US ERA ARCHIVE DOCUMENT

Transcript of Meeting of the Pesticide Program Dialogue Committee

NRECA Conference Center
4301 Wilson Boulevard
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ATTENDEES

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Robert Rosenberg National Pest Management

Gerret Van Duyn National Cotton Council

Carolyn Brickey Institute for Environment

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Dr. Richard Liroff World Wildlife Fund

Jen Sass Natural Resources Defense

Council

Patti Bright American Bird Conservancy

Amy Liebman Migrant Clinician Network

Erik Nicholson United Farmworkers of America

Troy Seidle People for Ethical Treatment

of Animals

Dr. N. Beth Carroll Syngenta

Allen James Responsible Industry for a

Sound Environment

Stephen Kellner Consumer Specialty Products

William McCormick Clorox Company

Dr. Leonard Sauers Procter & Gamble Company

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Jay Vroom CropLife America

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Allen Jennings Office of Pest Management

Dr. Melody Kawamoto National Institute for

Occupational Safety

And Health

PROCEEDINGS

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(Beginning of tape.)

MR. JONES: -- then we'll do a little -- we'll start off by, sort of, walking you through that and then we'll open it up. So, with that, I turn it over to Lin Moos, who is the Acting Associate in our Field and External Affairs Division.

MS. MOOS: You received about two-and-a-half pages on Environmental Marketing claims. I'm going to go through this very, very quickly because what we really want to focus on is what you folks are interested in and getting feedback from you.

Several stakeholders have approached the Agency asking that consideration be given to establishing criteria where people could make safer chemical label claims or marketing claims. Historically, EPA hasn't allowed that to occur. The policy was partly out of concern that claims would lead to a disrespect for products that exhibit toxicity, and the concern was

particularly acute for homeowners and concern that people wouldn't use the label precautions.

We've also functioned with the goal of high production in the office and any resources that we devote to establishing a claims program and monitoring claims would be diverted from our normal registration and other activities. So, what we're doing today, as Jim indicated, was seeking advice from you folks on whether or not we should consider pursuing a claims program and what role you folks would like to play.

I'm hoping everybody had an opportunity to read the paper. I'm not going to go through the pros and cons that are there. I'm just going to very briefly talk about the issues that we pulled out, and I know that there is probably a lot more issues that aren't included in the paper.

The first issue or framework that one could consider for establishing a claims program would be to expand the existing Reduced Risk Program and allow chemicals that have entered into the Reduced Risk to be

able to make claims regarding their reduced risk on their labels and through their marketing.

An alternative way would be to establish a low toxicity chemical program where some set of criteria are established that are black-and-white, not relative criteria, and if a chemical were to meet those low toxicity criteria they could make such claims on their label. They could have different, sort of, low toxicity standards as well. And one of the biggest problems there is establishment of the criteria. Other criteria we could use: Would criteria need to be developed? Could we get a third party to develop criteria, and what-not?

Another thought for a program would be to have two different types of programs. One type of program for consumer products and a second type of program for agricultural conventional products, with the view that our different user groups have different levels of education about the products and perhaps having a low toxicity criteria for household use products and a different criteria for our more professional users.

One of the other considerations is how would we handle inerts. If we're going to allow someone to make claims regarding their product should the inert ingredients meet standards as well as the active ingredient so that we don't have chemicals that have a relatively safe active ingredient, but a more toxic inert.

Should we require sun setting of claims on the label because as markets change over time a chemical that may be in a Reduced Risk Program at this point in time may not be a reduced risk chemical 10 years down the road.

Standardized label and marketing language. How would this all work into global harmonization and would we establish standardized claims or label requirements so that we would put some boundaries around what people could say.

A number of people have also raised the endorsement issue and raised the question of well, you know, if we allow these claims isn't EPA then endorsing

products, and I think it's important to note that there are a number of other programs in the Agency already where there are -- you know, there's the Environmentally Preferred Products Program that we have, there's Energy Star, there's Green Lights, there's Design for the Environment. You know, is endorsement a real concern here as a lot of people have raised.

And so these are just a few of the issues that we need to address if we're going to consider development of a program. You folks probably can identify another 10 or 15 or different frameworks for programs. And what we really want to do this morning, the next 20 minutes or so -- 25 minutes, is get feedback from you on should the Agency further explore development of a claims program?

Does PPDC see a role for itself in exploring the issues and making recommendations to the Agency? And, are there other approaches and other stakeholders that we want to involve or other things we ought to consider?

And so with that I plan to be brief and hope that you folks have a lot of comments and thoughts that

you want us to hear. Julie

MS. SPAGNOLI: Well, I think I was one of the people that had suggested this topic and I guess I was looking at in a little different way. I really wasn't looking for comparative safety claims or that there would have to be a program for comparative safety claims.

The regulations were pretty clear about not making claims about the safety of the product, and what I wanted to explore was the Agency's policy with regard to making claims about safe uses. If products had data and could support an objective claim to say whether the product was safe for bees, because you had bee toxicity that showed it wouldn't harm bees. If you had -- in the case of pet products, if you had data -- target animal safety data showing that the product was safe to use on puppies, then you could say it was safe to use on puppies. Or if you had a cleaning product and you could say this product is safe to use on a given surface.

That it was really more that you had an objective around the use of the term about safe, that you

didn't necessarily make a claim of a product being safe -just, you know, inherently safe, but that that may be a
particular use was safe. And I would still like to see
that, perhaps, explored.

The other issue that came up in this was the interpretation that by claiming a product does an alternative, that was necessarily an implied safety claim. You know, there's a number of times where a consumer may want an alternative product and you can't identify it as an alternative and not necessarily to say that it's safer, but just that it's an alternative. That a product may be a DEET alternative or it may be, you know, a Diazone alternative. Whatever, you know, the situation might have been that these kind of claims were not allowed.

And so, I would still like to see that that portion of it explored, as well as whether we want to go look at reduced -- you know, making some type of reduced risk claims.

MS. MOOS: I think the low toxicity chemical program did address what you were looking for, which would be this product is not toxic to bees or, you know, this product has little environmental toxicity, or however we would set those up. So, it was sort of looking at the Reduced Risk Program versus, sort of, a low toxicity program, and I struggled not to use the word safe for a number of reasons, I guess.

MS. SPAGNOLI: And I -- that's why I'm questioning that because that's where we run into some conflicts, especially, let's say, with veterinarian products that -- you know, a drug product has to say that it is safe. And so, veterinarians ask us is this product safe to use on puppies and we can't tell them it's safe to use on puppies, even though we have supplied data to that.

So, it causes some types of confusion in the marketplace.

MS. MOOS: Okay. I can't read --

MALE VOICE: That's okay. It's like 26 letters.

And this is really a very different part of this question and one I'm duty bound to raise. But, by way of background -- I think it's very much a related topic.

By way of background, back in the early nineties there was a lot of pressure from Capitol Hill to try to get the agency engaged in the question of claims made by commercial applicators, and there was, in fact, a Lawn Care Federal Advisory Committee that was formed.

A product of their work was, what I believe you still refer to, as a draft interim guidance document on lawn care advertising. The problem is two-fold. One, it's not draft or interim in the eyes of most people.

It's become a defacto standard that's been embraced by State Attorney Generals, State Lead Agencies all over the country and used as the basis for taking enforcement action against pest control and lawn care companies. And secondly, it, in essence, prohibits the use of virtually any health, safety or environmental claim.

Why that's a problem is this. In the world of pest control operators, I represent 6,000 companies,

5,000 in the United States. There's a wide spectrum of services. There's baseboard sprayers, and there are guys that practice nonchemical or very rigid IPM type programs and they have no ability at all to differentiate their service.

So, if you're a low-impact, low-toxicity kind of person and you want to tell the public, which presumably we want to do -- I don't think anyone would disagree with that -- there's no way to do that without running afoul of State laws that rely on EPA's guidance document.

So -- I know it's not a labeling claim, but if there were some way to maybe throw that into the mix as an issue that warrants, at least, some, you know, further attention or looking at, I would appreciate it.

MS. MOOS: Okay.

MR. JONES: Amy.

MS. ROBERTS: On behalf of the Biopesticide

Industry, we would definitely encourage OPP to look at
allowing claims -- like that a lot of our products are
safe and their mode of action or their toxicity or how

they're used, and we would like more latitude in the things that we can say.

One thing I would encourage is that you interact with the States. Frequently, we may have one claim that's allowable Federally, but we run into problems in California or New York. So, I would encourage interacting with the States if a claim program is developed. And that's sort of typing to what he said.

MS. MOOS: Yes, Dr. Lockwood.

DR. LOCKWOOD: Thank you. Well, we certainly would encourage steps that provide consumers and applicators with better information about the products that they may choose to buy and use, particularly in and around the home where there's an increase in demand on the part of the public for this kind of information. People want to make choices. Women who are pregnant or have small children around the home, and so on and so forth.

So, we would encourage steps to be able to provide the public with that kind of information. But having said that, one opens Pandora's box in terms of

regulating the nature of the claims that might be made. Certainly, the Agency would have to adopt programs and standards to be able to monitor that to make sure that they conformed with at least what was known about the science and common sense, and to prevent the kinds of claims, some of which have shown up on the informed consent documents for the human testing that's gone on, whether it was an implication that if you ate an organophosphate it might improve performance on neuropsychological tests. I mean, clearly that kind of thing can't be permitted to happen.

I think the Agency might be able to learn
lessons from the Food and Drug Administration, who has
standards for labeling of both products that are
available by prescription only to licensed physicians or
other qualified prescribers and products that are
available over-the-counter. This might be analogous to
the homeowner who walks into the grocery store or the
hardware store to purchase a product or a professional
applicator who goes to some more easily controlled source

for more toxic compounds, so --

It's a difficult question, but I think that it's one where the public is increasingly wanting better information. Good luck.

MR. KELLNER: In terms of product stewardship type logos, I would like to just sort of lay that out as an area that should be permitted. We've asked the Agency to consider that in response to our product stewardship program that Jay Broom mentioned yesterday. That does provide more information. The marketers would like to be able to do that. They feel like in taking the steps towards product stewardship they want to encourage others, as well as alert the consumers, that they're doing something very special to them and they want to just get the publicity of using the logo, and it doesn't entail a marketing type claim.

So, I'm open for discussion on that, but we would like to see the Agency to permit that.

FEMALE VOICE: Steve, can you give an example about what you're talking about?

MR. KELLNER: Well, they might just want to say the logo itself was on here yesterday and it's a globe. It would just say CSBA, product care. That's basically what it would be with the logo on it.

And to them -- I mean, if they're going to sign up and do these things, then we're encouraging that. We have 61 people -- 61 companies signed up so far. We think that they should be able to, on pesticide type products, go ahead and put that on.

We've also asked two other Agencies, the CPSE and FTC, and they've given us an okay to move forward with it.

So -- I don't know if anybody else plans on their folks doing that, and you were talking yesterday, Carolyn, about your people. We just feel that if you're going to subscribe to something like this you should basically get the credit for it and move forward.

MALE VOICE: Lin, I thought your draft paper, what the issues are and what you spoke about today was really good and I think it does hit on a lot of issues, a lot of, I think, unmet needs from the registrant's side to

make some of these claims. I think the format and the way we go about this, and just the spectrum of concern or maybe excitement about possibilities here, I think means there needs to be some work on this. There's a lot of energy about it. But it can also completely spin out of control.

So, I think one of the important things here would be to be fairly concise in what we try to go after and maybe, you know, do several buckets, maybe, on safety claims, toxicity, logo endorsements and all that.

But it is -- as you raised, if we start looking at toxicity and doing comparative talks or something like that -- I mean, there could be -- we could go nowhere with doing the work on this if it's too big a charter.

So, I would say let's work on it and do something that's fairly defined in terms of the expectations of the Agency and PPDC.

MALE VOICE: I would agree that the scenario that's definitely worth pursuing some of the points that Julie raised are -- I think would be equally of a concern

to the animal protection community when you get into safety and toxicity claims similar to, for example, antimicrobial issue. If you can go from being a soap to being a pesticide with one word, you know, and the data requirements go through the roof, I would be very concerned about claims of safety or lack of toxicity, and then having every test in the book thrown at a chemical to demonstrate that it's not toxic to anything that would — that could spin out of control as other speakers have said.

So, just flag that as an issue to consider as this goes forward.

MALE VOICE: I understand this issue was raised at SFIREG this week. SFIREG is a group of State lead agencies that advises the pesticide program on policy issues.

I also understand that it was not very well received. In fact, overwhelmingly not received from what I understand.

MR. JONES: Can you speak up, please?

MS. MOOS: Yeah, I can't --

MALE VOICE: I also understand it was not very well received.

There are a lot of other issues from a compliance point of view for why this would not be well received. We have to remember that according to FIFRA the label is the law. So, we need to have labels out there that people can understand and that can be enforced.

The more we dilute that label as the law issue, the more we dilute all of the training that's been done around pesticide issues since 1972 for our application community and our homeowner community. I think we have to remember those things.

I think Julie's issue was a little different than what was in the paper to some degree. But I'm really worried that we're going to tamper with these labels to the point where they're not enforceable and then what will we have for a pesticide enforcement program. We have enough trouble now with the general public trying to

enforce and have credibility in this program. I think we should tread real slowly, if at all, on this issue.

And I guess I would suggest that -- I'm concerned about marketing programs because I can tell you what the biggest type size is going to be on that label. It's not going to be the Health and Safety precautions or those kinds of things.

I guess if you're going to proceed I would like to suggest we proceed with an understanding that the type size for these claims be no larger than the smallest type size on that label and that would kind of level our playing field.

MALE VOICE: Yes. Thank you. Can you hear me?

I think most of us realize this is a very problematic issue and the only way to address it is to start to try to segment the market or segment the areas of claims. It is -- somehow do a pilot project. The questions will have you do that because by segmenting one sector or piloting in one sector you leave out another sector.

You're giving preference to one sector or another.

But it seems if you're going to do it at all you have to do something like that because it is too big of a -- too big of a field to look at all these different claims. It's not like Energy Star. The number of endpoints that you're certifying are to the limit in this area. It's almost unlimited in the number of areas you could do that in.

So you either have to segment by the sector.

You know, animal care products or lawn care products, something like that. You may want to limit it by the end-point that you're interested, like honeybees or something like that, or pollinators in general or something like that. And that gives you some way to limit the workload and also try to do this in a way where you're going to apply it in one area or try it in one area and then that allows you to learn from that experience, like what he suggests like the type size or whatever else is necessary to make it work. Otherwise, it's just going to be too big of an issue.

I think the other area is not the product

marketing claims, but the service side of it, I think, is a little bit different thing and I think -- and that probably lends itself to a little bit of different approach. For example, as having some kind of a certification program or something like that so that lawn care agencies or whatever providers can say that they are providing some kind of environmentally defined service in being able to do so legally. There's plenty of that going on now, which I -- from what I understand from my colleague here it's not, in most cases, legal for them to do that. But if you were to look in the yellow pages you would find plenty of cases where pest control services are saying that they are eco-friendly or something like that.

I think that's probably an area where it's a little bit more attractable and you have a little bit more of a defined way to go about doing that by having some kind of a certification system for the companies or for the -- you know, the applicators. Does that make sense?

MS. MOOS: Yeah, it does on both the points. Do any States do that independent?

MALE VOICE: Yeah. I think the only -- well, there's lots of States that embrace prohibitions on advertising claims, but don't provide guidance on positive statements.

The general enforcement framework for that kind of thing is to stay we'll tell you if it's bad, but we can't -- you know, we're not prepared to tell you if it's good, which creates a difficult situation for folks who do want to demonstrate some good.

Texas -- I want to say maybe Texas alone actually has a set of applicator advertising guidelines. They're not great, but they're a step in the right direction. I spent quite a bit of time -- they -- oh, god, they have a term for it. Like you -- I think they use the term low impact applicator or some phrase like that, which I don't think is a particularly attractive phrase, but at least they've grappled with the issue.

MS. MOOS: Thank you. Julie.

MS. SPAGNOLI: As far as an approach, I know a number of years ago -- I guess this is probably 10 years ago or more. We were struggling with the same kind of issues with environmental -- more specific environmental claims with just general consumer products and these were, you know, products making claims of being environmentally friendly or, you know, good for the environment, biodegradable and all those sorts of claims.

And we did put together -- there was, you know, an industry, stakeholders, work group working with the Federal Trade Commission, and as an outcome of that, you know, they did develop the environmental marketing guidelines that FTC has put together.

And so we could take, you know, a similar kind of approach as to say, okay, let's identify, you know, maybe -- you know, a few areas that we want to develop guidelines for and these will be the ones --

You know, we will come up with some criteria and some guidelines and, you know, specific types of claims

that can be made and maybe try that kind of an approach where there are some guidelines specific to certain types of claims and outside of those things, you know, then -- that that's - you know, limit it to that, at least as a starting point.

MS. MOOS: Thank you.

MR. AMADOR: I think there's been a lot of discussion, and I don't know if I can add anything specific as a way of recommendation, but -- (inaudible) -- person, to me providing information to the public and the people who are going to use the information that you're giving is the most important thing that we can do.

Paraphrasing a famous quote that many of you have heard before, you know, I'm always amazed to see how many wise decisions a well informed public can make. SO, the more information that we're giving, I think the better that we are.

I agree with Phil that we need to be aware of the fact that the label is the law. That's what we've been preaching all along. So, we have to be careful what

it is we put there because whatever we put can be interpreted as the law.

on the second page, the requests that you make of us, in bullet number one I say, yes, I think that the Agency should explore this issue. I think that you've seen enough consensus here to know that this is an important thing. I think it can be, if done properly, any information you put on the label is factual and it can be -- (inaudible). I don't see how that can be bad. Keeping in mind that once you put it there that's going to be part of the law.

And in answer to question -- to bullet number two, does PPDC see a role for itself. I think that yes.

I think that we ought to be involved in it. So, I think that this is something that PPDC and the Agency should continue to explore.

MR. NICHOLSON: From the Farmworker community, we definitely are interested in seeing and promoting the use of less toxic alternatives. But I think this

approach is problematic on a couple of fronts, primarily in how toxicity is defined.

We currently have serious issues with EPA in how it underplays -- (tape interference) -- and if we're going to make statements about the relative toxicity of pesticides, I think we need to look at a holistic approach. One of the things that has jumped out at me was the whole issue of inerts.

I don't know how we can make statements about the relative toxicity of a given chemical if we do not include inerts. I mean, that by -- it's not even an issue from our prospective. And I think -- I have -- I share the same concerns as Phil.

In the Farmworker community we spend a lot of time

trying to get workers, at least, access to the labels and then to understand, even if it's written in Spanish, but it's such a high technical level, what those labels mean.

We already have a culture in which farmworkers are actively told that pesticides are medicines and not

toxics, and if we have these statements going on there, that's going to promote that level of awareness versus looking at what are the impact of these chemicals -- the acute impacts and, again, the most important from our prospective, the chronic impacts.

So, I think the only way we could pursue this is by looking at toxicity in a holistic approach and then, perhaps, look at making claims. But I would be very wary of adding any such statements to a label.

MS. MOOS: Jay.

MR. VROOM: I think it's appropriate to consider statements -- and we can call them claims if you want to -- that make the product easier to use so long as they're based on factual information that is reviewed by EPA and regulated by EPA. We certainly want to avoid the doing unverifiable claims on labels which fall almost strictly in the area of advertising.

If a claim on a label could make it easier for the user of the product, the person actually purchasing and applying that product to the safety or the

permissibility, then I think that's a good thing.

For example, if the user has to determine that I can use this when these are present, but I have to figure that out because there's lack of a particular caution on the label, or there's some particular obscure twist in the use directions that makes it permissible to use on these. It's a lot simpler if it just states safe for use when these are present.

I was -- right now we have a certain, very crude level statement about safety in the caution -- or the precautionary statements and then the signal word on the label. But that may be difficult for users to interpret exactly what that means, whether it's caution, danger, et cetera.

I was intrigued by your statement about reduced risk status and something that might not be reduced risk status 10 years from now. How is a chemical going to lose its reduced risk status?

MS. MOOS: All I was trying to communicate was that there may be different chemicals on the market and

things that were -- are safer now, there may be even safer alternatives in the future.

MR. VROOM: That should not effect the particular toxicity or safety of a chemical that has been approved. And just by implying safer reduced in terms of a risk comparison makes these unfair comparisons among products in the marketplace.

We need to much more cautious about claims dealing with benefits of a product that are post-application, long post-application. Not directed at the user of the product.

I think it's appropriate for this group to consider the pros and cons of this in more depth and kind of partition it into separate categories of where claims may and may not be appropriate.

MALE VOICE: I want to maybe inform or remind

PPDC that I don't know when we initiated the consumer

labeling initiative, but it was out of a desire to make

claims -- environmental claims specifically.

And out of that, Erik, to your point, I don't

know if you know about CLI, but we came on fairly strongly and there was a really wonderful, sort of, joint industry EPA initiative, consumer labeling initiative, to try to understand what consumers really knew or could read from a label. Out of that we tried to simply some label language, which is in effect now and I think was a very positive program.

We did a lot of focus groups with consumers all over the country asking them to try to interpret what the standardized label as a law, kind of, language, which, quite frankly, nobody could understand.

I'm reminded of one particular individual in LA, who when he read it's a violation of Federal Law to use this product inconsistent with its labeling, was a -- about bombing. That it was a terrorist warning.

So, there's a lot of misinterpretation about what we're saying in mandatory language on a label and whether we like it or not, the average reading level of folks out there is not real high and we need to learn how to communicate succinctly and simply to, you know, the vast

majority of people we hope are reading the labels.

And there are some brochures that got put out by the Agency called, "Read the Label First". I would encourage people to take a look at that.

Having said that and trying to move this on, I would encourage PPDC to establish a working group to work on this issue and define where we want to go with it.

MS. MOOS: Thank you.

MR. JONES: Lori.

DR. BERGER: Yes. I just think that

communication is going to be really important in working

with a lot of craps that have a lot of high intensity

farm labor activities. It's not just a reduced risk

chemical, it's reduced risk practices that there needs to

be a clarification. And what the difference is, because

it might be a chemical -- I don't know what the best word

here is -- but a traditional chemical or conventional

chemical when it's used in a certain way is a reduced risk

practice.

And so I think that there's a lot of gray area

here that if some sort of claim or delineation is made that needs to be very, very clear because really what we're -- we're trying to go towards reduced risk practices, at least as I understand it. So I would be very concerned about language and semantics along those lines.

MS. MOOS: Thank you.

MR. JONES: Terry, I think -- John, is your card up again or --

MR. VICKERY: Oh, I'm sorry.

DR. TROXELL: I don't know what I can add to this. We have -- at FDA we have a lot of experiences with a lot of these areas. I must say I agree very much with people who are concerned about how to get consumer messages out. That's extremely difficult. You have to get -- it has to be simple and to the point. Attention span isn't very long and the language problems, we have to get it out in different languages and we're working, you know, with food issues many different ways.

You know, you're trying to get the message across

about how to use the product. Then, you know, if you put a simple message out that this is safer for bees or this is lower toxicity, they may -- the consumer may miss, you know, the rest of the information because that's very complicated and they stopped with the first -- the message about the relatively safety.

So, I think when you do something like this you really need to take it to, like, focus groups and look at what the total impact on will they receive the message you want them to get about a safer pesticide, but will they also get the second portion of the message.

You might want to look at some of FDA's experiences in labeling. I think maybe drugs might be the better model because -- in contrast to, like, health claims or dietary supplement claims because drugs -- you have the data just like you have the data, I believe, on the pesticides and reduced toxicity. And then if you think about drugs, you know, you think about the TB spots or, you know, the cholesterol or anti-allergy drugs and then, you know, you see how the focus is on the benefit

and, you know, at the end rattle through all the reasons that it scares your pants off while you shouldn't take that drug.

On the other hand, you know, if you look at the controversy that there is about appropriate labeling for, you know, health claims and nutrition claims for food, you can see -- some of the things that you might get into down the road and the commercial free speech issues that are involved in all of this, and it probably isn't a matter of will this -- will you go this way. I think it will happen. It's just when.

I think the other thing we always run into, whether we say you must put a warning on the food or an alert on the food -- you know, like cook your eggs thoroughly and refrigerate them. You know, whether you give prescriptive language or you basically tell people that this is the kind of information that you need to provide.

It's a little more difficult to go down the road and be thrust with totally prescriptive language. We

might give some examples of how you can do this and then people have license within boundaries. So, that's kind of where things have gone for us.

I guess finally to the extent that any of this information, as well as the things that we were talking about yesterday at the end of the day about these logo programs, end up on the finished food, then that's labeling and to the extent that it is misleading in any particular

-- it becomes a misbranding thing for us and that -that's resources we really don't have to try to referee
that kind of situation. But I think --

Anyway, I think -- I just wanted to point out that that's where it bumps into FDA's responsibilities.

MR. JONES: Go ahead, Melody.

DR. KAWAMOTO: Speaking on behalf of workers and my experience with them, I believe that what Lori had mentioned about the problems between reduced risk chemicals versus reduced risk practice is incredibly important because a lot of the situations that we see is

when people misuse products or do not follow directions in terms of process or safe practices that we have problems.

So it's, you know, saying that the product is reduced risk is one thing, but that doesn't really mean anything if it's misused. And this keeps coming up again and again. So, I think that's a consideration that has to be taken very seriously.

MS. MOOS: Thank you.

MR. JONES: That was very helpful. I think that this is a challenging issue for the Agency and I think that the discussion here sort of pointed out -- it was very much like the discussions we've had inside the office.

Let me just propose a framework. This won't be the last time, by a long shot, that we talk about this. I think we need to put it on the agenda the next time. Here's how I would like to propose we talk about it the next time.

First, I think it's pretty clear from the

discussion that if we were to try to do this, figuring it out will be difficult and it will be somewhat costly. It will be costly for the Agency and costly for the stakeholders in the sense that it will take a fair amount of our time, energy and effort to figure it out if we were going to pursue it.

So, understanding that, I don't think we can delude ourselves that it won't be hard.

I think that the things that we need to think about at the Agency as a classic, sort of, cost benefit - you don't sink a bunch of costs into something unless you think there's a benefit. And so the first thing is, is there enough of a benefit -- and I think that we have to think as the Agency it has to be about the benefit being to public health and the environment. If you do this, you do it because -- if EPA does this, EPA does it because we think that people make choices around the margin that lead to better environmental outcomes.

So that's, sort of, one thing I think we want to get feedback around -- the next time around. And the

second one is, then, the cost side of it. Do we think that we -- you want the Agency to make it a priority.

Given the other priorities that you know we have, do you think it's important for the Agency to make this a priority? And do the benefits of -- the potential benefits that we could reap in environmental protection, public health protection, are they worth the costs that it will take?

And so, the next time we get together that's the

-- that's what I want. And I think this is something that
you just don't think about for 20 minutes before the
meeting, an hour at the meeting, and stop. I think we
know where we're going to go.

I think the next time we get together we -- we all think about it in between now and then and think about it in that context. We'll send something out.

Probably use a PPDC form to, sort of, remind you of the -- sort of the construct, the framework we want you to think about, and we'll, sort of, ask those two questions.

Do we think that -- do you think that the benefits that we could get from something like this, if done right, warrant the costs that it will take the Agency and stakeholders to do the investment to make it - to make it work?

I think that will, sort of, be our next step and we'll make sure this is on the agenda for at least an hour discussion. It will be largely about just feedback, but I think that that --

The resource requirements, I think that it would

-- it would be -- it would clearly take a senior leader

within our organization -- someone along the lines of Lin

-- to invest pretty meaningfully of their time. It would

require a pretty meaningful investment from all of our

regulatory divisions. I'm not talking about FTE's from

each one, but -- you know, a quarter of an FTE of each of

those divisions.

And then if we were really going to do some of things Terry, you, suggested then you're talking about contract dollars and then the investment that's necessary

to have engagements, perhaps of a substantiative of this.

It would be a pretty serious policy effort. I would say
it would rank in the top five of the policy engagements we
have currently going on. Costly.

MS. SPAGNOLI: I'm just going to suggest to that if we're going to discuss this -- I thought of this after -- based on Bill's comments. We might want to go back and look at the research that we got from the consumer labeling initiative --

MR. JONES: Good point.

FEMALE VOICE: -- to see what were some of the information that consumers said was important to them and how might that, you know, correspond to this issue. If there's certain information consumers said they are definitely looking for, maybe those are the areas we could focus on.

MS. MOOS: That would really help us scope out some of the potential benefits.

MR. JONES: Thanks. That's very helpful. Great. Thanks, Lin.

Okay. Mary Frances. As I mentioned when we kicked off this session, the first topic was, sort of, you know, do you want us to go down the line of this one or not. The second one is there are things going on that, you know, we don't have total control over here in OPP. There are bigger forces engaged, but that doesn't mean that there aren't going to be choices that we'll need to make and we want to make sure you're, sort of, aware of the bigger picture around GHS and get some feedback as to how you would like to participate as we make the choices that will need to be made.

With that, Mary Frances and Debbie McCall.

MS. LOWE: Okay. Thank you very much. I appreciate the chance to talk with you a little bit this morning about the Globally Harmonized System of Classification and Labeling of Chemicals. I think it may be the first time it's been on your agenda, but I hope it won't be the last.

Many of you know this, what is the GHS? It's designed to be a common and coherent approach to defining

and classifying hazards, and communicating information on labels and safety data sheets.

Given that, the target audiences are workers, consumers, workers in the transport sector in particular, and emergency responders. And finally, it's designed to provide a very basic underlying infrastructure for the establishment of more comprehensive national chemical safety programs.

The mandate for the GHS came out of what was known as the Earth Summit, the UN Conference on Environment and Development in 1992. Negotiations went on on a tripartite basis for over a decade. When I say tripartite, I mean governments, stakeholders from industry and other NGO stakeholders, and it did --

(End tape one, side one.)

MS. LOWE: -- development OECD, developed the classification criteria for health and environmental hazards; a group involving the UN Committee of experts on the transport of dangerous goods developed the criteria for physical hazards; and a working group under the

auspices of the International Label Organization developed the hazard communication elements of the GHS.

This whole effort was coordinated by a coordinating group under the auspices of the Intergovernmental -- I'm sorry, the Interorganizational Program for the Sound Management of Chemicals and the US took a leadership role in the development of the GHS and actually chaired the coordinating group that managed the GHS development.

The United Nations Economic and Social Council, which is where the GHS will have its permanent home, gave the system final approval by consensus this July.

So, what is the scope of the GHS? The GHS proceeded from the premise that we wanted to harmonize major existing systems for chemicals in transport, in the workplace, pesticides and consumer products without lowering the level of protection afforded by existing systems. That was one of the guiding principles.

The major systems, in fact, are basically the Canadian system, the European system, the US system and

the UN system for the transport of dangerous goods.

GHS classification is based on intrinsic properties. It's a hazard based system, not a risk based system. So, classification of the GHS essentially is the hazard identification part of our risk assessment paradigm.

The GHS scope covers all chemicals, not just pesticides. But I hasten to add that not all chemicals would be covered in all use settings and this is laid out in the GHS document. We're not talking about labeling food additives or pesticide residues in food. We're not talking about labeling cosmetics or pharmaceuticals as they are ready for use by the end user. However, those same chemicals would be covered in the workplace and in transport, and that is consistent with the current US system.

So, why do people do this? Well, the goals were to promote safer handling and use of chemicals worldwide; to facilitate international trade in chemical products by promoting greater consistency in regulatory requirements;

to reduce the need for testing and evaluation; to meet multiple systems classification needs; and then, in particular, to help developing countries develop strategies for sound management of chemicals.

Now many things are, hopefully, aimed for harmonization under GHS, but many things are not. So, I would like to go through those.

First of all, what should be harmonized? The criteria for physical hazards should be harmonized and these are the physical hazards that have criteria in the GHS. I stole this slide from the UN website. Ignore the three. I don't know what it means. It means nothing here.

The other set of classification criteria are for health effects and these are the health effects that are covered by the GHS. We're talking virtually any human health effect because of this last category; specific target organ/systemic toxicity or TOST, as we call it. It covers everything not covered elsewhere. So that would be kidney effects, nerve toxicity and so on.

There's a possibility that more specific criteria would be developed for some of those end-points, although the US, in general, is not in favor of doing that because we would like to see the system be stable for a while. We think that the way that this particular hazard class is defined will cover those and we don't want to see the GHS become a perpetual motion machine that needs to be updated all the time.

All right. The GHS also calls for certain standardized label elements. Hazard pictograms. These are the hazard pictograms that are in the GHS. The only one that OPP currently uses, of course, is the skull and crossbones. The first three that you see in the first row are currently used in the transport system, as are the skull and crossbones and the corrosion symbol.

The exclamation point is a new symbol for us, basically for lower level effects as an attention getter for irritation. This funny looking thing would not have a white box around it. This was the last part of the system agreed to. This is our Swedish colleagues' view of

what should signify a chronic health effect.

MR. JONES: Mary Frances, which one are you pointing at? We can't tell from --

MS. LOWE: Oh, the one that looks like a man with a star in his chest. That's the chronic effect symbol.

And then finally the dead fish and tree or dead tree/dead fish is the environmental hazard symbol for the GHS. And you should have seen some of the candidates for the symbols.

A colleague of mine took some of the candidates to the Society for Chemical Hazard Communication and they laughed a lot louder than you just did.

So, what should be harmonized if we're going to be consistent with the GHS? The classification criteria for physical hazards, health hazards and right now the only environmental hazard we have is aquatic toxicity for substances and mixtures.

Standardized label elements are hazard pictograms. GHS only uses two signal words, hazard -- I'm sorry -- danger and warning. And then we have hazard

statements for each hazard class and category. Hazard statements in the GHS are a subset of what OPP calls precautionary statements. They don't get into precautionary advice. They are simply a statement of the hazard. Fatal if swallowed would be an example.

I put product identifiers and precautionary statements in brackets because the GHS says these things need to be on labels, but -- and sets out some criteria for them, but does not have standardized statements at this point. There is planned work for more standardization of precautionary statements in the future.

And finally, our goal is to harmonize the format and the contents of Safety Data Sheets.

So what doesn't need to change if we want to be considered consistent with the GHS? Well, what the GHS calls supplemental information and this was very important to OPP because we have a lot of things on pesticide labels that are not in the list of things that are being harmonized and we think that's important to maintain. GHS provides for that as long as it doesn't detract from or

contradict the GHS label information.

Testing methods and data requirements don't have to change. The GHS is testing and test method neutral.

The use of risk-based labeling for chronic effects for consumer products in the consumer use setting. This was of particular interest to our Consumer Product Safety Commission. A lot of countries are probably going to continue to use hazard base labeling, but use of risk-based labeling is an option and the GHS is protected.

The scope of hazards covered by systems doesn't need to change and this is called the building block approach and probably the clearest cut example is right now in the transport sector, world-wide and the US. They focus on physical hazards. Is it going to explode? Is it going to burst into flame? And the highest levels of acute toxicity.

If they want to adopt the GHS and adopt it for those classes and categories, they are considered consistent with the GHS. They don't need to pick up the chronic health effects, for example, in order to be

consistent with the GHS. But for the hazards you cover you should use the GHS label elements.

And finally, downstream effects. If there are other things, containment siting requirements, whatever, that are currently tied to toxic categories, the toxic categories in the GHS are for hazard information purposes. So, everyone needs to look at the downstream effects and see if it still makes sense to have them linked to toxicity categories.

The general implementation expectations. GHS is a voluntary international system and by that I mean it does not pose binding treaty obligations on countries.

This is unlike the PIC convention or the POPS convention, which is a binding treaty obligation.

However, we have been negotiating in good faith and the intent is that countries with existing systems will adapt them to be consistent with the GHS and that the countries that don't have systems will start with the GHS as their basic system. And, again, one point we try to make clear is although the GHS is a voluntary system in

the sense of not being a treaty to the extent that countries change their regulatory requirements to be consistent with the GHS, it will be binding for the regulated industry.

Timing. I guess the good news may be is that there is no international implementation schedule. The World Summit on Sustainable Development and the Intergovernmental Forum on Chemical Safety set a goal of 2008. The Asia-Pacific Economic Cooperation Forum, of which the US is a member, set a goal of 2006, and that was largely at the instigation of US industry.

We've tried to point out, with acceptance from the others, the different systems, different sectors may have different time frames. My personal basis is to point out that most sectors don't require review and approvable labels like the pesticide sector does, and that may well take a little longer.

This is a list of some of the things that we need to do and we've begun to do. Analyze our policy.

Identify what might need to be changed. Coordinate with

other agencies because we would like to have more harmonization within the US Government. Work with our NAFTA partners. To do this OPP has formed an internal working group that Debbie and I co-chair.

And finally, as Jim said, you never want to forget the benefits of what it is you're trying to do. The people who develop the GHS believe that countries, international organizations, producers and users all benefit because greater consistency will enhance protection of health in the environment, it will facilitate trade, reduce testing and evaluation needs, and help countries and international organizations promote sound chemical management.

MR. JONES: Thank you, Mary Frances.

MS. LOWE: Thank you.

MR. JONES: Okay. This is going to be really hard for you to follow my instructions. I expect you all won't, but that's all right.

What we're looking for at this point is some guidance from you as to what the Agency and the PPDC

should be doing next. And if you feel like you want us to spend more time educating and forming -- you and others -- say that. Let's not try to use the next ten, 20, 30, 40 minutes answering your specific questions about what it is and what it isn't.

If you feel you don't have enough information the best thing we could do is have an all-day workshop where we educate you on this -- say that. If you say that -- you know, here's who I think you really do some outreach with -- say that. If you think that you would like this to be on the agenda every time for the next PPDC for the rest of our natural lives so we can tell you every last thing that we're doing and then you can tell us what you think about it -- say that.

So, we're looking for your advice about how we should engage you and others as we make choices and move forward. So, let's see if we can --

MALE VOICE: Am I allowed to clarify and question on that first? I think it's important to know one thing before we start that.

MR. JONES: Okay.

MALE VOICE: The clarifying question is this said it was voluntary, but is EPA going to go this route -- are we going to go this route for pesticide labels?

MR. JONES: As Mary Frances said, we feel that the US Government negotiated this in good faith and the plan is to go forward.

MALE VOICE: Okay.

FEMALE VOICE: And is it 2006?

MR. JONES: Well, those are the kinds of things that I think that we're open for input. I mean, those would be the kinds of questions we could come back to the PPDC for input advice and --

MS. LOWE: And we would want to coordinate with other agencies.

MR. JONES: -- other agencies.

MS. LOWE: And defining what constitutes implementation is also a little --

MR. JONES: Fuzzy.

FEMALE VOICE: And we would also like to

coordinate with other countries -- have them roll out some of the time frame as well.

MR. JONES: There are a lot of issues that haven't been resolved. But the plan is to move forward. Whether we move forward in 2029 or 2006, 2014 -- things that we're going to be working out. Troy.

MR. SEIDLE: Okay. I'm going to try and follow your guidance.

MR. JONES: Thank you.

MR. SEIDLE: The one area that strikes me as being very ripe for multi-stakeholder input is just to try and get -- to further the internal working group that you have, but also to involve stakeholders, and I think that's possible. I don't know if it's better to bring it to a forum like PPDC for that or to hold a workshop or something where you can not only get the input from relevant parts of EPA, but also other US agencies and try and get everyone together to flush out some of the many issues that I could raise right now and I won't.

But, you know, I think there really does need to

be a lot of, you know, very open discussion as this does get rolled out.

MR. JONES: Amy.

MS. LEIBMAN: I will follow your guidance and say that I think we need more information. The one thing that, sort of, struck me was the two signal words. Of course, I want to know why there's only two signal words and why there won't be a third caution, which covers a lot of products and how that will work. So, I think there needs to be more information about how this system will be implemented into the current labeling system.

MR. JONES: Would you suggest, sort of, a kind of half-day tutorial for PPDC? You know, sort of a broad, kind of open public --

FEMALE VOICE: You know, I'm not sure. I think
- I want to know where caution is, you know, and how -
all the products said or how the signal word caution would

fit into this. And so, I don't know if that's something

for all of PPDC or more for registrants and for labels.

MALE VOICE: When I look at this document my

first thought is how -- there are about a million questions that our members will ask us that I won't be able to answer. And so, there are, of course, some broader issues that PPDC needs to look at. But one thing that would be important to think about now is the fact that this will have an implementation date and the sooner we can start communicating with our own members with some facts and be able to answer some of their questions early on so that we don't come up within a year or two years of an implementation date and then they say, oh my gosh, we haven't been thinking about this for the last four years.

So, maybe a way to address that would be if there was a real expert on this issue from EPA that could be available for smaller meetings. I'm talking about meetings of groups of 25 or 30 where people could actually ask the kind of questions they're going to need to have answered early on to be making the philosophical shift, think about how they'll implement this some years hence.

MR. JONES: Okay. Thanks. Julie.

MS. SPAGNOLI: I would also recommend that we

probably need some type of a workshop to get more fully into some of the details. If there is going to be harmonized criteria, a little better understanding of what those criteria are. I think just to get a better idea of what kind of changes we could expect and then we can think about how to best implement them.

But I think until we have a better feeling for how is this going to impact our labeling, I think it's difficult to say, well, here's the best steps for it. So, I would recommend maybe some kind of a workshop because I think there's a lot more other stakeholders that may need to be involved.

If we're going to be looking at material safety data sheets, that is another -- you know, that's another area with occupational safety that's not, maybe, within the expertise of this group.

I have one clarifying question since I did -- I followed the instructions first. But was it looked at or what is the determination for products that have different jurisdictions in different countries, especially between,

like, Europe and the US where some products that are regulated as pesticides in the US are cosmetics in Europe or that are pesticides in the US that are regulated as drugs in Europe. How are those products going to fit into this?

MS. LOWE: I think, in general, the idea was that all chemicals will be treated alike. Our European colleagues told us they weren't going to do anything different for pesticides than for any other chemicals.

But I must say I don't think they involve their pesticide stakeholders when they made that statement.

So, I think if it's defined as a drug it will be labeled as a drug, which means the consumer -- the ultimate consumer label will probably not have the GHS on it unless the country decides to do it.

MS. SPAGNOLI: Okay. So, it's really going to be up to the country's jurisdiction -- so you're not necessarily for those kind of products going to have harmonized labeling?

MS. LOWE: No.

MS. SPAGNOLI: Okay.

MS. LOWE: And, for example, if one country does hazard based for chronic and another does risk, the labels may not be the same.

MR. JONES: Larry.

MR. ELWORTH: Well, I would underscore the comments about getting as much information to people as soon as possible about changes, especially from the user community side. I mean, people have enough trouble figuring out -- you know, dealing with all the changes in REI and things like that. If you start changing the basic information on labels it will change the kind of training that people get and also how they deal with that stuff.

The other thing that occurs to me is that regularly we'll hear some discussion of international programs at EPA and I'm relatively familiar with the acronyms and know kind of what's behind it. My guess is that the whole PPDC, as a group, probably isn't, so at some point it would be useful to put the international —the things that have international implications, not just

the international programs maybe, that OPP is involved in and lay them out. Not with a 40 minute discussion of each one, but so people know what the context is and maybe some time line of what kinds of things you're coming down the pike, as far as issues, so that we can -- people can know about them and find out on their own if they're interested. But also, so that if we want to cue some up for later meetings, that would be worth doing.

MALE VOICE: That's a perfect segway into what I wanted to raise. I think from the workers' side we're very much interested in learning more about this. And also, kind of, on a bigger and a national picture, you know, we're tracking the workshop coming up in Brussels with EU on the probabilistic methods to assess worker exposure.

We want to be part of that and we want to make sure the farmworker community is involved in these decisions that are going on either nationally or internationally that impact our communities.

So, the more that we can have these discussions, be informed ahead of time and identify key places for our

participation, the better.

FEMALE VOICE: My comments actually, sort of, relate to Frank and Julie's comments. Actually, our organization has been receiving a lot of questions about how -- for manufacturers and distributors about when is this going to be implemented, how long will we have to change the labels and what -- you know, what are the changes, and are we exempt if we only do business in the United States, or whatever.

So, I would say when we do have this workshop definitely a practical side would be for the people who are not only using the products, as the last two gentlemen emphasized, but also the people who are going to be actually changing the labels so that they can get up to speed with that.

MR. JONES: Thanks. Lori.

MS. McKINNON: I do agree with others in that we do need to have more education and clarification on the harmonization issues. It's something that drives me to be seriously engaged in this issue as well because we do have

a lot of tribes that border other nations and have dual citizenship.

So, I think for the tribal side that we need to have some serious discussions about this and be included in those type of discussions and talks.

MR. JONES: Thanks.

MALE VOICE: As I understand the explanation, this is a program that's already been decided on and approved on an international level, but the US is making decisions about an implementation schedule.

It's unclear on what opportunity there is for stakeholders to shape that implementation or if it's already a fate accompli and we --

MR. JONES: I think there's a lot of opportunity.

And one of the things I'm, sort of, picking up as I go
that the -- all of you getting much more facile and having
a greater depth of understanding is probably necessary to
figure out for you and for us how to participate in that
shaping -- decision making.

MALE VOICE: So, our near term needs are

understanding how and when it will effect pesticide label regulation and if there is to be any effect on data requirements. If that's a long ways off the need isn't so urgent. But if it's going to be in a few years, you know, we need to hear very soon.

MS. LOWE: It's not designed to effect data requirements. I want to make that clear.

MR. JONES: Beth.

DR. CARROLL: I would like to echo what Julie said and underline the need for a workshop because I don't feel like I'm being close to knowing enough about this to make good comments. And our MSDS sheets, if they're going to be affected, that's another whole department in my organization that needs to know about it, and also our production facilities. You know, that's another area.

So, I would like to have the ability to go back and talk to those folks and find out how much they know about it because I don't really know -- and maybe submit that to the forum for another workshop because that's a whole different sector, you know.

MS. LOWE: Can I just add something?

MR. JONES: Sure.

MS. LOWE: This has been an inner-Agency process, so OSHA -- in fact, it was someone from OSHA that did share the overall effort. In your -- I don't know if it's in your packet or on a table, but there are some websites that have more information as well.

MR. JONES: Frank and then Bill.

MR. KELLNER: Okay. From the CSPA standpoint, we believe that you should encourage stakeholder briefings, that the sector working groups should meet with the Government Steering Committee. We are in favor of workshops and continued education there. We think we should coordinate the US plan with other US agencies.

North America, NAFTA, TWG on pesticides. And the transition would be two years and we should start ASAP.

MR. JONES: Thanks, Steve. Sorry. I'm calling you Frank.

MR. KELLNER: No problem.

MR. JONES: Bill.

MR. McCORMICK: This program, at first blush, doesn't appear to have a major impact on State lead agencies, but in reality it does because in the end it's training and certification, and most of that training and certification originated around the labels. So, if we make major revisions to labels it's going to make a major -- it's going to require State lead agencies and extension services to make major revisions to their programs to educate farmers and consumers.

So, there's a lot of impact, but I think this is a topic that needs to go to SFIREG often as a matter of fact.

MS. LOWE: We were actually at SFIREG two days ago.

MR. McCORMICK: I assumed that, but I just thought I better enforce it.

FEMALE VOICE: I have to say it's actually been to SFIREG a couple of times and it's been to the extension. Based on the discussion around the table, I might actually hazard to guess that our State and

Extension folks may have more broad knowledge than I'm hearing expressed by the label community, the product producers.

MR. JONES: I think you've given us exactly what we need. We clearly need more outreach and we'll get back to you about how we're going to do that. I think the idea of having a workshop is a good one.

I think that there are a lot of questions about

-- that we'll need to figure out and we will. How to tee

them up? How many to have? Should we focus them on

different sectors or have a big one?

But it's pretty clear we've got a job in front of us to get you and clearly a lot of others out there, as you tend to be the most informed, more informed, and then we can ask ourselves the questions how do you want to participate in choices that need to be made once you have a better grasp of the issue? Great. Thank you.

Well, I'm going to propose we just take a five minute break. Since you passed that last test, I'm confident you'll pass the five minute break test. And

then we'll reconvene.

(A brief recess was taken.)

MR. JONES: We're just going to talk about the budget now, resources, you know how much we spend on this or that and we will start without you.

FEMALE VOICE: Okay. Could everybody take their seat, please? I'm loud.

MS. MONELL: As you all hopefully are aware, I'm Marty Monell. I am the Deputy Office Director for Management in the Office of Pesticides. And today I'm going to talk to you a little bit about how we spent our appropriation last year and what we're hopeful for in terms of an appropriation for physical year '04.

Last year, if you will recall -- actually I think it was at the April meeting, we had just received our appropriation for EPA and that was after five months of operating under a series of continuing resolutions. We finally did, in fact, receive our appropriation in March.

Uncertainty was very difficult because in this particular instance we had no idea what our maintenance

fee situation was going to be because that was not provided for in the continuing resolutions.

We ultimately decided in December of 2002 to go ahead and send out a billing for the maintenance fees based upon previous years experience with the amounts that were authorized. So, we sent out billings for a total of \$17 Million to get the ball rolling in terms of our collections and ability to meet payroll and contract needs.

In May, after we had our appropriation, we sent out the second billing to collect the additional \$4.5 Million that was authorized. We had a total of \$21.5 Million authorized in maintenance fee collection last year.

This pie basically shows you what we did with the total of \$135.2 Million and in that \$135.2 Million the \$21.5 Million fee collection is incorporated into that total amount. So, this pie represents the expenditures of the total amount that we had available to us.

You'll see that salaries and benefits in

Headquarters are 63 percent of our budget, or \$85.2 Million for fiscal year '03. The portion going out to contracts and grants, our extramural budget, represents about 21 percent or \$28.2 Million.

The contract funds were broken out as follows -and this material, by the way, in more detail is in your
folders. The contract funds for registration activities
were about 20 percent or \$5.7 Million; for reregistration
activities it was 45 percent approximately or \$12.7
Million; our field programs accounted for \$7.1 Million or
25 percent of that contracts and grants -- again the
extramural slot of the pie; and information and
communications management \$2.7 Million or 9.5 percent of
the, again, extramural piece of the pie.

We received two Congressional earmarks. These have been fairly common -- I should say they're repeats from year-to-year. They total \$0.5 Million. And then our STAG funds, the amounts -- the grants to States and Regions, those totaled \$13 Million and that has been a fairly steady allocation.

The tiny little slice of the travel budge there, we had \$859.3 Thousand, which basically accounted for less than 1 percent of the total OPP funds available. \$46

Thousand of those funds we set aside for invitational travel to fund events such as the PPDC meetings, the CARAT meeting, any workgroups that we fund pursuant to agreed up activities by these fact committees -- the funds come out of that allotment.

About \$36 Thousand we allocate to the regions for travel so that they're able to participate in various activities that support our program in the field. And then \$15 Thousand in travel was used to support homeland security types of activities, which basically left about \$870 per Headquarter FTE for our travel fund. So, we're not -- we're a very large organization, but we don't spend our travel dollars frivolously for per capita travel fund.

Another slice of the pie, next to travel, is the administrative expenses. We spent \$2.5 Million on that of the total funds allocated or about a little less than 2 percent of the total fund. And administrative expenses

includes things like staff training, supplies, computers, equipment and furniture.

We really believe strongly that we're pushing the staff to do a lot more and do a lot more in a shorter period of time and to be accountable. And so we're committed to giving them the tools and the training that will enable them to do this.

About \$5.5 Million went into the working capital fund. Basically this is a fund that the Agency sets up that every organization contributes to and it funds things like our local area network, the LAN, desktop services for all of our computers, all of the web applications across the agency and for us in OPP, our service, the Agency mainframe, telecommunications. All of that we're billed for and so we have to set aside this pot of money for those expenditures.

Any questions about '03 at this point? Okay.

For '04, since we don't have an appropriation yet, the only thing that we can really address or talk about is the President's Budget and the President's Budget this year

includes almost a \$4 Million increase over our 2003 allocation and it -- we are anticipating an additional \$21.4 Million in fees. So, we're probably looking at about \$139 Million. This is the President's Budget proposal.

We've added -- we've picked up two FTEs or we hope to pick up two FTEs to help us with our homeland security efforts. We have been involved in a lot of activities, as you're probably aware, and it came out of existing resources. So, we requested that we get an additional two FTEs so that we'll have a total of 812.

Payroll dollars will be increased to almost \$6 Million, which would put us at the \$91.1 Million mark, which, if you'll recall, it was 63 percent of our total budget in '03. So, we're going up a couple percentage points in terms of our salary and benefits costs.

Some of the reasons for the substantial increase are related to -- first of all, EPA was given buyout authority -- I'm not sure if you all are aware of that or not -- recently and there is a short time frame during

which folks that are eligible for retirement and eligible under the rules of this buyout program will receive -- can receive a \$25 Thousand buyout bonus, if you will, plus they're entitled to all of their leave that has been accumulated. They can buy that out.

So, we're anticipating in OPP upwards of \$800

Thousand in payroll costs that has to come out of our '04

budget to accommodate that. The Agency felt that this is

really an important program to pursue with OMB and OPM

because we really need to get a handle on our payroll

costs. So the EPA program is targeted specifically at

higher graded employees, GS-14s, 15s and those in the SES

ranks. And then there are some other categories as well.

But primarily they were targeting the higher salaried employees for this buyout option. It not only saves payroll dollars, but it also provides a vehicle for succession planning in the Agency. We, like everyone else, are facing a vast majority of our upper graded ranks eligible for retirement. So, there was a method behind the madness, but it's going to cost us some money.

Another area that is causing the increase in our salary expenditures is the anticipated shortfall in the fee revenues and also there is a likelihood that we will, again, have to pay out of our appropriation for any cost of living increase that Federal employees get across the board. Each Agency will, more than likely, be required to pay for that out of their appropriated funds.

We've given a lot of thought to the issue of EPA, the program for pesticides being run so heavily by Federal employees -- why we have so many FTEs devoted to it, as opposed to running it primarily by contract dollars or other kinds of extramural resources.

We believe that the licensing decisions that we make in the pesticide program are inherently governmental. So that accounts for, you know, sort of a philosophical approach that we ought to depend on Federal employees to be a part of this decision making process.

We've also determined that it's more cost effective to have Federal employees run this program than contractors. We recently underwent a cost comparison

exercise under the FAIR Acts. You may have been reading some various articles about its implementation recently in various departments.

Well, EPA and the Office of Pesticides, in particular decided to go through the exercise. We really believed that if we matched what we do and the cost of what we do against a comparable activity by contractors that, in fact, our employees would fair pretty well and certainly be very competitive.

So, what we did was we put together what they call a Performance Work Statement and in this -- it's similar to a statement of work under a contract. And in that we looked at primary reviews of acute toxicity, product chemistry studies and survey reviews of inert ingredients.

So, we defined, sort of, the universe of activities that we were going to look at for this cost comparison. Then another independent team that was created, developed, sort of, an in-house cost estimate and by that they looked at the proportion of FTE salary that

went towards these particular efforts and we costed it out over a period of five years and projected what the FTE costs and what the dollar costs would be for each year.

Then another team of folks from EPA -- not even in OPP now. It went over to our Office of Acquisition Management. A bunch of auditors and procurement analysts. They took a look at four existing contracts that OPPTS has for doing similar type of work and -- similar type of work that was described in the original Performance Work Statement.

And based upon their analysis of the statement of work in the contract, the existing contracts, specific task orders involved and then periodic progress and cost reports, the team estimated, again, the cost of doing the work by these contractors, both in terms of FTEs and dollar costs. And they did it for each of the four contracts. They did it for a five year period of time and costed each one out over annually. And the result was that our -- the in-house estimated costs were significantly lower than those of the contractor.

The contract dollar of costs ranged -- remember there was four contracts. Ranged anywhere from 1.6 to 3.2 times greater than the in-house estimates. And the estimated contract FTE costs averaged more than twice that of the in-house FTE projection. So, it was nice for our employees, nice for us to have our theory validated, if you will, that, in fact, it is more cost effective for us to do the work in-house, hence our continued support of our FTE base.

More for the 2004 President's budget. With working capital fund, administrative expenses and travel, all of those little slices of the pie that I previously discussed for '03 -- we're projecting that they're going to remain about the same proportionate to the overall pie and we also anticipate that the STAG funds, the funds that are specifically identified to be sent to States and Tribes remaining constant.

We're, again, facing the realty of funds
available for contracts and grants to shrink again, and
that is inevitable in order to somewhere cover our

anticipated increase in the FTE cost.

So, we're projecting it's going to go down about 2 percent, which could be about a \$2 Million shortfall. In the past Congress, in our appropriation, as protected the registration and re-registration programs, so we can't take any money out of those programs to offset anticipated shortfalls.

So, most of the \$2 Million reduction that we're anticipating will have to be taken against our field programs and those field programs, in particular, that could be impacted would be all of our Outreach activities, the PESP program, the Certification and Training Program, Worker Protection, Negotiations with our Partners -- that includes the work that we do with other Federal Agencies, as well as with the Tribes -- our Endangered Species Program that you've heard that we're so actively engaged in, and our Water Quality Program.

Last year we faced a similar dilemma, I believe.

We mentioned this to you at the PPDC Program. We hadn't

made final decisions at that point, but we did. What we

did was we looked at all of the field programs and we looked at everything that we had spent money on the previous year that could be argued to be discretionary.

And in looking at the money spent, it --

(End tape one, side two.)

MS. MONELL: -- years, which we always will want to be supporting. But there was this \$3 Million balance hanging out there that had not been drawn against for a period of time -- a sufficient period of time that we believe that we could withhold the funds for that fiscal year from that IHE and still not have the program negatively impacted.

So, that's where the bulk of our cut went where it seemed appropriated to not fund. Unfortunately, after extensive negotiations with USDA and the stakeholders in the field, as well as APSI (phonetic), and I'm sure Amy would support this, we had many meetings and many discussions and we're finally able to get, sort of, a handle on exactly how the payment and reimbursement process worked. It basically was different -- the way

USDA handled the money and the reimbursement program was different than that which we had experienced here in EPA.

So, once we arrived at an understanding of how it worked and, through Amy's efforts, got the States to actually bill in a more timely fashion, we realized that the program was going to be underfunded -- that the State Extension Services were, in fact, going to be running out of money and would potentially face layoffs and shutdowns and so forth.

Well, that was exactly what we didn't want to happen. So, we had to make some last minute tough decisions and pulled some \$700,000 out of other field programs to which we are committed, to be able to fund this IAG with USDA. Then at the end of the fiscal year, through the good graces of Earlton Smith, USDA was able to find a pot of money to enhance that IAG. And so we ended up with about -- I don't know -- a little over \$1.1 Million for the IAG. Historically it had been funded at \$1.8 Million or something, depending on how much the recision was in any given year.

So, even when we think we've got an answer to shortfalls and we make some tough decisions, we're not always right and then we have to go back to the drawing board at the last minute and try to figure out, all right, what's the highest priority and then can other things be spaced out over a longer period of time so that we can get everything done that we need to. So, it's not a one a year exercise. It's ongoing. And that's it.

MR. JONES: One of the things I would like to get some advice from the PPDC on -- so you know, I tend not to be someone who takes a cut and then says, oh, well, it's 6 percent -- cut everything 6 percent. I just don't think that that's the way you should do business. I think you should have priorities, you should fund your higher priority things until something falls out of the bottom. It may take a 60 percent cut.

Given that that is the framework that I operate under, it is useful to know what people think of the priorities, so that I'm not doing this solely by myself.

I'm just saying here is what my priorities are. And since

we actually have a group of people who represent a pretty broad, if not complete -- close to complete set of the stakeholders here, as we go through it's going to be -- unless -- you know, for some reason that I can't anticipate, but, you know, miracles happen -- we actually see an increase in our contract dollars, I'm pretty sure we'll be facing some significant cut in that part of our program.

As Marty mentioned, typically you can really narrow it in on where the cuts have to be because Congress often protects a vast majority of our program and it tends to be the field programs. And so it's possible to envision -- we could do it by a conference call at the appropriate time -- where we come in with, you know, here are the programs that are on the table because all the other programs are protected by the appropriation, by the law. Let's talk about the priorities and see if we can -- I don't know if we'll get a consensus, but at least we get an opportunity to hear from you what you think the priorities are and then we make our choices around how to

distribute -- allocate the cut.

And so, get some sense from the group as to whether or not it's an exercise you think it's a useful one; is it just too small an amount of money for you to really participate. I don't plan on basically saying, you know, let's try to, as a group, make these decisions together. What I think is important is for the Agency to know what you think the priorities are so we can make choices that are more informed.

Or you could say to me, Jim, you know what you should do? You ought to, like, just take 10 percent across the top from everybody and that would be the best thing to do. And if the stakeholders think that, then that would be taken under advisement. Yes.

MALE VOICE: I had a couple of questions. First,

I was curious if you have a number on what legal expenses

arising from OPP decisions have been and how those have

been historically?

MS. MONELL: Are you talking about adverse costs
-- Court cases or --

MALE VOICE: Right.

MS. MONELL: Well, OGC basically has their own budget and I'm not even sure that it has been costed out by program office. If it's something you're really interested in, I could certainly inquire and get back to you on it.

MALE VOICE: Okay. And follow-up from what you're asking, Jim. I mean, just in light of what we were talking about earlier about endangered species and see Worker protection even mentioned here scares me. I mean, we've talked about, yes, they need to be more of a priority in the Agency than a seat on the cutting block.

It seems to contradict yesterday's discussion.

And WPS, especially from the farmworker side, boy,
implementation and oversight of it from our prospective
has been extremely weak. So we would welcome the
opportunity to talk more about those cuts.

MS. MONELL: We consciously did not cut a nickel from the Worker Protection Safety Program last year.

MR. JONES: Yeah, those two programs tend to, for

obvious reasons, because we think they're a high priority, tend not to be. That, sort of, gets to the issue of where you're just going to take -- you know, cut 10 percent across the top. That's what would happen and that has been something that -- that's something that happens a lot, I think, in Agencies when cuts occur.

Jennifer.

MS. SASS: I'm sorry. I thought you were going that way, so I can get ready.

MR. JONES: Sorry. I can go back over here.

remale voice: I just want -- I'm impressed and not surprised by your analysis that it's more cost effective to do the in-house work with your skilled technical staff than to out source. I'm not surprised with that and I know from my own short stint of reviewing the outsourced risk assessments are opposed to an -- (inaudible) -- for instance and some of the documents that are coming in now -- I'm currently reviewing the CAPTUM (phonetic) document -- and also a quote from Paul Lewis confirms that it is far more time and labor intensive to

review and fix inadequate assessments that come in from contractors that don't really fulfill the needs or the prospective of the EPA.

So I just want to go on record strongly supporting the Technical Staff and the decades of really scientific and risk assessment experience that the EPA has and encourage you to keep that as your most valuable asset.

And also, you might want to also consider throwing some more work at Fish and Wildlife, as I mentioned yesterday. I'm trying not to accost too much of their work, since they also have a tremendous amount of technical ability and experience to lend credibility to documents.

MR. JONES: Thanks. Larry.

MR. ELWORTH: I would actually be really uncomfortable with the thought that the Agency would put its programs in front of this group or any advisory group for their -- in terms of saying, which program we think is important.

I would be comfortable with this group saying here are the kinds of things that we hope you're looking at in the way you make decisions. I would be much more comfortable with that because, I mean, in terms of where people think your programs -- where the levels they ought to be in terms of priority for funding. I mean, we all have members of Congress and people in the Senate who want to help you set priorities that way.

So, I think I would be really much more comfortable with looking at how you make decisions rather than what the specific decisions are. Does that make sense?

MR. JONES: Yes, we get what you're saying. A little cautious bureaucrat in you there, Larry?

MR. ELWORTH: No. It's partly cautious bureaucrat and partly also I'm not sure we would actually give you any useful information after that. There are obviously programs that each of us would think are really important. At the end of the day all you know is that the four programs that we think are important we still think

are important, but it doesn't help you make a decision.

MR. JONES: Where I think you could -- we could learn something is if there's consensus around something that we wouldn't have thought there to be about priority, that that tells you something.

It's something that we've always put a priority on and you go around the room and it's last on everybody's list. That tells us something. I mean, that's the general kind of engagement. I don't expect we would get consensus and everybody's list would be the same. But if you find the same theme always at the top and the same theme always at the top and the same theme always at the bottom, you've learned something. That could really be helpful in how you go forward. So, that's, sort of, what I envision.

Janine and then Julie.

MS. RYNCZAK: I'm also not going to focus on what the priorities should be, but just on the economic analysis. First, I would like to commend that the Agency is putting more resources into a technology for -- when you're expecting your employees to produce more they need

tools to do that.

Second of all, I'm very fascinated and impressed with that study you did with -- I'm not surprised either, as Jennifer stated, that full-time employees are more productive. But when you compared the costs of the contract employees versus the full-time employees did you compare the cost of benefits? I'm assuming that the benefits are higher levels for full-time employees?

MS. MONELL: It was a fully loaded FTE analysis for employees of Federal Government and then it was the salary costs plus the overhead for the contract side.

MR. JONES: Fully loaded means benefits.

MS. RYNCZAK: Right. Well, that's great because I think that definitely shows that there is a very positive relationship between perceived jobs capability and productivity. So, I think that's something to consider. Thank you.

MR. JONES: Pat and then Julie and then Bill.

MR. QUINN: Jim, I guess I -- you know, I'm sure it must be appealing to do the 6 percent across the board

kind of approach. I mean, from the standpoint of not making any one division director less happy than another and can understand why you might go that way.

But I think your question goes to something I've wondered about for a while, which is the rigor of the budget development process for OPP and, sort of, how you ask your division directors in the budget development process to make their case on an annual basis for increases in funding and the complexity of the projects, the urgency of projects, relative importance of new initiatives.

I would be interested in just hearing a little bit, if we have a moment, about how that works because presumably that would help inform the question you're asking.

MR. JONES: Yes. Basically what I do, this being in this position, but I've done it in all positions I've had in management, is I ask all the division directors to present a plan of work. What are you going to do in the coming year, assuming you have a steady state of

resources? And then we all look at it in the context of are there -- is this going to be satisfactory for us programmatically, or are there enhancements or the things frankly that are not a priority for us, and use that to help inform where we need to invest more and we want to disinvest.

So, you know, basically there's an expectation from me that they're going to be committing to what they can do with what they've got and then you're looking around the margins for where you want to invest more. I mean, we've been pretty clear about where we think we need to invest more. I think endangered species on the top of that list and then optometry assessment to make sure we meet the deadlines of where -- so those are the two priorities we've articulated.

And then you try to figure out how you can do that without compromising other commitments that you know you can't throw the towel at. Registration is usually the bulk of that -- of that work.

In a nutshell, that is how we do it. Bill.

MR. McCORMICK: Yeah. I think you have a great opportunity -- I want to echo what Jennifer was saying about the analysis of the quality of the work of the contractors. I think what it does is when it's poor there's, you know, registrant rage often about the review that happened and there's a lot of work that then has to happen with regular employees to fix the analysis or whatever and make it right.

So, there's some opportunity, I think, in improving what the work of the contractors. But there's another thing. I was at a pine oil re-registration meeting. Six of the people in the room were contractors who were there, they said, normally to take notes. Six contract employees. They're strictly to take notes; only one of whom took any notes and actually one of the guys said I don't know why I'm here.

So, you -- I mean, if that's what's happening there's a lot of opportunity to hard manage the contract dollars and I think just extract maybe \$3 to \$5 Million out of \$19 Million out of the inefficiency of that. I

mean, they don't need six of these guys showing up to build an Agency because they've got employees they got to pay.

So, I think the Agency needs to go, you know what, send the one guy who is taking the notes and don't bill us for the other five.

MR. JONES: Thanks. And that's a contract management issue and I take that point seriously. So folks know, we cannot -- the Federal Government has got all kinds of rules that are govern by laws. We cannot turn contract dollars into FTE. We have a ceiling we can't bust by law. For us -- it's not by law. It's been designated down, but there's an Agency cap and that's 812 FTEs.

So, unfortunately we can't learn from this analysis and take contract dollars and turn them into FTEs. So we got to just be smart about -- our contract dollars.

MR. McCORMICK: I understand. I know it's not -I know you can't -- I know how hard it is to get an FTE.

That's, sort of, universal.

But, I mean, if they're soft dollars you can turn them to other programs.

MR. JONES: Right.

MR. McCORMICK: If they're soft. I don't know if they are.

MR. JONES: It's about managing them smartly. Right.

MR. McCORMICK: Yeah.

MR. JONES: Yes.

DR. LIROFF: I'm glad to see that your analysis shows that it is cheaper for government employees to do the work. I may be saying the obvious, but, you know, a major difference between having one of your employees, one of your career employees doing the work and having a contractor doing the work is the contractor is basically trying to make a buck, makes his or her services available to the highest bidder, and I would like to believe that those who are working for the Agency are committed to the Agency mission of protecting public health and the

environment.

I don't know that you can put a price on that and I think that commitment to the Agency mission influences what the quality of work is going to be. I understand there's -- you know, there's a desire in a lot of sectors to, you know, prefer the private sector over the public sector. The realty is there's no way you can capture commitment to organization of mission, whether it's EPA employees in many cases, whether it's archeologists and National Park Service, whether it's people committed to wildlife protection in the Fish and Wildlife Service. You simply can't put a price on that.

At least, thank goodness, your analysis of the things that are measurable support the idea that work should stay -- is better down with the public employees.

MR. JONES: Thanks, Rich. Phil.

MR. BENEDICT: If you're going to have a group look at cuts I think the States want to be involved in many ways. You do the registration process and the States do the field activities, and I think it's that combination

that made this program successful.

There haven't been many increases in funds and certification and training in many of these programs and pressures are in the States as well as they are at EPA, so I think you need to be careful where you got those programs.

MR. JONES: If we do it -- and I'm definitely not hearing an arousing rally to do such an exercise -- we would need to do it with the PPDC. You have to have -- to get that kind of advice you need to operate under the FACA rules and this is our FACA. But since, Phil, you are here as a representative of State lead agencies, this would be the form we would use. Nancy.

DR. LEWIS: I just want to be an example, I guess, of what Larry said and talk about -- I feel moved being from a land grant university to say something about the extension program. I think there is an impressive set of data collected on exactly what is done with that money and it seemed like it is well used.

So, I just want to speak to trying to make that

available. It seems like it would -- the background information provided would save problems in the long term. It seems to me like money well spent.

MR. JONES: And Julie.

MS. SPAGNOLI: On these programs, especially these ones that may be subject to reduction that they listed, I guess I would suggest that we look -- that the Agency maybe look for opportunities where costs could be shared with other programs. And I think Jennifer mentioned that even with Endangered Species with Fish and Wildlife Service, either -- instead of cutting the program -- and there are opportunities maybe to share the costs somehow with, you know, Fish and Wildlife Service or with the Office of Water. If it's a program that the two programs can jointly work on, it may be a way to find synergies.

MR. JONES: All right. Well, you know, again, I did not hear, sort of, a consensus around any particular approach, but we'll go back and think about what you want to think of as the next step with respect to the PPDC. If

we were going to ask you to give us some advice around priorities we do it by conference call because we can't wait to make choices until our next meeting. Like we will be making these choices in December/January time frame depending on the speed with which the appropriation arise.

Thanks a lot. Thanks, Marty. Mosquito Labeling.

Is Jim Roelofs here? Yeah. All right.

This is an issue that we talked about at the last PPDC. We teed up a number of issues and got your feedback on that. We also described a process that we were going to use to try to bring these issues to resolution, and I think today we're going to hear from Jim on our tentative resolutions and our plans for going forward. Jim.

MR. ROELOFS: Well, let's see if I can actually run this machine and talk at the same time.

Okay. At the April meeting, as you probably recall, we had a panel discussion about issues surrounding mosquito labeling, and we are -- what I'm going to do -- I'm not comfortable with this. Just a second.

What we're going to do is -- I will remind you of

the recommendations that we brought in at that time. This was an informal group of EPA and State regulators, who had been discussing their concerns about mosquito control labeling for sometime and put together some initial recommendations or ideas for discussion and we brought them to this committee to get an input -- comments on them -- recommendations as to a way forward and also whether we were basically on the right track in general. And, in general, we got positive response.

One of the things PPDC suggested was that we do some more outreach to groups that were not there or had not been contacted up to that point, and we did do that. So, as I go throughout this I will, kind of, comment on some of the feedback that we got, which led us to modify some of our approaches.

Specifically, the American Mosquito Control
Association gave us comments and we also got comments from
several USDA Agencies, consolidated by Al Jennings'
office. Thank you. That was useful. And also two
members of the panel -- of the committee, RISE and

National Pest Management Association, also subsequently sent in written comments.

So, I'll be making reference to that.

And, of course, I'll be spending most of the time talking about where we are now because some of the things have, in fact, changed a bit. We brought seven initial recommendations and we still have seven recommendations, but they're not quite the same. I merged two of them and added two new ones.

So, of course, we're asking for your comments on the process on how we should be proceeding on, for example, whether we need some more outreach or just charge ahead with a draft PR notice, which is the course that we are now taking. We ask for your comments today and afterwards, if possible, on the recommendations that we now have, which are somewhat modified.

Two specific issues I'm going to zero in on, which we'll get to later, and this is language which kind of authorizes special circumstance uses of these chemicals. And, of course, your suggestions for next

steps. We're planning a PR notice, but if there are other things that we should be doing as well, please feel free to say that.

Now I'm going to briefly run through the recommendations that we actually brought to the April meeting, and I had to -- I'm not going to print them all out because those are no longer specifically on the table, but these are descriptions of them.

There's a feeling that applicators should be trained and the suggestion that, perhaps, restricted use was the way to do that. I'm going to go through each of these later, so this is just a quick summary.

There was concern that some labels have instructions other than mosquito control on them and that just confuses things. This specific term is an example of one that causes some confusion.

There's broad inconsistency in the way current labels deal with precautions related to water and aquatic organisms, and so we are seeking something that would allow application over water, if needed, to target

mosquitoes. That was the recommendation we brought.

A feeling that hazard language should be as specific as possible. This means species specific, rather than general terms like aquatic organism.

There was a recommendation that applicators be advised or directed to consult with a State lead agency to find out if there were State level permitting or other requirements. And finally, there was a general statement that calibration instructions needed to be improved and that's all it was. That was just a one sentence statement of the problem.

So, the overall problem with mosquito control labeling is inconsistency and these seven items identified things that that initial workgroup thought would benefit from having some models put forward for the industry. I mean, that's what a PR notice is -- it's addressed to the Pesticide Registrant community -- and it's the tool that we typically use for trying to achieve label improvements.

So, let's go through what we -- in more detail what's happened since then. I'm using this then/now

format. Then refers to the April meeting.

The suggestion was perhaps voluntary restricted use was mentioned in our recommendation in April or some other way to ensure trained people are using these things. Remember we're only talking here about adult mosquito control products applied as ultra-low volume sprays or fogs, and this is a fairly -- well, it's a very complex use pattern. We're not talking about larvicides, which is a wholly different use pattern, and we're not talking about any home use products.

These are things that are dispersed over a wide area, mostly by trucks and airplanes. It can be done by backpack, but for the most part this is -- this is done by public agencies or sponsored by them and covers wide areas that often include residential areas.

So, everybody agreed at that meeting, as I recall, that training was really a good thing, but not all agreed on how to accomplish it. The comments we received were mixed. Some people thought restricted use was the way to go, but a lot of people were pretty vehement that

it was not the way to go. They thought that restricted use should be a tool to address and identify potential for unreasonable adverse effects, and that that was not the case for most of these chemicals, and, also, it's very unlikely that registrants would voluntarily do it.

The thinking that we have now is that they're basically correct in those objections. It's very unlikely it would be voluntarily done and it's not necessarily the best way to go. So, this is the language that we're contemplating now and --

I don't want you to zero in on the exact words here. I had to condense -- I'm just trying to convey the approach. We're not locked in by any means. We're still in a drafting process and your comments will be welcome on how to deal with this.

But it would be something like this. For use only by personnel of public health or vector control agencies, or persons certified in appropriate category for mosquito control, or people supervised by such people. That's the general direction that we're heading in.

And the logic of this, aside from the objections to restricted use that I just cited, is that public health and vector control agencies do train their people. It may not be through the State certification process. Maybe their own. And it's likely -- and if that's the case, it may very well be better training because it's highly specific to their need, whereas the State program may, in fact, have a relatively small amount of mosquito training shoved into another category and there's no consistency among the States.

Very few actually have a mosquito control category for certification. Some have a public health category; some even put mosquito control in the general use category or even structural in some cases. Don't ask me why.

But our thinking is that this language gets to where we want to be. An identifiable group of people who have been trained. So, this is the direction we're going in.

The clarification issues, I don't think, are

particularly controversial. In April we had two, which are really the same issue, which is to make it very clear -- oh my goodness, the typo. Sorry about that.

Completely separate and different from nonmosquito labeling. And so I simply merged those into one recommendation, which are essentially the same.

This issue about terrestrial uses -- I think we did discuss it. It's a term of art that we use on labels and it's -- when it appears the whole statement is very standard and it appears on literally thousands of labels.

It says for terrestrial uses do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Unfortunately, we do not intend terrestrial uses to include mosquito control and that information is in our label review manual and has been, but how could a person reading a label know that. And so they do not apply to water or the areas where surface water is present can really complicate the interpretation or hinder an

application that otherwise would be all right.

So, the thinking is if it appears on a label it should be qualified by saying see separate instructions for mosquito control. And if it's a mosquito only label, it shouldn't be there at all, although it is on some current products.

The water precaution language. Again, there are serious inconsistencies between labels and how these precautions are conveyed to the user. All of these products have a statement about toxicity to aquatic organisms of some sort. Some go beyond that.

So, the recommendation such as buffer zones for some products, or do not apply over water for some products -- well, here is a product, Naled, that says do not apply over water except to target areas where mosquitoes are emerging or swarming. This is the language that we brought to the April meeting and we're still thinking that that is appropriate, although we've tweaked it a little bit to make it even more clearer that it is a targeting thing -- water is never the target -- except to

target downwind areas where mosquitoes may be present.

Our thinking is that the ability to apply over or near water is needed at times to effectively treat a mosquito population, and that some of these other things, like buffer zones or avoid application over water, which is the Resmethrin (phonetic) language, either interferes with a legitimate and needed application, or it simply leads people to choose another product that has a more flexible label.

The species specific hazard statement is not -it drew no comments and I don't think that's controversial.
We think it would be better if a label said this is toxic
to fish, clams -- you know, oysters, whatever -- whatever
the data will support rather than something vaguer than
that.

Consult with a State Lead Agency. We thought it was a good idea then; we still do. Our workgroup, since it was made up of, in part, State Lead Agencies thought that that was reasonable. The current label situation is most are silent, most do not refer the user to any agency.

So, the general premise -- ignorance of the law is no excuse.

If there's a State requirement out there, it applies regardless of what's on the label, and some labels refer the user to the State Fish and Game Agency, which a lot of vector control people have told me is not appropriate in many States. The State Fish and Game people don't know anything about pesticide regulation.

The State Agency is usually not the Agency that has permitting requirements, but they know about them and they are the most likely to consistently know if there's regulations that effect pesticides.

So -- some of the commentors, however, thought that -- they perceived it as a potential burden because it sounds like if you say before the first application season consult with the State Lead Agency for pesticides, well, how -- is that meant to be enforceable? I mean, does -- and, if so, that implies a record keeping requirement and so on? So, they objected on the grounds that it sounded like a burden and little value added.

However, we still think it's a good idea to encourage compliance with environmental measures, even if we don't know what those are. So, our thinking now is that we'll still refer the user, but make it very clear that it's advisory and that there is no intention to burden the State Agency with records or whatever.

And finally -- well, no, this is not finally.

Calibration instructions. In April we simply had a general statement that they needed improvement, that labels are very inconsistent. What we're trying to work out now is a specific statement that can be a model, in which we will ask the registrant to identify droplet spectrum.

For example, the medium -- am I using the right term? Volume medium diameter? Is such-and-such. Take 20 microns. And no more than X percent of the droplets are above 50 microns and no more than Y percent is above 100 microns. And then refer the user to the equipment manufacturers', the nozzle manufacturers' instructions to achieve that spectrum.

This is actually a little more problematic than it looks because it's a question whether nozzle manufacturers are, in fact, providing adequate information and we think we may have to touch base with that industry, but we're willing to do that.

Now finally, we came up with some new issues. So these were not presented and not discussed at the previous PPDC meeting.

Repeat as needed. This phrase occurs on virtually all mosquito control labels. The only one that I know of that has a specific limitation is the new label for fenthion and, of course, fenthion is on the way out. But it has a seven day limitation. Do not treat the same site more than once in seven days. That's the only specific frequency limitation that I know of. Most of them have this or a variation of it.

And that presents us with some problems. Our labeling regs say that use direction shall include frequency and timing necessary to achieve effective results without posing unreasonable adverse effects. I'm

afraid, repeat as needed doesn't quite do it.

We're also concerned that it sets up fertile ground for misunderstanding, that a vector control agency might have a different reception of as needed from the general public and the regulator is kind of left scratching his head also as to what's appropriate, what's legal, what's safe.

And, of course, it doesn't help EPA either.

Eventually we do risk assessments on these chemicals and we make assumptions about how they're used and so on, and we get to this use what do we assume? What is as needed means? What are we going to do?

Well, we have to think up a scenario. Perhaps, a typical use scenario, or a worse case scenario, or something. We have to make assumptions, which have little foundation.

However, we recognize that if you put frequency and timing limitations, public health protection may still require retreatment of an area in a way that cannot be predicted. And it is certainly not our intention to set

up any kind of arbitrary numerical barrier to a public health application, hence the problem.

Our thinking now, in my PR work group, is to ask registrants to go ahead and specify a frequency and timing limitation. They have the environmental fate data; they know the toxicity of their chemical. It should be possible for them to come up with something reasonable. But at the same time, we want to craft a label statement that will allow treatments over and above those limits, if needed, for public health protection.

This is something I really -- we're asking the committee to zero in on. If you do not wish to zero in on it today, think about it and e-mail me, which is --

How can we do this? How can we credibly and effectively make an allowance of this kind? It isn't that it hasn't been done. Actually there are some models out there. The fenthion label is an example, which uses some language along these lines, and there are others as well.

What we're thinking is something like this. Do not apply this product more than once every X number of

hours, or to the same site, or more often than X number of times in a month, for example. Except when a threat to public health has been declared by a State or local health department. And, perhaps, we should include vector control agency. That threat to public health declared by language does occur on several current labels.

Another approach that we're thinking of is the second one there, except in accordance with recommendations of State or local health departments.

What we're trying to get at there is the idea of criteria.

That those agencies may set things like trap counts, the presence or absence of a known human case of disease, that kind of thing as criteria that would be considered triggering the allowance of extra applications.

I'm using the word "threat" here quite deliberately. We're avoiding the use of the word emergency for two reasons. Threat is anticipatory, rather than after the facts, and States may avoid declaring emergencies because it causes panic and so on.

However, if anyone has suggestions about another

way to get at this to authorize this kind of additional treatment in an appropriate way, we'll certainly welcome comments on that issue.

This isn't wholly new. At the April meeting we did give you all an issue paper and that issue paper had at the end of it a brief mention of the bee protection issue. However, we didn't have a specific recommendation on it.

The issue of bee protection language is that the current statement, which has been standard for 20 odd years, reads, give or take a few words, something like this. Do not apply this pesticide to blooming crops or weeds when bees are visiting the treatment area. Some of them say, actively visiting the treatment area. Whatever

There's no exception to that sentence. It is an imperative sentence. It has no exceptions. So what that does, in theory, is it could make almost any daylight application in warm weather in an area where there might be blooming anything a violation.

Now luckily most mosquito control applications are made in the evening, at night or the very early morning. When mosquitoes are active, bees are not active. This is a good thing. So, for the most part mosquito control doesn't have a track record of being a huge threat to bees. But it can happen, as I said, if daylight applications are necessary.

So, our thinking is, again, as in the previous case where we talked about frequency limitations, someway to authorize it in response to a threat. So, the first part of this refers to that, except when a threat to public health has been declared or whatever language we think is appropriate.

Or, if authorized by the State as part of a natural disaster recovery effort. What I call the hurricane clause. In fact, that's exactly what it is because that's where the issue came up was Hurricane Floyd. It caused very widespread surface area flooding in Virginia and North Carolina and had to be treated during the day because the Air Force was doing it with fixed wing

aircraft. They wouldn't fly at night and they were covering 60 to 100,000 acres a day from these tankard planes loaded with the stuff. And they killed some bees.

No question about it.

So, I think this authorized by the State language also occurs on the fenthion and we think it's appropriate.

And that's pretty much where we are now. What I would ask of the committee are comments now. I'm going to take notes. Of course, I will have the transcript. But also that's my e-mail address and you're more than welcome to send any comments on these specifics. If you have suggestions for additional outreach, we would like to hear them.

The Pesticide Regulation Notice that I have in draft could be published this winter if we really push ahead with it and that will be another opportunity to comment when you really have specific language in front of you. Right now, we're basically discussing approaches.

And, Jim, at this point do we want to ask Bill

Meredith to say a few words?

MR. JONES: Yes, that would be good.

MR. ROELOFS: Right. Bill Meredith represents the American Mosquito Control Association and requested to make some comments before we open for general discussion.

MR. MEREDITH: Thank you to Jim and Jim for the opportunity to address the group. This is the first PPDC meeting I've attended and obviously as representing the American Mosquito Control Association, we're kind of an important stakeholder in the decisions that the EPA is making here.

I'm the Director of the State of Delaware

Mosquito Control Program and we're actually right there on
the front lines, quite affected by the decisions that are
made here. In our little three county state, we do
everything for mosquito control. The surveillance, the
monitoring, the treatment and dealing with any of the
public relations issues that come about as a result of
that type of effort.

I'm also representing the AMCA. I'm the Mid-

Atlantic Regional Director. I'm currently serving in that capacity and I was drafted about two days ago to come over and observe and, if possible, make some comments about where we are right now with addressing this label issues. So, living in Delaware that's, I guess, a penalty being close to DCS. I, sort of, got drafted to come over and do this. But I'm glad to have the opportunity. So, again thanks --

(End tape two, side one.)

MR. MEREDITH: -- issues on the labels got a lot of attention due to the West Nile Virus outbreak. All of a sudden there was a really enhanced notice by the public and by regulatory agencies what does mosquito control have to do to control mosquitoes.

In looking at our practices, it was obvious that there were problems on the labels. There was often conflicting or confusing language about spray practices.

One part of the label said you could do A, the other part of the label said no you couldn't do A. There were also environmental hazard statements or human health statements

that were kind of alarming if not given proper context.

So, there were problems with the labels.

The EPA conducted a workshop almost four years ago, started taking a comment from a wide range of constituency and at first the progress, I think as a result of that meeting, was kind of slow. But, boy, it has really speeded up and the resolutions that Jim has proposed here this morning, it's a quantum leap from where we were only about -- for a little over, maybe, three, four years ago.

So thank you very much to the EPA for getting us to this point, and I think we're probably on the verge of adopting some of these that make a lot of sense. They're very practicable; they're very reasonable and it will help make the lives of us, as applicators, better and still the public will be very protected, I think, in adopting what's being proposed.

What I want to do is quickly tick off some specific comments to some of the proposals this morning that we just heard from Jim to, sort of, give you an

update from the prospective of an applicator and from the American Mosquito Control Association.

We agree with the issue of how to address who can use the product. We didn't want to see it -- all of adulticides declared restricted use. I think the compromise that has been reached is good. There is a downside to making everything restricted use.

That is a connotation that really isn't helpful, but what is being proposed is the reality that most of these products are put out by trained, qualified people working for public vector control agencies and that -- that's, sort of, the limited use of the product -- that's good -- and you also have to be appropriately trained if you are in the private sector. So, I think what's being proposed handles that pretty well.

The issue of being sure that if there are things on the label specific to mosquito control that they stand out as being specific. We had a taste of that this summer with some of the language with spray drift mitigation that's being proposed where the US Fish and Wildlife

Service went to issue the State of Delaware a special use permit and actually put into the permit conditions for applying aerial adulticides that were appropriate to crop land spraying. It was absolutely absurd.

But there was some confusion on the part of either identifying what's applicable to mosquito control and what's not, or the US Fish and Wildlife Service had trouble interpreting, at least, what is out there. So, there were some absurd conditions applied in the labyrinth of the bureaucracy of the service. It took almost a month to undo, but finally we got that straightened out.

So, it is important to distinguish clearly on the labels what would apply to mosquito control practices versus what wouldn't.

Great progress was made concerning the issue of spraying over water. That was one of our biggest problems four years ago. When somebody would read the label that says do not apply over open water or do not apply over rivers, ponds, lakes, streams, bays, essentially what they were getting at don't apply over waters of the US. Now,

wetlands are waters of the US and quite often when we apply adulticides it is to control mosquitoes that have emerged, they're swarming or they're staging as adults over wetlands. We were actually in violation of the label if you interpreted that part of the label that says do not apply over water. I think those wetlands are waters of the US in great part.

What's being proposed now will go a long way towards resolving that. I think Jim's statement is do not apply over water, except to target downwind areas where mosquitoes may be present. I'm not sure if we have to say downwind areas. You just might want to say areas where mosquitoes are present and you probably want to say adult mosquitoes since this applies to adult -- labels to adulticide products.

The downwind aspect, I think, was probably to address the practice where you may be doing stack spraying or offset spraying over water, or you intend the product to drift into areas where the adult mosquitoes are. And that's a subtle to here that if you want that clarified

fine, but some people might find that a little confusing because quite often we will spray just to treat within the swath. We're not necessarily targeting something downwind.

So, adding the downwind adjective helps, but, you know, maybe it's something that could cause more confusion. So, perhaps just saying do not apply over water except to target areas where adult mosquitoes may be present captures an awful lot of things there.

The hazard statements. I'm going to go for a home run here and I think it's the third time I probably proposed this to the EPA, and there's some reluctance, I think, to adopt this and I can understand both sides of the argument.

But when we deal with some label statements that say -- well, let's take an example. This product is toxic to fish and aquatic invertebrates. Or a statement, do not allow contact with skin. That's primarily intended for the undiluted full-strength product or for people that spend a lot of time handling the product. Applicators,

mixers, loaders.

When the product is used in accordance with all the label instructions there really is very little risk.

It's a dilute application and it's an infrequent exposure to the public. So, we're, as front line applicators, often confronted by the public or elected officials saying how dare you use this product. It is toxic to fish and aquatic invertebrates. Or, don't let my little boy come in contact with it. When you spray it, doesn't it contact his skin?

What's the retort that we have? Well, we're put in a tough situation of what do we have to resort to. And the EPA has helped us out very nicely on their web page by updating things and coming with a statement that we've seen many times now on the EPA's website in regard to mosquito control products.

It says something to the effect that when this product is applied in accordance with all label requirements it has been determined to pose no unacceptable risk to human health, wildlife or the

environment. That says a lot. It really does. I think it's a beautiful statement.

It addresses the real world of how we use the products. It doesn't pose unacceptable risks. If it did, I wouldn't be using it. I work for a State Fish and Wildlife Management Agency. That's where mosquito control is housed in Delaware. If I can't believe that statement, I wouldn't use the product.

So, it would be nice if EPA could put something like that on all registered mosquito control products -- that they can be used without posing unacceptable risk. I think it's a realistic statement.

If you don't believe EPA science that doesn't alleviate that problem and it wouldn't be intended to. It doesn't attempt to define what is acceptable risk, what isn't. That's always subject to debate. But it would help provide some leavening to offset those very bold stark statements -- this product is toxic to fish and aquatic invertebrates or if you're human, do not have it contact skin.

It puts it in a good context. When used in accordance with all label requirements it doesn't pose unacceptable risks. It's just something, maybe, you really can't adopt because of concern about, perhaps, you're going too far.

I don't think it's a product endorsement. It certainly doesn't get into a marketing issue because you would apply it, I think, to all products. It will be helpful, real helpful to people on the front lines using the product in terms of allaying the public's fears. You know, you consider levels of risk and the EPA, based on good science, says that it is acceptable to use.

We're in agreement with the consultation with the State Lead Agency. I think it should be advisory. That avoids an awful lot of potential problems.

In terms of specifying spray droplet spectrum, that's good. Let the registrant or the manufacturer do that. Something like that should apply to all products and be as product specific as possible. Don't try to over-standardize your droplet size spectrums. You're

really going to have to customize that to the products, and I think that's the intention of the EPA to do that.

The "repeat as needed" -- that's a really interesting problem. I don't have an easy answer for that outside of what will chime in here from the standpoint of a Mosquito Control Agency. If the registrants define the rate of application and the frequency of application, the timing, that's fine. That's going to be based on good science that the EPA will scrutinize.

But then if you want to go beyond it, I think you really do have to involve several players here. It's when the threat to public health is identified -- probably the word "identified" is better than "declared" because "declared" has some type of official connotation of some type of emergency.

But maybe when the threat to public health is identified by a State or local health department or by a vector control agency because, quite frankly, in many states public health agencies are clueless about the need for vector control, particularly in the preventive mode.

Public health agencies become pretty good in terms of reacting to a problem, but they aren't really at the forefront of preventing problems. That goes back to, usually, the vector control agencies.

So, I think that call could be made by both the public health agency or vector control agency -- and I know you're into this issue of accountability. Who makes the calls? It's going to vary widely from State to State. So, I think you got to allow for a lot of latitude in terms of who makes that decision.

And then, finally, with the bee issue, that's good. That does allow us to deal with some real world situations where we do have to apply during daylight if we have a public health emergency or if we have some type of a natural catastrophe. We go to great lengths in notifying beekeepers when we do spray. Most States have pretty good protocols about getting their beekeeping associations involved in knowing about our activities. But this would allow that to occur in daylight without being in violation of the label.

So, those are the comments I want to make. Thank you very much, Jim and Jim. Thanks.

FEMALE VOICE: (Inaudible.)

MR. JONES: Well, you actually know them though.

FEMALE VOICE: Okay. I'll call them. Allen.

MALE VOICE: This may be a question that reveals my own ignorance, but I'm wondering whether there are actually data available that indicate that spraying with adulticides reduces and controls outbreaks of West Nile virus, or whether it would be more effective to exhort people to drain standing water, use repellents containing DEET and wearing protective clothing.

MALE VOICE: Well, as a self-appointed expert here -- no, there are experts here who could probably answer that. But I think the emphasis on every program that I've ever heard, including the guidance issued by CDC, is, by all means, larvicide. Get rid of breeding grounds. Do everything that you can before you get to adulticide. That's the preferred strategy.

MALE VOICE: It certainly is impressive to have

helicopters flying over your house spraying at a time of perceived emergency, but whether it's really effective or not, I think, is an important question.

MALE VOICE: I think at the last meeting of this group, the Maryland Mosquito Control Director had some interesting numbers pointing out differences in Maryland counties adjoining the District where they did do aerial application for adults and in the District where they did not. It showed interesting numbers of higher frequencies of West Nile infestations in the District. Again, that was just a snapshot in time.

FEMALE VOICE: Can I comment? This is obviously a subject that's near and dear to my heart. For those of you who don't know me, I'm a veterinarian. I did three years of post-doctoral veterinary work in epidemiology. So, this truly is something that I have a strong interest and background in. And I also have a strong interest and background in public health.

In terms of the comment that Allen just made, I think that the figures that Sy Lester (phonetic) was using

in comparison with Washington DC versus Maryland was the fact that, at that point, DC had -- I don't believe had begun doing any type of preventative or very little preventative work. And in the past year, they have begun doing exactly what CDC has recommended, which is the larvaciding, the reducing breeding grounds.

CDC has put out some very impressive recommendations. There are about a hundred and some pages. They were put together by industry, by CDC scientists, by epidemiologists, and CDC -- and I've spoken extensively with CDC folks on this and vector control folks, and they, themselves, have said that spraying is the least effective method of controlling West Nile.

It doesn't matter if you came in and you put off an atomic bomb tomorrow with mosquito spray in the United States. You would not get rid of all the mosquitoes that are out there. They've already laid eggs. They're already going to breed.

So, anyway -- but aside from that -- so, no.

You're right. Spraying is not the most effective method.

I do have some -- and I'm sorry to interrupt you,

Jen. I do have some very serious concerns about some of

the things that were presented here.

Number one, we did have, as many of you know, a very long discussion on restricted use -- whether there should be restricted use at the last meeting and I think several -- and I think there were quite a large number of people on the PPDC committee who felt that it should be restricted use.

And while some people have said the risk doesn't justify that, I think the fact that you're dealing with such broad exposure to a nontarget species does justify that. And, yes, I understand that mosquito control folks have training, but as -- you know, and I will bring up the same example I brought last time. If I'm going in for open heart surgery my general practitioner has a lot of training too. But am I going to go to him or am I going to go to a cardiologist? I'm going to go to a cardiologist with specialized training.

And I think given the broad distribution of

pesticide sprays and the broad exposure to nontargets, I think that restricted use should be strongly considered.

Some of the issues here as well, I have some real concerns about the slide 12, repeat as needed. I think asking the registrants to specify the timing and their frequency is inappropriate. That needs to be coming from EPA.

One of the issues that we've dealt with over and over again with fenthion was the fact that the spraying was just way too frequent. Birds, which were the main nontarget that we were obviously concerned about, did not have time to recover from the cholinesterase depression.

Right now the fenthion label says every seven days, although I understand at least one of the counties in Florida that has managed to get an exemption, is doing it every four days. However, prior to this label the spray records from 1998 through 2000 from Florida indicated some counties were spraying as frequently as every two days between June and September.

So, I think it would be -- I think the

environmental issues need to be looked at. I understand this is an extremely complex issue when you're trying to balance public health with environmental health, and I understand the need to protect public health. I'm as concerned about my health and the health of my family, as is everyone else here, but I think it's inappropriate for someone other than EPA to make those decisions.

As far as working with the local health department or someone else to determine when spraying should occur, the person from the American Mosquito Control just said he feels that it shouldn't be when a public health emergency is called, but rather when a public health emergency is identified. That's just way too vague.

We're sitting here right now in Arlington County

-- I'm sure all of you have walked either from the Metro

or to the -- you know, to park your cars in Boston. Were

any of you concerned during that time about getting

rabies? In the few blocks that you walked were you

looking around thinking, oh my God, I hope I don't get bit

by a rabid raccoon? No. But you know what, we have a rabies epidemic here in Arlington and the medical definition for an epidemic is when any -- anytime you have one case above normal that is -- that is the medical definition for an epidemic.

So, to say that someone should be able to identify it as a public health emergency is just way too vague. We really need to have someone who is an expert in making that determination. I don't think it's fair to have -- to have that vague description out there. Frankly, anything can be a public health emergency.

We have West Nile virus. We have Eastern Ecline encephalitis. We have a number of vector diseases out there. So, in reality you can say there's a public health emergency every day of the year in every State in the United States.

The person from American Mosquito Control also talked about the fact that he had worked or they had worked with the Fish and Wildlife Service and the Fish and Wildlife Service had come up with some rather absurd

requirements for them. That tells me that clearly Fish and Wildlife Service is not involved and educated enough about this issue. Someone from Fish and Wildlife Service should be here right now. They should have been invited to this meeting because this is an issue that involves wildlife and natural resources. And so that tells me that there is obviously some lack of communication there if that's happening.

In terms of the bee protection language, I
wondered did he -- has EPA contacted anyone from, for
example, the North American Pollinators Protection
Association or any of the other major bee associations.

MR. ROELOFS: One of our staff is a member of that.

FEMALE VOICE: Okay. Because I think that they do actually have a pesticide working group -- subgroup --

MR. ROELOFS: Right, they do.

FEMALE VOICE: -- and it would be very important,

I think, to ask them to give you formal comments on that.

I think that would be appropriate.

Sorry. I obviously wrote down a lot of notes as we were going through here.

Also -- my other concern was that the person from the American Mosquito Control had some pretty strong feelings about the hazard statement and made the comment that when a label states that a product is toxic to aquatic animals or to invertebrates, it's referring simply to full concentration of that pesticide. That is absolutely untrue.

Chlorine bleach has -- you know, has toxic effects. Would any one of you be willing to drink choline bleach if it were diluted down half with water? No.

You know, as a veterinarian, you cannot -- I can tell you --

(Inaudible conversations.)

FEMALE VOICE: Well, that's just it. I mean, what's not toxic to a human may very well be toxic to a bird or a shrimp because you're dealing with a smaller size, you're dealing with different exposure issues.

So, to make the broad statement that when

something says it's toxic to specific species, that it means at full strength, that's not true. How much dilution you have to do depends on the species, depends on the physiology, depends on the exposure rates, depends on how often they're exposed. It depends on a lot of different things. But it's completely inaccurate to say that it's only at full strength. That just isn't true.

Sorry. I'm not done ranting. It passes over to you.

MR. JONES: That's Betty. Jennifer.

MS. SASS: Some of my comments were touched on, but actually I wanted to just say I think that the beekeepers should be involved even in these kind of discussions. I mean, if you invite someone from Mosquito Control, then if the issue is bees, have someone from there because I know they're well organized. I've been working with them.

I have a question. It was in the phrase that you guys spent a lot of time discussing the downwind issue, but I actually am more concerned about a word change and

it's from mosquitoes are to mosquitoes may be present.

How did that arrive?

Do you want to throw it up? Do you want to throw up the slide and see?

MR. ROELOFS: Do you remember which slide it is?

MS. SASS: No, because I don't have copies of them. But it was the one that had the downwind statement and there was some discussion that you wanted to remove the downwind.

FEMALE VOICE: Slide seven.

MR. JONES: Slide seven.

MS. SASS: But the language actually changed from mosquitoes are swarming to mosquitoes may be present. So, there's two issues there. The are to may be and then there's the swarming to present, which gets into the probably the daytime versus evening spraying issue without saying so directly.

And those are my two concerns is how did it get from are to may be with no discussion; and how did it get from swarming or emerging, which is obviously when you

want to hit them, to may be present, which opens up the possibility of spraying during times that aren't effective?

Those seem to me to be major issues.

MR. ROELOFS: I agree. That's an issue. But don't say there was no discussion. I mean, these are developed by a workgroup.

MS. SASS: Okay. Then --

MR. ROELOFS: The workgroup --

MS. SASS: Then I'm concerned about the weakening of the language --

MR. ROELOFS: Okay. That's a good point.

MS. SASS: -- to what appears to me to be a lot of spraying at times where I don't think it would be effective. I'm all for, like, not having mosquitoes bite me, but there is an issue of daytime spraying and things that just aren't effective. And that's kind of, I think, been problems with mosquito spraying is it is done -- I've seen it done during daylight hours where there's no mosquitoes and then they come out at night and they're all

biting me.

So, that seems to me to be a weakening where it's also ineffective. So, I don't think it's necessary.

I feel the same way about the word "downwind". I don't know why anybody would spray upwind anyway, so I have no problem keeping it in there and I'm not sure why a sprayer would have a problem with it since they're going to -- they're not going to go upwind anyway because it's going to do in the wrong direction, right. So --

If it's not effective, why -- if it's not going to be effective to spray, you know, the wrong direction of the wind nobody -- nobody pees in that direction because they know what's going to happen, so why quibble about having something on the label that says don't pee on yourself.

And then the other one was about the -- it's the part that you brought up at the end. If somebody says to me, you know, what am I going to do if my little boy gets sprayed with this stuff. I would really have to ask why you're spraying little boys and I know you're not spraying

little boys. I recognize from your talk that you're clearly the compliant professional, but -- and you clearly have training and some in depth knowledge that I don't have.

But, again, other people shouldn't be spraying little boys. It's not supposed to drift on little boys, so that shouldn't be part of the discussion. If that is part of the discussion then it should be on the label.

Don't spray little boys. So --

I've been dissed, but --

MR. JONES: Thanks. Phil.

MR. BENEDICT: I want to talk for a minute about "repeat as needed." I don't think it's going to work tying frequency of application to public health threats or emergencies. A lot of mosquito control spraying is done to prevent public health threats and emergencies.

The other reason I'm a little concerned about this is most mosquito control chemicals today have no residual value and areas get repopulated with mosquitoes, generally speaking, by a wind and blowing. So, you can --

we don't have Florida's problem. I don't know what I would do if I was in Florida with those kinds of frequencies of application. I can understand your concern there, but at least in the north country mosquito spraying is usually tied to population counts, you know. There is an assessment made that an area has been repopulated with mosquitoes and needs to be retreated.

So, I honestly think if you're going to do something -- and repeat as needed, in many ways, has worked for us, at least, because of that. If you got a commercial

-- not a commercial. I guess I would say a controlled district or something like that doing it and that's generally what occurs in my neck of the woods.

So, if you're going to do something with this issue, I think you need to go back and tie it to mosquito density in some format because that's what is really important. It's the population -- it's the biting frequencies that you're trying to control.

So, time doesn't work necessarily with biting

frequencies. You've got to tie it to the biting frequency. And how you do that across this country, God, I haven't got a clue. I'm just a small town, country boy.

So, again, I guess I would suggest you rethink that and tie it back to something that has a biological connection and I really don't think you should tie the public health and public threat to that because nobody ever wants to declare those things anyway because when you declare a public health threat or one of those kinds of things, everybody goes out and buys chemicals so they can protect themselves and that's just exactly the opposite of what you're trying to do.

Tie it to a science based thing or a biological thing and I think you can be successful. I think if you tie it to those kinds of things you're just going to create problems.

MR. JONES: Thanks, Phil.

FEMALE VOICE: I'm just going to further what

Phil is saying, you know, I think as far as frequency. I

mean, generally I think these -- these chemicals are not

cheap and I don't think that they're being sprayed indiscriminately. I would assume that -- you know, all the mosquito control districts, who is doing the application -- there is some threshold under -- you know, that triggers the need for spraying.

And so I would say that -- I don't know how exactly you would word it, but maybe this is something to be considered that, you know, not to apply more often than -- if you want to put a time frame in there -- unless needed to achieve threshold levels or something tied again to some type of threshold, and how to do that on a national basis or whether it's, you know, based on what the local thresholds are -- but I think it does need to be based on what's necessary to achieve the mosquito control, which is what the goal is.

The second question I had was regarding the calibration instruction. This, I guess, is more of a question of what's going to go into the PR notice. Are there going to just be specific -- are they going to identify the information that needs to be in the

calibration information or specifically what calibration instructions

should include?

I mean, obviously the droplet sizes may be different, but -- and what the actual, but -- I think what we are looking for, maybe, is that there should be consistency because I think one of the complaints has been is the inconsistency in this calibration information.

So, is the PR notice going to specify specifically what needs to go into those calibration instructions as far as you know at this point?

MR. ROELOFS: As far as I know, no. What we're working on is kind of a general statement in which you, as a registrant, would propose the droplet spectrum and then it refers to the nozzle manufacturer's instructions for achieving it, and that would be it. It's, sort of, a model short statement.

FEMALE VOICE: Because we know right now there's some labels that have, you know, full blown calibration instructions, some that don't, and that -- you know, that

there probably should be some consistency as to what type of calibration instructions are on the labels.

MR. ROELOFS: Right. That continues to be a topic that's being kicked around and how best to do this.

MR. JONES: Thanks. Okay. Patty and Allen, and then we'll wrap this session up.

MS. BRIGHT: You know, I think your suggestion is a great one. I think that's really what we need is a subjective scientific way of deciding when spraying needs to be done, and from an epidemiologic and infectious disease standpoint, mosquito density plays a very important role in whether or not transmission occurs and how much transmission occurs.

I know that CDC is looking at this issue. I

don't know where they are, but I know that different

States are working on this. Gary Clark, who was here at

the last PPDC meeting, I think, would probably be a good

person to, perhaps, contact and talk to about this. I

think in the past Dwayne Goobler has worked on this, but I

think Dr. Goobler has since retired. So, he may not be

available.

But I just want to reiterate I think that's a great idea and I think it makes perfect sense.

MR. JONES: Thanks. Allen.

MALE VOICE: Well, Patti really addressed the point that I wanted to make here and that is it would seem to me that it would be important for someone to make a determination as to whether or not spraying is an effective method and, if so, how effective and what thresholds ought to be applied.

If it's not effective for controlling disease outbreaks, then labeling requirements ought to say that -- restrict the use for the agent for that particular purpose.

MR. JONES: The last word.

MALE VOICE: I don't want to wait for the disease outbreak. I don't want to get bit by mosquitoes. So -- you know. The biting frequency makes more sense than the disease outbreak.

MR. JONES: Okay. Well, let me just wrap this up

with a thought. The approach we've taken here, and I'm not talking of the substantive, I'm talking about the process, which is that we have now twice come and talked to PPDC about how we were thinking about this issue before we even did a proposal is an approach that, I think, we want to use more often. It's frankly what we're using and we're being a little more participatory in registration review. But where we're getting a lot of stakeholder input prior to issuing a proposal is generally, I think, a better way of operating as opposed to put out a PR notice or some policy document then talk to you about it, or you catch it on the web.

So, that's generally something that we're going to try to deal a little bit more often with. I think we've gotten a good amount of feedback on these issues before doing the proposal. As Jim said, the next step is a proposed notice, which you will all get, which will be the form for you and the rest of the public to more broadly participate. And I will take that information into consideration in figuring out how to go final on this. So

there will be one last opportunity for a formal comment in this process.

FEMALE VOICE: Do you have any idea when -- is that, you know, six months or when you might --

MR. JONES: Jim, shorter than six months, isn't it?

MR. ROELOFS: Pardon me? What was the question?

MR. JONES: What timing for the proposed PR

notice?

MR. ROELOFS: What -- to get it out?

MR. JONES: Yeah.

MR. ROELOFS: Well, if we really push -- well, it has to go to O&B and that's always an unknown.

FEMALE VOICE: So, like three months -- six months?

MR. ROELOFS: Oh, less than that.

MR. JONES: Yes. Sooner rather than later.

FEMALE VOICE: Okay.

MR. JONES: Before we get together again I would expect it will be out.

MR. ROELOFS: Oh, yeah.

FEMALE VOICE: Yes. That's all I was looking for.

MR. JONES: Yes. All right. That's a wrap on that one. I think we've got a few things we're going to do updates on. Janet, you want to move yourself here. And I definitely want to get us back to endangered species and some discussion about participation. All right.

FEMALE VOICE: Thanks. This is just going to be one of our quick updates --

MALE VOICE: Microphone --

FEMALE VOICE: Oh, I can do that. I can talk loud enough probably too.

Just one of the topics that we have often brought

-- have been bringing to this group is adoption of

biopesticides and how we can enhance some of it. I just

wanted to give you a quick minute or two on some of the

things that we have been doing in the division and

internationally.

In October -- the first and second, I think, of

October, but right at the beginning of October, we had a field trip with IR-4 and it was just aimed at biopesticides. This was the first one that IR-4 has done that way. And it was really a terrific trip.

We had about 20 people from my division go and about 20 others from other parts of EPA, and certainly some USDA folks. Others were there.

One of the visits was to the Appalachian fruit tree lab, which is an ARS facility, and it was just really exciting to me that virtually all of their research and all the work they're doing is on biological pesticide.

And I sat in lots and lots of ARS meetings and Extension meetings all over my years in it. For those of you who don't know, I actually used to work for the Extension Service. So, I've sat in lots and lots of these meetings.

I've never had one that was so concentrated on biological pesticides and it really did energize me just to see the work they were doing. And it wasn't just initial research. They were really looking up products

that had already been registered and how they could make them work for the fruit tree growers of the entire East Coast, because that's their -- Georgia to Maine is their mission in doing that.

On that field trip we actually had invited
members from PMRA, which is the Pest Management Regulatory
Agency in Canada; and also three officials from Mexico.
We had someone from Health, we had two people from
agriculture and someone from the Environment Ministry.

Through our NAFTA work, we are really trying to help the Mexican Government understand our approach to regulating biological pesticides and help them to be able to use a similar approach. We are especially working in the area of pheromones where you may realize we have a very expedited process in the United States for straight chain pheromones and these products have been very important in some of our transitions away from organophosphates.

So, we think this is really an excellent tool and we have been delighted that PMRA adopted our approach and

also OECD has adopted our approach. We are hoping that we can convince more and more of the world to help bring these much safer products to it. So, we want to work with our colleagues in Mexico and see what we can do to actually help them understand the process and get some of these products more easily brought into Mexico.

I'm sure a lot of you know and understand that we eat a good deal of food from Mexico. So, not only do we care about the fellow North Americans, but we care also what's in our diet and I would rather have pheromone residue any day.

So, this will be work that we will continue.

I've asked actually to put it on for the next NAFTA

meeting that's just in early December to see what more we
can do in working with our colleagues. It was great to
get a, sort of, face-to-face and have some real discussion
that way.

The last one I want to bring back to IR-4 and talk about the work we are doing to enhance our relationship in working with IR-4. You may know that they

have had, for many years, a biopesticides area for their research grants and VPPD staff scientists do some of the reviews of those grants, as well as participate in trying to direct and figure out what are good areas for the future work. And over that we have moved from more of them being basic work, to more of it being in the demonstration area.

It's really gone very well over the last few years. We're getting some excellent projects in there, and to recognize also, though, that the biopesticide industry is coming up to problems and the people say they want to see how well a biopesticide works and they want to do it one row of a biopesticide and one row of a chemical pesticide, and all you do is that season long, all -- that's the only treatment. And most biological pesticides don't work that way. They fit into programs. They work early on in the season, et cetera.

So, we are embarking on a new program with IR-4 where we're going to try and provide more funds and more demonstration grants for registered biological pesticides

to show how they really do and can integrate into existing programs, whether they be IPM programs or just more even conventional agriculture just to really help show that they really have a role and that they are good products to be used.

Thanks.

MR. JONES: Yeah. Sure, Lori.

FEMALE VOICE: I just have a quick question,
Karen, on the demonstration grants. Will those be
available through an EPA program or will it be an IR-4
grant program?

FEMALE VOICE: It will be -- it will be combined funds, but we believe right now that IR-4 is going to do the RFP. We have had discussions back and forth and how best to do it, and that is our current process. We are drafting the memos of understanding, et cetera, to be able to put that program in place.

FEMALE VOICE: And that will be an '04 program?

FEMALE VOICE: We're going to start it in '04 and we believe it will be enhanced with more funds in the

future.

FEMALE VOICE: Thank you.

MR. JONES: Okay. My policy, right hand and left hand, are occupied right now. The one is on travel and the other one is at a meeting. And so, you're actually going to hear me try to describe some of the challenging policy issues we face. So, I'll try to stay true to the facts here.

Human testing. As most of you, I expect, know - we have talked about this a number of times -- the

Agency put out, I think it was about two years ago now, a

press release that described an approach on human testing,
which is that we wouldn't -- we would not rely on human

testing for third party intentional for the establishment

of no effect levels in our regulatory decisions.

And last June, I believe it was, we got a Court ruling that the Agency couldn't make such a prohibition just through a press announcement -- that if the Agency wanted to do something like that, it would have to do rule making, if that were the Agency's choice.

We have, since that time -- or actually we began this a little earlier. We started a project with the NAS to ask them to give us some advice about the ethical as well as the scientific issues that surround human testing. NAS is scheduled and, from all reports, are on schedule for having their report to use in the December/January time frame. So, by the time we get back together again, we will have in hand an NAS report.

The Agency is -- we did an ANPRM, Advanced Notice of Proposed Rule Making, where we basically laid out all of the possible options and asked for people to comment on. We have all of those comments now and are sorting through those. So, our basic schedule for the next step we would take, which would be a Notice of Proposed Rule Making, involves --

First we need to sort through all the comments.

We're doing that now. We really need to have the NAS

report and their advice. And when we have those two

pieces, we will then begin policy formulation and decision

making. I expect it's going to be the proposal, which I

can't really predict a time frame because there are a lot of people at very senior levels of this government, across multiple agencies, and I would expect at OMB and other parts of the White House, who are going to want to play in those choices before our proposal comes out.

But the two key things to have done are, sort of, sort through the comments, get the NAS report and then begin the inter-Agency dialogue around what the proposal will be. Of course, then you do notice and comment rule making, which will then ultimately lead to a final rule.

So, that's where we are on human testing -actually the path forward really hasn't changed since, I
think, we last briefed you up. I bet the next time we get
together, since we have the NAS report, there might be a
little more factual information to share.

I don't know if anyone has any questions on that? Yeah. Gary.

MR. LIBMAN: Yeah. On the NAS report, how focused was that on pesticide issues versus the broader human testing issue?

MR. JONES: It was broadly -- although they focused on pesticide issues, broadly as it related to third party intentional dosing for the establishment of, you know, identifying adverse effects.

MR. QUINN: Jim, what are you doing on a day-to-day basis now? What's the policy that you're using to look at to decide whether or not some human tests, for instance a clinical patch study, would be acceptable and others would not be?

MR. JONES: Well, if it isn't intentional dosing
-- third party intentional dosing for the establishment of
identifying adverse effects, then we're operating as we
have been previously.

If it does fall within that category, we're holding it in abeyance until we've made some choices. And so we're not making -- we're not relying on them and we're sometimes punting on decision making around the chemical. Al.

MR. LOCKWOOD: As I recall, the Court ruling indicated that any test that were used by the Agency had

to conform to, quote, I think, high ethical standards, unquote. How is the Agency going to interpret this requirement of the Court?

MR. JONES: Well, the Agency has said -- I'm not

-- I'm generally familiar with the Court's ruling, but I'm

not that familiar. But I can tell you what the Agency has

said and we have said this before during and I expect

we'll continue to. That if the Agency were to rely on

such tests that we would bring the highest ethical

considerations as well as scientific considerations.

Again, the choice hasn't been made within the Agency, whether or not to, in this rule making, allow for consideration or not, but we have consistently said if we were to we would use the highest ethical considerations and those are some of the questions we asked NAS.

Troy and then Carolyn.

MR. SEIDLE: Thanks. I don't want to belabor the question that Pat had raised, but it is, I guess, a fine line between if you do a clinical patch test if it's carried out by a third party and you are intentionally

applying it to somebody's skin, does that constitute dosing. It's local. It's not systemic.

But do you have a sense as to where EPA would draw the line on that if it's -- if a company submitted that kind of data to demonstrate lack of skin irritation as an example? Do you know if that would be in or out?

MR. JONES: That kind of study is the kind of study that we have considered before and during this period. Those studies are not attempting to identify a no-observed adverse effect level. They're often, sort of, yes, an effect occurs; no, it doesn't. But they're not trying to find the no element.

As you say, it is a very slippery slope and very hard to, sort of, figure out where do you -- what was prohibited and what wasn't prohibited. I prefer not to try to figure out where on the slope we are in this meeting.

Carol.

MS. BRICKEY: Yeah. I would just observe that in past discussions of this topic the scientific and ethical

issues have gotten mixed up and blurred to some degree.

So, when we have a discussion at the next meeting,
hopefully, about the NAS findings, I hope we can create
some kind of structure in which we talk about the
scientific issues and we talk about the ethical issues and
it is clearly delineated as possible.

MR. JONES: Okay. All right. The second topic is spray drifts. Actually it was our experience in the spray drift PR notice that gave me and our team the insight that we really needed to rethink the processes that we use to roll out policy announcements. It went so poorly, and frankly that, I think, has, sort of, led to our work and registration review and mosquito labeling. Where, before we roll out some announcement where we have some intention and it blows up on us, why don't we get a little more transparent participation.

I think in spray drift we thought we had -- we were getting -- we were doing stakeholder outreach, but it wasn't transparent clearly or people wouldn't have misunderstood us.

But about two years ago we issued a PR notice -
(End tape two, side two.)

MR. JONES: -- a level playing field and in doing so I have to agree, after the fact, that we actually did change the standard, and that's what we had a lot of stakeholder input on. There were people, who strongly supported the change, and there were people, who strongly didn't -- opposed the changed.

We got into very senior level discussions within the Agency and within the administration. We couldn't get a consensus on within the Agency about how to do it, on how to go forward. We withdrew the notice and we said, you know, we've got to go back to the drawing board here.

We have since gone back to the approach that we have taken over time, which is it is not -- we're not being completely consistent across labels, but we are trying to make sure that labels that are approved prospectively are -- they're enforceable and they're clear, and that they are managing the risks that we're worrying about.

But we have not attempted to re-engage, reissue another notice. We've, I think, got to figure out how we want to engage the stakeholder community much more effectively than we did the last time before we attempt to take another stab at this issue.

And when I say this issue, I mean the issue of -because we have been doing spray drift labeling for 30
years and our colleagues at USDA did it for the 20 years
before that without any clear guidance, the statements are
all over the map.

So, the issue we were trying to address was the inconsistency of spray drift language. Again, how you sort of talk about that -- make it consistent and not change the standard is easier said than done.

And so -- but the next time out, regardless of what we ultimately do, we clearly have to do it with more participation, broad participation, up-front, there's a possibility we could use this group, there's a possibility we could use other mechanisms for sorting that out. But we have not yet got a plan -- a concrete plan that I can

say, here are the five process steps we want to go through before we have a revised draft. So, that's where that issue stands right now.

All right. Endangered species. The question that I asked you to think about overnight and I realized, given how hard it is for we, in the Agencies, to think about the appropriate role for stakeholders to have -- I mean, if it's hard for us and we're thinking about it all the time, I can imagine it can be hard for you on a day's notice to give advice. And so we will likely use the PPDC forum over time to, sort of, stimulate your thinking about it, get more input from you.

There are a couple things I'll just throw out there as the kinds of things that we could consider. I certainly don't -- this is expected to be the laundry list. I expect you'll have some ideas.

We have had a lot of success, I think, when we take our assessment process and really spend a significant chunk of time. We did it throughout the cumulative process where we would take parts of our assessment,

whether it was drinking water, occupational, dietary and did a day long workshop where we're just explaining this is how we do it, and you're learning about it and telling us where we can improve it.

We tend to do that in a very open way. We did that under the auspices of CARAT, but there are always public meetings. We gave notice in the Federal Register.

I think that if folks wanted to do something like that, that certainly could be entertained, probably not in the next three months, but before we got together again as a committee. So, that's an option.

How we set priorities about moving -- getting into compliance is another area, as clearly choices need to be made and resources are scarce. The intention is we're going to get ourselves into compliance with the procedural requirements around the Endangered Species Act.

Well, how do you do that? There are a number of options. Getting your sense as to what priority to give to that is another issue we could have dialogue around it. Those are the two we've been able to think about. I want

to get any additional thoughts you may have -- and, again, we'll use the PPDC forum coming out of this meeting to remind you periodically, have you thought about this -- do you have any ideas.

And the PPDC's forum, just so you all remember, if you're all linked into it -- but just like this meeting is public. It's public, too. So, you're talking not only to us, you're talking to everybody, which is good. That's transparent. It's the way we operate here. It's the way we ought to operate electronically, I think.

Steve.

MR. KELLNER: I just had a suggestion about an update on fixing props or whether it's -- perhaps the next meeting.

MR. JONES: Okay.

MR. KELLNER: The implementing legislation.

MR. JONES: Thoughts around Endangered Species and the PPDC's role. I think that's a good idea, Susan.

MS. BRICKEY: Jim -- I'm sorry.

MS. SPAGNOLI: Go ahead, Carol.

MS. BRICKEY: I was just going to say I think it would be really constructive for us to help you look at priorities because that would give all of us who have been looking at this issue for many years a sense that, you know, there's a plan and there's a strategy and the thing is moving forward. I think that would be very helpful.

MR. JONES: Okay. Julie.

MS. SPAGNOLI: I was going to agree with your suggestion. Maybe having some type of a workshop to really more fully understand how it's being approached from various types of use patterns because I think some questions have come up and I think there's the traditional crop applications and how those are looked at.

But I think for other noncrop applications and how assessments will be made for those or how mitigation can be implemented for those, that may be a good point for discussion.

MR. JONES: All right. Lori.

MS. BERGER: I would like to hear and/or meet some more people from Fish and Wildlife and just hear

their thoughts on how all this can be integrated in a workable and peaceable format.

MR. JONES: Okay. Any other thoughts. Oh, yeah -- Lori.

MS. McKINNON: In terms of yesterday's question about stakeholder involvement, I think the tribes would like to have some serious discussions about the Endangered Species and Water Quality issues for the Clean Water Act, and how those integrate with pesticide registration and re-registration.

So, again with what people had said yesterday promoting distribution of information through usual channels that OPP goes through, I think with the Tribal Pesticide Program Council that would be very effective.

MR. JONES: Okay.

MS. McKINNON: Also having a tribal prospective because we are, sort of, between States in regulating pesticides and then also the environmental community and NGOS and protecting species, we have, I think, a unique prospective on how pesticides are used and how they should

be used and how those relate to species, and not only endangered species, but also tribal trust species where the Federal Government has an obligation to protect.

MR. JONES: Okay. Thanks. Has. I'm sorry. Has and then Patti.

DR. SHAH: Do you have anything for this workshop in mind?

MR. JONES: I think we'll need a couple months to do that. So, it will be after the first of the year.

DR. SHAH: Okay. So, like early spring?

MR. JONES: Yes. Late winter, early spring.
Patti.

MS. BRIGHT: I think the idea of having some Fish and Wildlife Service folks at the forum would be a great idea. What I would like to see are some of the rank and file of the contaminant folks because those are really the people who would be working with the issues rather than some of the administrators.

And it would be, I think, particularly helpful -we talked yesterday about the fact that there's just a

water quality group that works between EPA and Fish and Wildlife Service that I mentioned that Diane Keener is involved with. It might be very helpful to have a couple of those folks come in and give a short presentation about how -- you know, how they're integrating, what their process is, what were some of the obstacles they had to overcome, and perhaps look at that as a potential model.

MR. JONES: Thanks. Ray.

MALE VOICE: For timing of the workshop, you might consider early in the public comment period on the proposed rule so the Agencies, including yourselves, can be more open

in their discussion of it and kind of fill the folks in on the details as they're preparing their comments.

MR. JONES: Okay. Beth.

DR. CARROLL: I think the workshop idea is great and I think you should include the task force folks because they've done an awful lot of work on this.

MR. JONES: Sure. John.

MR. VICKERY: I think the two important issues in

making progress here are where are the endangered species and where are the exposures, and those are two pieces of data that we need to, kind of, think in terms of the overlap. And that brings into play some other sectors that haven't been mentioned.

Usually in most states -- even though the authority and responsibility of the Fish and Wildlife Service for these listed species, the folks that actually know where they're at are actually folks in the major conservancy and the individual State Departments of Natural Resources or Fish and Wildlife, as the case may be. They're the ones that are mapping them on a county level and so forth and have those databases and natural heritage programs and so forth.

One of the speakers yesterday mentioned Nature Serve is, kind of, set up as -- to have that system with the databases. So, I think those are the people to involve in that discussion in terms of where the listed species are.

But the other, bigger, harder picture is where do

we get this data in terms of where the exposures are likely to be because that's the crux of the issue. I mentioned it yesterday. We don't really have that data in a good format to deal with in most cases or it's not available publicly. And those -- that's a very important issue to figure out how do we deal with making decisions about likely exposures where we can't really have good -- where we don't have good information about what's being used where, when and all that kind of stuff.

MR. JONES: One of the things that we have learned over and over again when we do these workshops explaining how we do our work is people who know things about like you're describing come forward and say what about this. And so we then get more and more information and it enhances our data that makes for better assessments and better decisions. So, I think that that is one of the things that we could really -- we could benefit from by having a broad stakeholder participation in understanding how we do our assessments.

That's a very good point. All right. That's very

helpful.

We do have one public commentors and then we'll do some wrap-up -- thank you. We have one public commentor and then we'll do some wrap-up and then we'll be out of here I'm sure on time. Steven McFadden.

MR. McFADDEN: Yes. Steven McFadden, independent scientific research advocate. Some of us believe that cholinesterase inhibitors and people should never meet. High risk uses of pesticidal cholinesterase inhibitors include indoor uses. For instance, problems with chlorpyrophos (phonetic), which is some delayed neurotoxicity; persistent agricultural pesticides; i,e, aldicarbon, potatoes and watermelons and so forth; and urban aerial pest eradication programs; i,e, the Med Fly spray programs and mosquito spray programs.

The key point is that most of these high risk anticholinesterase exposures are involuntary. The organophosphates are, in particular, centrally acting, neurotoxic and has central sensitive human subpopulations, including with serum sudo-cholinesterase. These are the

people who are extremely sensitive to the muscle relaxant, succinylcholine (phonetic), polymorphism and paraoxonase and, quite likely, with neurotoxic esterase, which is important because it's membrane bound and can't be replaced. There may also be a secondary mechanism of action, such as second neurotransmitters.

Some of us remember the California Med-Fly spray programs. I lived through that 81/82 spray program in the Bay area. More recently there have been problems with West Nile Virus. This summer in Dallas the head of public health in Dallas County proposed aerial spraying when there was a spike in West virus cases and about two to three deaths. Fortunately, that didn't happen.

We pressured the city of Dallas for a year to focus on source reduction, larviciding, education, arguing that adulticiding is ineffective, trying to get the city to front load their control efforts.

The city did extensive monitoring of West Nile virus and ground spraying on about 15 to 20 percent of the city. Fortunately, they didn't aerial spray.

By way of comparison, in 1966 Dallas had an epidemic which had 20 to 25 people killed with St. Louis encephalitis and the Army came in with C-123 tankers and sprayed about 2,000 square kilometers with melothyon (phonetic). St. Louis encephalitis is, more or less, much more of a health threat than West Nile Virus.

My impression is that they like to use the organophosphates for mosquito control because they can use a larger droplet size with heavier oil, get it to drip to the ground and therefore, spray it from fixed wing planes from a higher altitude.

Also, registered for mosquito control is Nalid (phonetic). It's a direct inhibiting oxodone (phonetic), about a million pounds per year produced. About two-thirds is used for aerial mosquito control. There's a lot of restrictions. It's got to use a cockpit or cab with organic vapor filtration for any use other than mosquito control; it's got a 48 hour reentry and a no drift requirement. But for mosquito control they can do what they want pretty much. My impression is Nalid is pretty

hard stuff.

Some of us would like to see some labeling restrictions to suggest that public health officials really ought to have a health threat before they use these hard things.

I would like to close with a quote of Sheldon

Samuels, the AFL CIO, saying, failure to consider

sensitive subpopulations is social, as opposed to natural

selection against those individuals. Thank you.

MR. JONES: Thank you. Okay. I'm going to go through quickly some of the next steps and then I just want to open it up for some general feedback before we break up.

I feel like we got -- the Agency got a lot of very valuable advice, much of which has informed the next steps I'm going to describe.

On registration review, the workgroup is going to continue. We'll get back to you shortly, those of you on the workgroup, with the next steps which will likely include another meeting. We're going to start drafting

proposed rule with the feedback that we've gotten so far and continue to work issues that have been identified. I expect we'll see some more issues identified by the group that will need to get work through.

So, you'll be hearing from Jay and Betty shortly.

If you're not on the workgroup and you want to be, just

let Margie know.

On alternative testing, I feel like we have -from the exercise that we engage in -- at the advice of
PPDC, have gotten our act together much better in this
area than it had been just a year ago. We're going to
continue that work and we'll keep individual members of
the PPDC posted as per your wishes and we will only use
the update session of the PPDC prospectively. Five and 10
minute updates on that work as we're going forward.

I think we got some good feedback around how to engage this group on endangered species. I'll want to make sure I've talked both with the people who will have to do all the work, in particular Steve Bradbury and Artie

Williams, on the workshop, although I'm just shy of saying we're going to do it. It's likely we will, but I got to talk to people who actually have to pull it altogether. I am pretty sure if we do do it it will be after the first of the next calendar year, that being January 1st '04.

After that.

I want to also engage in some discussion with my management and some folks on my team and who I report to around a prior discussion, which I think actually is a good idea.

The environmental labeling claims. We're going to, sort of through the PPDC forum, ask a couple of framework kinds of questions that I described earlier to provoke and stimulate some thought on your part and then at our next meeting we'll spend an hour talking about, you know, what do we get from it and is it worth the cost. And then we'll make a choice as to whether or not to pursue that further.

Global harmonization. I'm, frankly, pleased that we talked about it here because it was obvious that there

is a need for more information broadly and we're going to figure out how we can disseminate that information. There will likely be a workshop of some sort and then I think we'll work with trade associations to make sure that we can use the regular meetings that they have to communicate the information.

And for others, if you have meetings that bring together large numbers of your -- the people who belong to your association or the associations you belong to, we could also think about using those meetings for us to do information dissemination. But I think, ultimately, we'll have to do at least one large workshop information.

And after that, we'll then begin to, I think -well, I think, we'll be more intelligent about thinking
through how the PPDC wants to participate in decision
choices that need to be made by the Agency around
implementation. So, I think we can expect to see that as
a future topic in this group.

The PR notice for mosquito labeling. The next thing you will likely see will be a draft PR notice that

you all -- you will all get and it will also be broadly disseminated for notice and comment.

On the budget issue, I heard very lukewarm response to my very, I think, bold and daring proposal. You know, we got enough to do. I don't need to do things just because I want to do them. But if people feel strongly about it and you didn't convey that, you know, let Margie know or use the PPDC forum and we'll take that one from there.

Those are the follow-up items that I had. I thought it was a real productive meeting. You often ask us to make sure that we're getting what we need. I feel that we, pretty much, got what we needed and we'll use the PPDC forum to help build the next agenda. I think we've got a couple of items coming out of this and we'll want to work to identify with all of you additional items.

There's an administrative note. As I mentioned yesterday, our charter expires in about a week or two. We're going through all the work we need to do to make sure that the charter is renewed, which it will be.

All of the terms for two years now expire, I believe, when the charter expires. Is that right, Margie? And so we'll go through some process to reappoint the membership. There will likely be a handful of vacancies that will need to be filled, but I don't expect it will be very many. And so, we'll keep you all posted on how that's going.

Anyone want to give us any feedback, advice around the meeting in general, we'll be happy to take them now, or you can tell us later?

FEMALE VOICE: Actually I have a question about the forum. How is it public? The e-mail forum?

MR. JONES: Margie, how does the public sign onto the forum?

FEMALE VOICE: Or at least to view it?

MS. FEHRENBACH: There is a way sign up electronically and I'll send that information to you. But all the PPDC members are on it. They talk to one another on it. They can send messages that everyone sees. The public's messages will only come to me and then I can

either send them, if it's a message that needs to --

MR. JONES: So they can read it.

MS. FEHRENBACH: Oh, yes. Public reads everything that goes back and forth.

MR. JONES: Ray.

MALE VOICE: On the reappointment of members of this committee, those who are serving on the committee now need to indicate their interest in being reappointed, is that correct?

MR. JONES: Yeah. To be reappointed or to be appointed you have to let us know. And Margie, I believe, has been rather aggressively making sure everyone knew they needed to re -- be renominated or nominate. You know how I am about starting the meeting on time. If you haven't put your name in, sayonara, you know. To take care of you, you need to take care of yourself sometimes in these things.

So, if you haven't gotten your name to Margie before next Tuesday, it would be my advice --Nancy.

DR. LEWIS: Just general feedback on the meeting.

I found it most helpful. I'm still learning quite a bit.

But I especially like your questions at the end of some

of the handouts and you've rephrased those, sometimes,

when they weren't in writing that this is what you want.

That was very helpful.

I'm not sure if you're asking for more topics, but

I'm interested in the whole topic of endocrindosrupters

and a broader picture on that and how we could get some

overview on it.

MR. JONES: That was mentioned a few times, but -- yes. Okay. Thanks. Erik.

MR. NICHOLSON: Also on that note, I really appreciated how you organized the meeting. I found it very informative. And also thanks to all your staff, including Margie, that helped pull this together. They did an incredible job.

Two topics I would like to follow-up with in future meetings is: one, hearing back from the folks at WPS about the results of the national review. I know many of us are anxiously awaiting their formal report, but I

would welcome a presentation here at the PPDC about that.

And also -- I don't remember if it was a year ago, two years ago, we heard about extensive work that the inter-labeling -- there was a subcommittee or some formation of that. Whatever happened with that and what the EPA is doing on inter-labeling.

MR. JONES: Okay. All right. Thanks. We are adjourned. Thank you.

(Whereupon, the meeting was adjourned.)

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