you might be able to give us some insight on how you view both the hazard, how you would define hazard and obviously that's pretty broad, but also how you would use that to also then determine what is a minor, unresolved risk. Because when you do get to that point of evaluating a

product, you've done a risk assessment. And a lot of these issues should have been or should be very close to being resolved.

So if there still are some that are not, it would be really helpful to understand that thought process and to arrive at that point.

MS. SMITH: I want to start by making two quick points and then I'll let John answer. First, what I would say is we agree with you, it would be the rare case where we would need to exercise this kind of flexibility, where we'd want to be able to potentially consider it approving something with conditions.

MR. STONE: Cindy, could you speak up a little bit more, please?

MS. SMITH: We agree with you that we think it would be the rare case that the majority of what will come through the system would come through the system and achieve, as is the current case, full deregulation or approval without condition, assuming all the safety requirements are met.

So what we're really intending to do with this provision is to look at building additional flexibility into the system for those rare cases, and these may be cases that we're not aware of what they are yet. One of the things we're trying to do is

we're aware that part of why we're evolving the regulations now is because we want to make sure that we're positioned for the new technologies that we're aware are in their infancy stages. And given that, we are trying to be mindful that this system needs to be as flexible as we can. We want to build that flexibility in to address things that -- some things we may be thinking about, but some things we may not even be aware of yet. So I just wanted to make that point, this is really about building in enough flexibility to really keep the system strong in the future.

John can probably speak a little bit more specifically to it.

MR. TURNER: That's a great segue and I can't really be too much more specific, because it is based on this concept that the regs are going to be forward looking. We see now issues with PMPs and industrials that we weren't thinking much about in the late 1980s. And so this will allow us some flexibility for different types of things. Certainly don't have a class defined at this point --

MR. STONE: Yes.

MR. TURNER: -- and hazard is definitely case by case.

MR. STONE: Right.

MR. TURNER: There's no specific hazard in mind that would kick this end. But it's something really depending on how you look at it, you can think, wow, there's going to be an extra regulatory burden, or alternatively, to let something go forward into commercialization that wouldn't be if you didn't have this mechanism. That's our thinking, just to allow flexibility and to amplify what Cindy said, in rare cases.

MR. STONE: Yes.

MR. TURNER: Certainly this is probably not going to be the norm.

MR. STONE: That's helpful. So I would guess, then, from the teleconference that you had a few weeks ago prior to the release or the day of the release, listening to what you're saying, it seems that products that are either in the process or have gone through the process probably would be characteristic of those things that would be more likely to continue to be deregulated without these kinds of conditions potentially.

Whereas other traits that may or may not be understood at this point are probably different than the kinds of input traits, are probably looking, have

the potential to be -- it gives that flexibility for you to allow those products to get to the market with perhaps some condition.

MR. TURNER: Certainly we're not thinking about second looks at that.

MR. STONE: Yes, I would hope not. Let me ask you something, because from a perennial standpoint, this is a pretty important issue for us. If you do go down that road, it makes sense, I can understand why you would and actually I think it's great that you're looking at ways to be flexible, because technology is going to continue to change and there are going to be a lot of different traits, will that kind of -- I'm just going to use the word approval, okay -- will that kind of approval mean that -- and I'm thinking about it from a perennial standpoint, so where people are making an investment over five, ten years or more, they'll be much less likely to do that if there's a belief that that approval, whatever that is called, is taken away because of a particular issue, versus allowed to, well, based on this, you know, will continue to gather information or use another mechanism to be able to restrict the use but not necessarily say that that product can't remain on the market. Do you see where

I'm going with this?

I know you can't envision it all, but there's a certain amount of, certain concerns that hopefully you'll consider when you're going through this, that those are, it's different than an annual. Perennials have a much greater economic commitment that's being made when the decision is before they go.

MS. SMITH: That's a good comment and we'll certainly factor that in. I would say that if there is some low, unresolved risk that we were to make a decision, if we move in this direction of having this kind of flexibility and we issue, say, an approval of the conditions, let's say, for the sake of argument, and it was something that we wanted to gather information on, we certainly would do a legitimate evaluation of the information gathered through that period and come to a conclusion in terms of what we learned as a result of that information that we might have looked at.

And whether that would be addressed, you know, let's say if something were to show that was more of a risk than we had anticipated, then we would certainly have to decide at that point whether one option was to change the approval.

MR. STONE: Right.

MS. SMITH: But, you know, what I would say is that's really not entirely different than the situation we have today.

MR. STONE: That's right.

MS. SMITH: We have the ability today that if there is some unanticipated effect, to revisit our regulatory decision and bring something back in. So we would look at what the results were with that, you know, what we learned in that time period and consider our options at that point.

MR. STONE: Sure, because right now if there's an adverse risk of some kind, you're required to look at that anyway so you could take it off the market. So we're appreciative of that.

It seems that you probably would not go forward with actually deregulating a product if there was an unresolved risk that were to be realized. It would probably be something that you would have to pull off. I guess that's where it's at, okay. Thanks, that's helpful.

MS. SMITH: That's correct.

MS. FITZPATRICK: And one bit more of clarification. When you talk about the potential for conditionals, would you see that as something that would have a sunset or a point in time that the

conditions would exist for a certain period of time?

MS. SMITH: I believe that would be the case.

MS. PARKS: I have an additional question that's kind of a clarifying question. Terry, you used the term unfamiliar when you were talking about minor unresolved risks. And John used the term products in their infancy. There are a lot of products in their infancy, but by the time they come forward, I would guess probably aren't unfamiliar any longer. I'm just trying to get a distinction between something in their infancy. Is that related to your definition of being unfamiliar at this point?

MR. TURNER: Familiarity, and we talked a bit about it the other day, there's familiarity with the trait in that species, but in a general sense, it's having enough information to do a risk assessment, enough knowledge about the host plant, enough knowledge about the trait and the receiving environment and how they might interact.

MS. PARKS: Okay, thanks.

MR. TURNER: Not necessarily the same, I think, as infancy.

MS. PARKS: Okay, yes, because infancy was a term that had been used as what might characterize

something in the tieing system. So I just wanted to make sure that with enough information, it doesn't matter if it's new technology, it's the amount of information that's available.

MR. STONE: Just out of curiosity, if you were going to approve a product or deregulate it or say there was a condition placed on it and it required, I'm thinking like the EPA with insect resistance management and the need for monitoring it or the need for a refuge being placed or something like that. If that happened, how would you enforce something like that? Would that enforcement be placed back on the developer of the technology or the distributor who delivered it or the people who are actually the farmers or whatever?

MS. SMITH: That's exactly the kind of question that we're looking for comments on so that we can evaluate what the options would be in that case and come to some conclusion. At this point, we're really open.

Another thing that's also worth noting is that as we are considering this option of maybe approving something with the condition to gather a certain amount of data over a certain number of years to see if it really can be moved to a full approval,

that gathering of information is something that, in terms of the sources of where that information can come from could be, you know, we're looking at lots of options. So it might be a requirement to the company, it might be that we're going to establish some kind of a grant or work with another agency to do research or professional scientific society to do some research to gather some information.

So a lot of this really, at this point, is really open. And even when we come to our conclusions, we really want to build as much flexibility in terms of how we proceed as we can.

MR. STONE: Right. Maybe this is a segue into it, because we continually are talking about flexibility. You guys know this better than us, it's taken a lot of time to get products through the system and realize fully that there's a lot of issues that you've been dealing with between lawsuits and changes in regulations and compliance investigations and all of that.

But is it possible that, and we would like you to consider that, that if you're looking at a product that, especially if it's vegetatively propagated and you need to each time, just like potatoes was, you need each time to retransform

another variety for, you know, same, it's going to be planted in the same area necessarily, same trait, same construct oftentimes, is it possible to get to a point where you're essentially -- given that there's bridging data, molecular data there to demonstrate, you know, what's been inserted in the biology data can bridge easily to the existing or the original line that was approved, the antecedent.

Can you get to a point where this is really more of an acknowledgement, where you can provide that data provided to you and within 60 or 90 days, similar to a permit, frankly, that you can review that data and say this is consistent with the antecedent? There's no unresolved risk at that point, because you really dealt with that with the antecedent organism. It allows that to go forward.

I can tell you for specialty companies that are dealing with that kind of an issue, that would be incredibly helpful. It doesn't take away any responsibility, of course, to EPA or to FDA or even internationally, because you'd still be developing the same data set. But the important thing is actually being able, especially for a smaller company, being able to get through with USDA, which is really going to be the agency on those for something that adds just

so much.

MR. TURNER: I would encourage you to lay out that argument as a response to a number of -- expedited review.

MR. STONE: Good, okay.

MR. WACH: Would these be articles that would not qualify for notification?

MR. STONE: I'm sorry, could you repeat that?

MR. WACH: Would these be article that would not qualify for notification, the ones, the particular --

MR. STONE: Right.

MR. WACH: When you say 90 days, that's longer than we'd take to review a notification. So you're talking about articles that would require an annual permit, is that what you're --

MR. STONE: In the case I'm talking about, it actually would be whether it's an annual or a perennial. As long as an antecedent was already approved. Let's use potatoes again. If you have a BT potato variety that's been approved and it has --

MR. WACH: Approved meaning deregulated?

MS. SMITH: Deregulated.

MR. STONE: Yeah, I'm sorry, deregulated.

I'm not talking about registration at EPA, I'm talking about it's deregulated by USDA. The promoter, the gene of interest and the terminator and perhaps even, you know, the selectable marker, were identical. And then you had another one and you deregulated that and then you had another one that was coming through. It wouldn't matter in my mind if it was annual or perennial or whatever, because the original risk assessment would have been done on that antecedent. The assumption would be if you can bridge to that original data base, either by the gene of interest, in particular, with that second article, that as long as you can bridge to the original data set, that it would be more a matter of reviewing that that second line is no different than the first line.

You would do the same data set, you'd do the same studies, more than likely. That's where the guidance documents offer so much value, but then the review process would be really short. Because it would be more of an acknowledgement that, and what APHIS would essentially be saying is this line is no different from the antecedent, which is the risk assessment was based on, and then you'd be able to go forward.

MR. WACH: Thanks.

MR. STONE: Does that answer your question?
MR. WACH: Yes.
MS. KOEHLER: Thanks for the comment.
MR. STONE: Oh, sure. I've got to tell you, if you guys are able to do something like that, it would be tremendous for this industry.
MS. FITZPATRICK: Moving to point six, familiarity can be established through science. Science should be the basis for making scientific decisions regarding safety and risk. The National Academy of Sciences describes familiarity as having enough data for regulators to make a determination of safety. Many new products that will enter into the regulatory system may be new to APHIS, but have substantial underlying scientific familiarity through product performance standards based on biology of the organism, trait and management practices.
Additional information about the trait is gained through scientific research, laboratory work, greenhouse experimentation and field trials. APHIS should allow applicants to use all of this information to demonstrate familiarity. Anything else?
Point seven. Finally, we are supportive of APHIS' effort to insure transparency in the process of assessing risk. Input from all interested

stakeholders should be considered when determining the regulated status of a new product. We believe that APHIS should continue to work towards increasing the public's understanding of how biotechnology is tested and regulated. Doing so will further enhance the dialogue regarding these products and help to insure potential risks are evaluated appropriately so that this valuable technology continues to be employed and its benefits realized.

MS. SMITH: I'm sorry, can I ask you to back up to APHIS would continue to work toward --

MS. FITZPATRICK: We believe that APHIS should continue to work towards increasing the public's understanding of how biotechnology is tested and regulated. Doing so will further enhance the dialogue regarding these products and help to insure potential risks are evaluated appropriately so that this valuable technology continues to be employed and its benefits realized.

MS. SMITH: Thank you. We agree.

MS. FITZPATRICK: With that, that completes our formal prewritten. There are a couple of other comments that we'd like to kind of bring up. Should I offer one? Sort of the miscellaneous at the end here.

Regarding the question in the Federal

Register surrounding performance based containers for movement of interstate movement, etc. I guess we believed we kind of would like to put forward the idea that currently we write performance standards surrounding our field trials and that they could be encompassing and performance based and also encompass the containers under which you would move. And they would need to be appropriate trait by species again, as well, rather than prescriptive.

We clearly support that, but we believe that the mechanism could be quite easily molded, the mechanism right now for field trial performance standards could actually be consistent with that or compatible with that for containment to during movement. Any other comments on that?

MR. STONE: No, I think you said it really well. It's all about containment. Your performance standards are about containment in the field, then it would just transfer over to how it would ship. Rather than being prescribed, it would just be part of the performance standard.

MS. PARKS: I have one question. In point five, you all discussed the notion of non-viable material and we were curious as to how far does that extend? What are some of your thinkings? Is it

really plant material?

MS. SMITH: As far as our thinking, well, to clarify it, if you look in the definition of the Noxious Weed Act, it refers to not just plants, but plant parts. And so you can have some non-viable plant material -- it's not the whole plant. We're just acknowledging that within that definition, it can go to that authority, that that's a new component that we've not dealt with in the past. So we're just laying that out for public discussion to consider and make recommendations to us about whether there's some way that we should take, whether there's some way we should be addressing non-viable plant material?

MR. STONE: Was there a particular example that you had in mind when you were thinking about it, or was it just --

MS. SMITH: No, not really. It's just the fact that within that noxious weed definition, we're just trying to highlight for the public that that's a change from what we can regulate currently, since currently we're regulating viable plant material.

So we really don't have something in mind for what we're looking at there, but it's just the recognition that that's something different than what we had done in the past. We just want to put that out

for comment.

MS. PARKS: The question refers to plants, it includes not only plants, but plant products, but I heard you say plant materials. There are products from plants, so I'm just trying to -- is it actually the plant, the growing material?

MS. SMITH: It's not our intention to look at -- well, actually, no. We're early in the process. I guess I don't want --

MR. TURNER: Our thinking is in our infancy here.

(Laughter.)

MS. SMITH: One thing I would feel comfortable in saying clearly it's not this that we're thinking about, but acknowledging John's remarks this morning that our thinking will need to evolve based on the issues that are raised. Maybe it's better just to say that that's something that's in the noxious weed authority. We could look at that and we'll have to think about that.

MS. PARKS: Great, thank you.

MR. STONE: It's been an interesting one to discuss. Here another one for the AP question and the issues related to that. Rather than give you our perspective so much, we would be very interested in

understanding what kind of data or information you would need to be able to establish an AP threshold for a product? What would that look like, for you to be able to make that happen? You're aware of how important it is for the industry to have something like this and certainly internationally being able to have the United States establish a precedent. What would you need to be able to make that happen?

MS. SMITH: Well, in order for us to consider if something should be exempted, if it occurred at a low or an intermittent level, that would have to be determined by criteria that we would set. And so, of course, the data would have to speak to those criteria.

MR. STONE: Right.

MS. SMITH: So, for example, it might be not a known allergen, you know, it's safe for human consumption. So whatever that series of criteria is that we would establish would be the kind of information that we need to be able to --

MR. STONE: So are you looking for input on what that criteria would be at this point?

MS. SMITH: Yes.

MR. STONE: Okay. How would you view, well, that's all right, I won't go there. Okay, thanks.

MR. TURNER: And those criteria may relate in some way to the tiered system, which is the low risk category for which there would be allowable AP.

MR. STONE: Thanks, John.

MS. SMITH: That would be a logical fit.

MS. FITZPATRICK: Another brief topic would be also one of the questions in the Federal Register talked about exemptions from interstate movement notification for Arabidopsis, that question. If a group were interested in asking for an exemption, what would the process be to get that exemption?

MR. TURNER: What we're really asking on this one, Arabidopsis is already exempt, so you don't have to ask for it.

MS. FITZPATRICK: Right.

MR. TURNER: In the regulations. We're saying should we list maybe some other plants that are exempt from needing a notification or permit for interstate movement. So maybe we didn't ask it clearly. Should we treat some other types of plants. So it wouldn't be granting it on a case by case as maybe saying these types of plants are exempt from interstate movement permit requirements.

MS. FITZPATRICK: These types or these species?

MR. TURNER: It would be some sort of specific listing.

MS. FITZPATRICK: So then you would offer a specific listing at this point in time, but for future flexibility, what would the, how could you amend that list, I guess, is what would be the process?

MS. SMITH: Consider also what a process would be?

MR. TURNER: Yes.

MS. SMITH: So we'd want to lay out, potentially, in our regulation what the process would be to -- with a list, to add to the list.

MS. FITZPATRICK: For example, I'm just thinking in terms of fairness and benefit to the public at whole. If one company had an interest in an organism on the list and that's great, it's already on the list and someone wanted to add one, they would be the first ones to bear the burden of, you know, pushing it through the process. And if it's -- I'm just trying to look for some guidance around how would that process move forward, be thinking about that.

MS. SMITH: That's the part I think we'd be open for comments on.

MR. TURNER: Yes, and to check legally, can we do that without amending, but yes, that is a good

point.

MR. STONE: Maybe just a process question. And when we were developing our comments to finally submit to you in written form, how would you like, are you splitting up the questions amongst yourselves, you know, or is one person going to get the whole list and then go through them? We want to be able to develop them so it's easy for you to be able to review and consider our comments.

MS. FITZPATRICK: We're building redundancy --

(Laughter.)

MS. PARKS: Do we need to be so redundant as we answer the questions, so if there is one group that was considering question two, you wouldn't refer in question three back to question two, if they didn't have those responses in front of them as they were working through it. So it's kind of the process.

MR. STONE: Process oriented.

MS. SMITH: We appreciate your willingness to make the process easy on us. The concern I have is we could give you some suggestions, but since we wouldn't expect that everyone else would get the same suggestions, asking you to repeat in every section, for example, you know, it would be a lot more work for

you, but as a system, it's probably not going to work overall. So my suggestion is just follow in the order of the questions and use your best judgment and we'll have a really top notch process put together with some top notch, talented individuals that will be reading through the comments and evaluating them.

MR. STONE: Retain flexibility.

MS. SMITH: That's right. We appreciate your sensitivity to our situation.

MR. STONE: Let me just ask you a couple of other process type things. So are the transcripts of each of these meetings going to be in the docket? Is that how it will be made available?

MS. SMITH: There will be some kind of documentation related to all of these meetings, as part of the public record. I'm not sure, yet. We still need to check with our lawyers and see what's appropriate. I'm not sure if that's a verbatim transcription of each of these sessions or if it's some kind of a summary.

MR. STONE: Okay.

MS. SMITH: But something will be in the administrative record and then we're also looking at whether that would also be useful just to post on our website so others have that information, as well.

MR. STONE: Okay, that's great. Then the other question, then, is so after these scoping meetings which you're having now, are you planning on having additional public meetings for scoping purposes and then --

MS. SMITH: Well, not for scoping purposes. At the moment, we're not planning public meetings for scoping purposes for the EIS. We are talking about a number of different kinds of meetings, some on more general topics, some specifically scientific meetings that will be public in nature.

MR. STONE: Okay.

MS. SMITH: We see probably more of those coming in conjunction with putting out the proposed rule, where we have more specific proposals for people to talk to and react to and talk with us about.

MR. STONE: Okay.

MS. SMITH: But we're really very open. As we go through the process, our thinking evolves almost daily in terms of how we plan to proceed. So we're --

MR. STONE: So then you do look at, then after this series of meetings here, you'll be able to go back and draft the EIS?

MS. SMITH: Actually, we've already begun the initial work of kind of laying out the framework

for the EIS.

MR. STONE: Oh, great, so then the public meetings would be a round, commenting on the EIS and the rest?

MS. SMITH: Well, we're thinking that the public meetings may be more commenting on the proposed rule.

MR. STONE: Oh, on the proposed rule? Okay.

MS. SMITH: But again, we may change our thinking there.

MR. STONE: Okay, still looking for next year to be able to have this done, or is it two years?

MS. SMITH: Well, our intention is to try to complete the EIS this year. That will be largely influenced by the kinds of comments that we get and the range of issues that we feel like we need to address.

MR. STONE: Okay.

MS. SMITH: I guess our mantra is this is a priority for the Agency, we're bringing a lot of resources to bear. We certainly are giving it full attention, but we also are not going to rush through to the extent that it compromises the integrity, so it is a priority.

MR. STONE: You'll also keep as a priority

the products that are in the que for deregulation, I guess?

MS. SMITH: And all the other work that we have on our plates.

MR. STONE: Just kidding.

MR. HANDLEY: Can I ask who those six companies are that were on the Coalition?

MS. PARKS: Sure.

MR. STONE: Sure.

MS. PARKS: It's ArborGen, Scotts, Forage Genetics. We also have U.S. Sugar, Applied PhotoGenetics and Plantgenics.

MS. SMITH: Good question, thank you. Do we have some other questions?

MS. BECH: Yes, I had a question. When you were talking about the AP issue and you said that of course looking at this issue is very important to the industry and what kind of criteria you would be considering. Did you say something about establishing some sort of threshold or something and could you elaborate a little bit on what you mean by threshold? Are you talking about like .9?

MR. STONE: Yeah.

MS. BECH: Do you mean to go to that level or here's a set of criteria that we would consider

eventually talking about?

MR. STONE: Maybe, I don't think you can set a certain threshold for every species and every crop. Certainly, it's got to be case by case in that respect.

And some of that probably would be based on the ability to actually meet that. But, you know, maybe really, and from what John said, too, maybe a way to look at that is based on a threshold based on what the potential risk is. I don't mean of it occurring, I mean for the trait, for example. Thresholds being considerably higher, more flexible for things that have a very well documented safety record.

For those that, and I mean the trait in particular. For those that don't have that same kind of record, perhaps it could be a tighter threshold, lower, based on, you know, again the degree of potential risk, either to the environment or to humans in that target safety.

MS. BECH: Okay.

MR. STONE: That's kind of off the record, but generally we're weight considerate is a way to think about it. Having a threshold of some kind is very important and for perennial crops or even for

specialty, and you're thinking of minor uses and the like, it's when you talk to companies and individuals who are trying to bring those products to the market, regulatory is the hurdle. I mean, it is the barrier to entry.

So when you have a situation where a company is wanting to bring something forward but they're faced with having to get approval in every country in the world that has regulations where there may be even a small portion exporting to, especially now with the CBD, the Convention of Bio Diversity, frankly, it's not doable.

So being able, and not only that, the risk and the uncertainty of even attempting something like that makes getting any kind of venture capital funding impossible. Having something that enables you to take some of that risk away, and if it is a threshold, then you're able to design a system, whether it's identity preservation or distribution or whatever, that allows you to work within that framework, so then your product concept becomes based on what that limitation is and you're able to actually move forward.

So take a vegetable, for example, that you can develop strictly for a fresh market. It's going to stay in the United States, although there are

frozen product that is also exported to Japan. Well, if you can establish a threshold and you know that you can bring that product to the market, to the fresh market and that it's not going to go into the frozen market, you have an ability to have a product. You have something you can bring to the market. And that's very encouraging versus, again, the idea that you've got to go to every potential country where something might be exported. That's where thresholds can be helpful.

MR. TURNER: One aspect of that and, of course, we're open at this point. I'm sure you're aware there's been discussions within the Government and the outside as to whether there should be an actual number or whether the concept of low and intermediate, if it meets certain criteria, then some low level would be tolerated. So, I mean, you're clearly coming down on one side or the other of the issue.

MR. STONE: Yes.

MR. TURNER: We'll be hopeful to see that in the comments.

MR. STONE: That's good.

MS. SMITH: This is great discussion.

MR. STONE: Yes, thank you very much for

your time, everybody.

MS. SMITH: There's a lot of information to share. We need to bring this to a conclusion, so I'll just thank you again. This has been really great. Thank you all.

(Whereupon, at 12:25 p.m., the meeting was adjourned.)

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REPORTER'S CERTIFICATE

DOCKET NO.: N/A

CASE TITLE: Stakeholders Meeting

HEARING DATE: February 26, 2004

LOCATION: Riverdale, Maryland

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

Renee Miskell
Official Reporter
Heritage Reporting Corporation
Suite 600
1220 L Street, N.W.
Washington, D.C. 20005-4018