Transcript of

Pesticide Program Dialogue Committee Meeting

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ATTENDANCE LIST

Jim Aidala	Associate Assistant Administrator for Prevention, Pesticides & Toxic Substances, EPA
Marcia Mulkey	Director, Office of Pesticide Programs, EPA
Susan Hazen	Deputy to the Director, Office of Pesticide Programs, EPA
Jim Jones	Director, Registration Division, EPA
Rick Keglin	EPA
Margie Fehrenbach	Designated Federal Officer, EPA
Ian Tinsley	Oregon State University
Warren Stickle	Chemical Producers & Distributors Association
Bill Tracy	National Cotton Council
Larry Elworth	Center for Agricultural Partnerships
Steve Balling	Del Monte Foods
Dan Botts	Florida Fruit & Vegetable Association
William McCormick	Clorox Company
Sarah Lynch	World Wildlife Fund
Robert Rosenberg	National Pest Management Association

ATTENDANCE LIST (Cont'd)

Phil Benedict	Department of Agriculture
J. J. Steinberg	Albert Einstein College of Medicine
Jose Amador	Texas A&M in Weslaco, Texas
George Pavlou	Director, Enforcement & Compliance Assistance Division, EPA Region II
Al Jennings	USDA
Terry Troxell	FDA

Day One

November 29, 2000

PROCEEDINGS

MS. MULKEY: If we could take our seats, please.

MR. AIDALA: Well, why don't we get started, Marcia.

MS. MULKEY: Well, greetings to all of you. Jim is going to formally welcome you, so I will not step on that by spending a lot of time about how pleased we are to see all of you.

I will simply start by introducing Jim Aidala, well known to all of you because of his long and distinguished service in this arena on this topic and in this place. Jim is the senior representative of the Executive Branch leadership for this program, and is here today to kick us off.

MR. AIDALA: And thank you, Marcia. We thank you for coming to the PPDC. We haven't met in a while, and it's been an interesting year and an interesting few months to go here.

But generally notwithstanding all the other geo-politics or whatever you might describe them as, this is

an effort to really do the work -- more of the day to day work of the program. And we very much appreciate all the members here taking the time to come and help us out and work on the variety of day-to-day issues and the important issues that make the program run.

Some of the members that are on the panel here are not able to be here because of some other reasons, and we are pleased to have some substitutes for some of those folks. For example, over at USDA there is the Biotech Advisory Committee ongoing right now. I suspect that's where Carolyn is. That's where Keith Pitts is, and he offers his apologies. We've got Al Jennings here, certainly no small substitute for the Department.

Terry Troxell is here from FDA for Bob Lake. Adrienne Quintera will be here for Eric Olson from NRDC. Nelson Carrasquillo, who is getting ready to be a grandfather in Minnesota, is unable to attend. We hope to have tomorrow Teresa Niedda. And then Ian Tinsley representing Dr. Sheldon Wagner. Again, we appreciate everybody taking the time and coming in to help us out on the Dialogue Committee.

We've also added a few new members since our

last meeting. Let me talk about that. That's in order to replace some of the members who have retired or left their affiliations and were no longer able to participate as part of the PPDC. Edward Zuroweste from the Rural Community Health Center in Chambersburg, Pennsylvania, a practicing family physician who specializes in farm and ag health issues, will be joining us tomorrow.

And we've also invited representation from the animal welfare community, specifically PETA, the People for the Ethical Treatment of Animals. They're unable to attend today, but as we -- and Marcia will get more into this later in terms of the re-chartering of the PPDC. But as we reconstitute the PPDC, we will definitely have animal welfare community representation on it.

And it has been a while since we met as a committee -- as this committee -- and there has been -- some of you know some of the other ongoing activities as members of CARAT, the Committee to Advise on Reassessment and Transition, as well as its predecessor, TRAC, the Tolerance Reassessment Advisory Committee. And obviously those two other FACAs are where we've had a number of public meetings to discuss transition, reassessment,

organophosphate risk assessments and other things.

Obviously there has also been a lot of Science Advisory Panel meetings which are also public. For example, the -- did we get a report of how long last night they went on on StarLink?

FEMALE SPEAKER: 9:00.

MR. AIDALA: Until nine? Okay. A little bit earlier than expected. But they went on until 9:00 last night. But early reports were about to 11. At about two in the afternoon, we thought it might go on to about 11, so it's good that people got home. But the whole point is that there are, you know, other activities -- other public activities -- that we use as well as this committee for public outreach and to give us advice.

And in particular, this group, the PPDC, has been active in two work groups -- the inert disclosure and rodenticide stakeholder work groups -- and obviously the agenda today will include some reports from those folks.

Again, Marcia is going to discuss more fully in a minute about some of the issues behind re-chartering the PPDC. We will go through a public process to invite

membership to this committee and obviously for continuity, among other reasons, we'll expect many of you to be invited back. And we hope that you're able to continue participating in the PPDC. Again, tomorrow there is time on the agenda to talk about the role of the PPDC, and we'll ask your thoughts about the kind of topics that we might want to engage in for this group to cover during the coming year.

Again, this is, as always, an invitation to have an open and meaningful dialogue on many issues -- important regulatory and other policy issues. And the feedback is very important. The CARAT committee will continue to focus on transition and reassessment, but that certainly means there is no shortage of issues outside of that bailiwick that are important for pesticide regulation and pesticide policy. And obviously those are the things that we expect in having this discussion with you and the public in the next couple of days.

Obviously, kidding aside, it's unknown what will happen with the election. We can all speculate. But notwithstanding that, it's a message we give our staff.

Before, during and after early November is the -- you know, whatever it is, day 29 of the election, that, you know, notwithstanding whatever happens in the election, there are important regulatory responsibilities that we have as an agency, and those will continue.

It's a public agency and all that, and it is really a testament to the system of government that we have here that frankly notwithstanding all that other brouhaha that, you know, the work will go on and the government will survive. Things will get registered, etc., notwithstanding all these other activities. Things will get canceled, but that's a whole other discussion, too.

(Laughter)

We do plan to have a summary of the past fiscal year accomplishments, meaning sort of just a statement of some of the things that we've done, both in terms of -- and the various actions we've taken in all of those arenas -- registration, cancellation, etc. It's completed as of now, but we're kind of recounting, if you will, and making sure that numbers are square before we release it publicly. That was for Margie.

(Laughter)

So blame Margie for that one. Again, there has been a lot of progress made in the last year. I do appreciate this committee. Again, compared to CARAT and TRAC it's a much -- and to all of our credits, I think -- smaller, cozier group able to encourage more interaction. And, again, we appreciate that and do want to continue to encourage that. The issues are, again, larger than just risk assessment and organophosphate assessments, and those are the things that we especially are grateful to have the PPDC able to help us out with.

This morning I'm going to be -- after some initial sessions, I'm going to be away. I'll be back this afternoon and, again, I'll be back tomorrow morning. So, again, my apologies ahead of time for not being able to be with you the whole time. And, again, passing on Keith's apologies for not being here.

But before I do that, Al, is there anything from the Department?

MR. JENNINGS: You've already mentioned all the other advisory committees. And, I think like you, I always viewed PPDC as one of the more useful

interactions, mostly because it is smaller and the discussion and the dialogue does seem to happen better here. So, again, given the choices I had of which advisory committee to attend, I think I won in the drawing of the straws. This is better than the biotech one, for sure.

(Laughter)

MR. AIDALA: No comment on that, since my wife is a facilitator of the Biotech Committee.

(Laughter)

MR. JENNINGS: It had nothing to do with the facilitator, Jim.

(Laughter)

MR. AIDALA: But I'll let her know you said that, Al.

(Laughter)

Anyway, before we do move onto Marcia's remarks, I would just have the rest of the people around the table introduce themselves, including panel members.

Again, I'm Jim Aidala here from EPA.

MS. MULKEY: Marcia Mulkey, EPA.

MS. HAZEN: Susie Hazen, Marcia's Deputy.

MR. JONES: Jim Jones, EPA.

MR. KEIGWIN: Rick Keigwin, EPA.

MS. FEHRENBACH: Margie Fehrenbach, EPA.

MR. TINSLEY: Ian Tinsley from Oregon State University.

MR. STICKLE: Warren Stickle with the Chemical Producers & Distributors Association.

MR. TRACY: I'm Bill Tracy, grower member of the National Cotton Council.

MR. ELWORTH: Larry Elworth, Center for Ag Partnerships and Steve's Deputy.

(Laughter)

MALE SPEAKER: Well, he says he's your deputy.

(Laughter)

MR. ELWORTH: I know.

DR. BALLING: We're still counting. Steve Balling, Del Monte Foods.

MR. BOTTS: Dan Botts, Florida Fruit & Vegetable Association.

MR. MCCORMICK: Bill McCormick, Clorox.

MS. LYNCH: Sarah Lynch, World Wildlife Fund.

MR. ROSENBERG: Bob Rosenberg, National Pest

Management Association.

MR. BENEDICT: Phil Benedict, Department of Agric, representing states.

DR. STEINBERG: J. J. Steinberg, Albert Einstein College of Medicine.

DR. AMADOR: Jose Amador, Texas A&M in Weslaco, Texas.

MR. PAVLOU: George Pavlou, EPA Region II.

MR. JENNINGS: Al Jennings, USDA.

MR. AIDALA: Okay. Marcia, you're on.

MS. MULKEY: Thank you, and hello to all of you. I trust that you all know and understand that the fact that it has been some time since we convened as a whole group doesn't mean that you aren't important to us and that consultation is not important to us. In fact, to the contrary. It does mean that we have put some significant energies into other consultation processes, including the CARAT. At this time of the year, I hear jewels when I hear carat.

(Laughter)

Other times of the year, I hear long orange things that you eat.

(Laughter)

But this time of the year, I hear jewels.

MR. AIDALA: Bill was just telling us that's the money this year. I mean, I wouldn't knock on carrots here.

MS. MULKEY: Yeah. Well, I said other times of the year I think about the long orange things that you eat. But at this time of the year I have twinkling things in mind.

But in any event --

FEMALE SPEAKER: We'll have to tell Mr. Mulkey about that.

(Laughter)

MS. MULKEY: Yes. Yes. Anyway, we have been working hard to make that a meaningful consultation process, and many of you have been involved in that or aware of that. But we have had you in our hearts and minds all along, and we are pleased that we are back together as a group. We work to try to make this a good meeting. We really want this to be about a consultation.

And while we do -- we have attempted to frame some of the discussion with materials that the agency has

prepared, we really don't want this to be a talking heads meeting, at least not a talking government heads meeting, and we're going to try to avoid that. And we will try to work through our presentations in a way that gets the full hour we've allotted for discussion of the two heavy topics -- residential issues and worker issues -- and make that meaningful.

In addition, there are two areas where the talking heads are work groups of your PPDC. We have two very hard working, very active work groups, one on rodenticides and one on inerts -- inerts disclosure issues -- and we'll be hearing from them. So remember to the extent that that is a presentation, that is the work of a work group of this committee and not something that we are bringing to the table unilaterally.

I want to spend a little bit of time talking about a few hot issues, but first before I do that, I want to spend a minute or two on the future PPDC. We have a whole discussion set aside tomorrow about the future of PPDC. But I want to make it very clear that we believe the PPDC has a future, and that although the membership is expiring sort of by operation of law, for

lack of a better term, we are about to publish a solicitation for nominations. That should be published next week.

And so we are eager to know whether you individually are eager to continue. We will not be able to ask all of you to in order to have some opportunity to broaden and vary participation, but we certainly want to know who among you is eager to. And we also really value any nominations that you might bring forward, because you understand what is useful and what works for the PPDC, and we'll look forward to hearing your nominations as well as your own interests. And, of course, we will be listening to others in that regard.

And we hope to reconstitute the PPDC very quickly as soon as the nomination process closes, basically, and have the opportunity to have meetings whenever it seems best in light of what else is going on with CARAT and other things.

I also want to spend a few moments this morning talking about our senior leadership team in OPP. Many of you have met Susan Hazen, who introduced herself graciously by reference to my job. But in fact her job

is complete, important and in many ways very independent of mine. She has a broad range of major responsibilities in our program, including registration activities and biotech activities, just to name two. And not necessarily the two that on any given day are what dominates, but they have certainly been dominant. And we look to her and her considerable experience in helping us all get it done.

Joe Merenda, who will be here and in fact has an update for you, is our Deputy for Program Management. And he makes sure that among other things we plan and execute our financial human resources and programmatic activities responsibly.

So the three of us enjoy the fact that there are three of us, believe me, with the scope and difficulties of this program. And I'm pleased that both of them are able to spend some time here with us.

I want to spend a little bit time on the CARAT, what is going on with the CARAT. Those of you who are active in it I hope know as much as I know, because we've definitely tried to be as transparent as possible about what is going on. But at the end of the last meeting we

talked about both workshops and work groups as ways of having deeper and more comprehensive work of that organization outside of the CARAT meetings.

And we are proceeding as a committee there with two of each. We're going to do a workshop on drinking water assessment methodology. Based on consultation with the CARAT members and from our folks, we now think this will be scheduled in mid to late January. We're going to do a workshop on worker risk assessment methods. This is related -- interrelated with a lot of other activities involving worker risk, many of which you will hear about tomorrow, including a very significant public work meeting regarding the worker protection rule and the implementation of the worker protection rule. And in order to integrate this work with that work, the worker risk assessment workshop is now being contemplated for early March.

And then two work groups, one on transition issues to work on identifying barriers to the development and adoption of new, safer and effective pest management techniques, and also to help work with the agency to figure out how we can best participate in that process.

And we're contemplating soliciting participation in that work group shortly, and the current anticipation is that that work group can meet at about the same time as the next CARAT meeting, which could be as early as February if all goes well.

And then we also plan a work group on cumulative risk, focusing on the appropriate role for public participation in the regulatory -- in the risk assessment and the regulatory part of cumulative risk. And we hope to very shortly solicit participation in that work group and aim for a meeting in January for that work group.

So that's the basic framework for activities of the CARAT. We tell you, because quite frankly the amount of activities we do there and the timing for that also is, you know, sliced together with the amount of activities and time that we spend with this advisory committee. We also tell you because we know you are keenly interested.

The other two, for lack of a better word, hot issues -- we have many hot issues. All our issues are hot, right? Prominent issues is what we put on the agenda, because I didn't want to use the hot word on the

agenda. But the two that are probably most in the forefront of your minds -- or may be -- are what's going on with cumulative risk assessment and ultimately regulatory results from that, and what's going on with that protein that is showing up in parts of our food supplies -- the StarLink or Cry9C.

With respect to cumulative, just a brief -- I think the best thing for me to say about cumulative is to talk a little bit about the timetable. This, again, is not new news. I didn't come here to reveal something you shouldn't already know or couldn't already know, in any event. Just a few sort of backward and forward looking dates.

It was in February of '99 that we did our guidance for identifying substances with a common mechanism of toxicity. So that is, you know, the policy -- that first building block of the policy goes back to that date. It became clear as a result of that what the key elements then would be of a cumulative risk assessment. And in June of 2000 we actually published guidance -- proposed guidance -- on cumulative risk assessment emphasizing the four building blocks of

cumulative risk assessment: hazard assessment, dose response, exposure and then risk. How to think about the risk in light of those elements.

That was published for public comment. Public comment closed on August 28th of 2000 on that methodology. And we have had a number of Scientific Advisory Panel meetings, the most imminent of which is December 7 and 8, where we will have a case study of the cumulative risk of 24 of the organophosphates, which will take the methodology, take some available data, and work through the application of the process through those data for purposes of getting scientific input on the methodology as applied, which is one of the things that an earlier Science Advisory Panel urged us to do.

And then we expect to take the public comment process, all the learning we've engaged in as a result of our work with the Science Advisory Panels, the learning that we draw from having done this case study, and finalize our policy -- our guidance -- on cumulative risk assessment. And, of course as well, we are making progress toward our capacity to conduct the cumulative risk assessment of the organophosphates, which, as far as

we know now, is likely to be the first cumulative risk assessment that we will conduct.

So that's the timetable on that. That's the work that we're progressing. And as I said in at least one other public forum, there is nothing going on in cumulative risk assessment that you haven't seen, especially now that we have put into the public docket the work that is going to the SAP for the 7th and 8th. So you can study the effect of our work there, as well as hear what the scientists have to say and what public commenters have to say about that.

The other matter -- and by the way, we have made available to you as part of your packet, I think -- is it part of their packet, Margie, or is it outside?

MS. FEHRENBACH: What is it?

MS. MULKEY: This sort of Q's and A's on cumulative.

MS. FEHRENBACH: It's in the packet on the right side.

MS. MULKEY: It shouldn't have anything new on it other than some of the dates of some of these. In fact, I think we prepared this in connection with the

public comment process on cumulative.

The other thing worth spending a few minutes on is StarLink Corn. Those of you who have been following this very closely know more about it than I do, although not, I think, more than Susie does. But it is one of many -- or several -- Bt products that were registered as pesticides because the plant -- the corn plant in this case -- expresses a protein which has the effect of -- an insecticidal effect. And it's basically the same thing as in bt spray, except this is brought forward from the plant.

We had registered a number of these for use in corn, including corn for human consumption. But one of these is a little different. And in fact, part of the whole idea of biotech is to get slightly different proteins, because that had, as I understand it, some advantages in terms of less resistance, and in general -- in very generic terms -- a good thing and not just an economic advantage that comes from slight differences across the proteins.

But this was a different protein that had some different properties that raised issues that the others

didn't. In very simple terms, it didn't break down in the human digestive system or the mammalian digestive system as easily. As a result -- however, it does not carry forward into the milk. And so as a result, the company initially applied only for a registration for use in corn that would be in animal feed and in commercial products like oil. I don't think it goes in automobiles, but, you know, oil. Commercial uses of oil and that kind of thing.

And it didn't raise that issue there. We were concerned about that issue. We were concerned about the issue at the time we got the application and when we subsequently got an application for human food use. But we did register it for those more narrow uses along with some requirements that the company assure that it be kept to those more narrow uses.

Alas, in September of this year the corn was found -- that is, the gene -- the gene modification, this gene, was found in human food. Kraft store bought taco shells, to be specific. And immediately all the relevant parts of the government worked together and a number of steps were taken, including a work out with the company,

that all of the crop that was not yet distributed and processed would be purchased by the company. And I believe USDA has worked with them to store it and transport it at their expense. The company's expense -- ultimate expense.

And the company agreed to cancel that registration, in part because it was obvious that the -- at least obvious to us; I won't say for the company -- that it was not practical and not workable, or that they were not succeeding at keeping the corn from getting into the human food chain. However, the tolerance for animal -- the exemption from tolerance for animal food and these commercial uses remained in place.

So people were not -- people who had grown this corn solely for those uses, and the corn that USDA was taking possession of, still had a lawful use -- still does have a lawful use and so forth. And we then had to gear up to deal with any future application for this substance. But more importantly for the significance of this material in the human food supply.

And so we announced a very robust science and public participation process to look at the significance

of this. It's not as if that's the first time we had looked at it. We had actually had a Science Advisory Panel committee on the question of whether it's a food allergen and how significant it is.

But just yesterday we had another -- and that was this meeting that Jim was talking about. This very long Science Advisory Panel meeting on the subject of what are the health risks. We also heard a lot of public comment about what ought to be our regulatory posture -- ours meaning the federal government's -- on the material that may be in the human food chain now. And we expect a report from our science consultation as soon as like tomorrow or the next day.

MS. FEHRENBACH: Tomorrow or the next day.

MS. MULKEY: Very soon and extraordinary and reflective of the sense that it is very important that we get the benefit of the science advice. So that's the story on that.

MALE SPEAKER: Marcia, can you eliminate one thing that was raised in sort of an oblique way in that editorial in the Post on Sunday, where FDA comes in on this in terms of some of the decisions on the food

supply?

MR. AIDALA: Because, again as -- because part of it has also been part of the understanding for some of the folks that have now become players in StarLink, it's a question about why is EPA involved at all.

MALE SPEAKER: Right.

MR. AIDALA: And Marcia just said it's a pesticide that is engineered in the corn, and pesticides are our regulatory bailiwick per FIFRA. FDA is the enforcement arm, and so per se FDA is the folks who then go and say, hold it. If this is appearing -- a pesticide, even thinking in terms of conventional pesticides, if this appears in food in interstate commerce, it's a violation of the Food and Drug Act, and they're the enforcement arm of the pesticide regulatory mechanism.

So FDA per se is this, quote, this simple enforcement function, which obviously is not simple. But that gets into the issue of, again, is it -- who goes out and samples. Who goes out and says what can and can't happen to the food, etc., etc. And they also have jurisdiction over animal feeds, so obviously they are,

you know, responsible there.

And then this issue gets into things like what is allowed for export, because, again, right now per the agreement -- the original registration agreement -- it was forbidden to be exported per se. But obviously there has been some -- you know, it's going to be exported for animal feed. Should it be. Can it be. It's also gotten into international trade issues about, you know, whether our trading partners will accept and all that thing.

And that's been one of the ways the three agencies -- and frankly more than three agencies. But primarily USDA, EPA and FDA have been working together literally. You know, not just daily but, you know, hourly since this thing broke to kind of make sure that we're working together and in effect not tripping over each other. And we're doing a pretty good job on that part, at least.

MALE SPEAKER: Has any formal regulatory actions taken place, or has it all been voluntary?

MR. AIDALA: Per se, as I understand it -- well, FDA is not here per se. As I understand it -- oh, FDA is here? Well, speak up.

MIKE: Yeah. I'm representing Bob Lake, and I came in late and I apologize. But the question is about formal regulatory actions?

MALE SPEAKER: Yes.

MIKE: As far as I know, we would consider a recall a voluntary regulatory action. And as far as I know to date, that is the type of actions that have taken place, so we would not consider them to be formal, as would be something like an FDA seizure of a product.

MR. AIDALA: You may want to describe a class two recall business, because I think that may be part of what confuses some folks. It certainly confused me when I first heard about it. So you may want to talk about that, given that the private concern does a voluntary recall, what you all do with it.

MIKE: A recall is voluntary inasmuch as it is undertaken by the party that is responsible for the food item. Once the recall is initiated, however, FDA audits it according to a classification scheme. And our scheme breaks the classifications down into class one, class two and class three.

To make a long story short, class one recalls

are supposed to be done all the way to the retail level. Class two recalls are only required to be done to the distribution level. Class three recalls tend to be technical violations, such as labelling violations that may have no public health impacts.

So we have to date handled these as class two recalls. But my understanding is that the recalling firms have in many cases gone all the way to the retail level. But our auditing scheme for a class two recall would require that the responsible party only go to the distribution warehouse level.

MR. AIDALA: Okay, thanks.

MS. MULKEY: One thing that helps me to think about this is legal authority and sort of expertise, and they're not necessarily always exactly the same. And so we sort of each have our clear roles in terms of legal authority. But we are trying to collaborate around our respective expertise as well. I think one of the things that that article sort of missed was that distinction. And EPA is not trying to substitute its expertise for areas where it may exist elsewhere, or at least not to isolate our expertise from that of USDA or FDA or

wherever it may be.

MALE SPEAKER: Yeah. I thought the article missed the point in a couple of places.

MR. AIDALA: Yeah. And basically the way the three agencies -- and frankly there have been more than that, because there is also, for example, the trade rep's office and other folks involved, and the State Department in terms of international relations and things, too.

But in terms of the three agencies, the world of corn or the world of grain, if you will, we primarily look to the department for sort of the expertise, as Marcia just said. FDA is those folks that do food, if you will, and again, know the food distribution system and know how people make it. They have the expertise to evaluate claims in those regards.

And we're the pesticide regulatory authority per se, but that gives us sort of a dominate role in terms of the safety question, which is why we have empaneled the SAP and talked about, as Marcia indicated, the robust public process on trying to come to a conclusion about, shall we say, the -- it would be a misnomer to say the safety per se, but rather the formal before us is whether

or not to grant an exemption from tolerance.

MIKE: One other thing I would --

MR. AIDALA: Sure.

MIKE: One other thing I would say is inasmuch as FDA's role is enforcement, in many cases an enforcement action initiates when a firm comes forward and says we've found, you know, this issue with respect to our food and we're going to do a recall. In other cases it arises from FDA's monitoring programs which consist of our domestic pesticide compliance program, where we're going out and taking about 3,000 or 4,000 samples a year, and special surveys that we run to target certain situations which we think require our attention.

So depending upon how this plays out, we may have to make some decisions with respect to how we're going to monitor for this problem in the food supply as a result -- within our ongoing monitoring function. So if there are going to be future enforcement situations that arise, they could very well come out of a FDA monitoring program where we're out there playing the role of the cop on the beat, in addition to firms coming forward and saying to us, we've found this problem and here is what

we're going to do, where we would be auditing the recall.

MR. AIDALA: Again, thanks.

MS. MULKEY: Steve?

DR. BALLING: Well, actually the timing is good for this, because Mike just referenced it, and that is relative to monitoring. One of the really troubling aspects of this, for those of us in the food business at least, is the testing part of the procedure, the lack of repeatability and reliability of the tests, and the number of false positives that have been seen. When you send the same sample out to multiple labs, you get completely different results. We've certainly seen that internally with some of our products.

And yet we have to establish an enforcement system that relies on unreliable laboratory results. That's a really scary aspect of this whole thing. And I'm wondering if FDA or EPA, either, are doing some more work on trying to establish more reliability.

MR. AIDALA: Well, two things. One is in terms of having a method per se, as you know, that's part of the registration requirements.

DR. BALLING: But it wasn't in this particular

case.

MR. AIDALA: Oh, no, we had one. The question is whether FDA had it, used it, etc. The larger point -- two points. One is finding the DNA per se as separate from the protein. In this particular case, the protein is the question. For example, I'm told that -- and obviously we have no way of knowing about this. But NFPA announced yesterday they have a method to detect the protein and have some results from whatever, you know, tests they've done. Now, again, we've not seen that. We will see that. We will obviously consider that as part of our final deliberations if we can get a look at that, etc.

The larger question -- the direct answer to your question is, is right now the issue is what about the situation given the corn that is out there in commerce in corn products. We have not -- although we obviously know we will have to have sort of an assessment of what I call personally lessons learned, I do think -- and, again, personally predicting -- that you're going to see a change in a whole bunch of arenas vis-a-v biotech, including things like what you just said.

For example, if the formal regulatory requirement of FIFRA allows you to look at DNA but your issue is protein, shouldn't you make sure you have both. Shouldn't you make sure that -- again, we're sort of familiar with the world of conventional chemicals. In the world of conventional chemicals, even if it's hard in terms of a single assay method instead of a multi assay method, you know, there is some level of, you know, expertise and familiarity with it. This is part of that whole sort of more emerging technology arena.

So, you know, I do think basically the short answer is yes, we haven't thought specifically -- or had specific thoughts about it. But that's obviously part of what we're going to have to do in some kind of retrospective about the situation. And I do think that the kinds of issues that you raised are ones that will not be the same in the future, you know, after September when it was all started versus before September.

MS. MULKEY: Well, it's not surprising that there is a lot of interest in this committee, and I would suspect in the public here, in this topic. That's one reason why I included it in my earlier remarks. But we

really have not included it as a major agenda item. Susie is following it very closely on behalf of OPP. And we'll be here throughout most of today, if not every minute of it, and invite you to have side bars if that would be helpful on this topic.

Susie, is there anything you think you need to add?

MS. HAZEN: No. Just I'm here, and so if there are other questions on this outside, just grab me.

MS. MULKEY: Because we do like to take advantage of the fact that we're spending this time together even outside the agenda. But we also like to stay on the agenda and keep with our timetable, which calls for a shift to a topic involving experimental use permits.

Those of you who are in the registration business, or interested in transition issues, or have an interest in even nonagricultural pesticides -- although most of the EUP issues have been agricultural -- know that for some time experimental use permits can require so much work and science that they have not been necessarily readily available. And we've heard about

this and we've understood some downside to that. I'm talking now about experimental use permits where you can sell the food. There is no real -- it's not as hard to get one where is destruction of the crop, but that can be a pretty pricey business.

So Jim has -- Jim Jones, who directs our Registration Division, has been working, hearing you, trying to get input from you and wants to use this opportunity to further that with regard to a proposal relating to experimental use permits.

So, Jim?

MR. JONES: All right, thanks. I'm going to give a little bit of more context and then turn it over to Rick Keigwin who is going to walk you through the details of the proposal that we've got here today.

As Marcia mentioned, we have not been issuing very much experimental use permits with a tolerance, meaning that not only could you experimentally use the pesticide, you could then sell your crop legally after you had done that. And that has been a problem for many of those in the user community in particular, but also for the registrants as well.

A little bit of the context behind that, back in 1997 -- and actually this is somewhat unrelated to FQPA, although it did happen around the same time -- we initiated after a significant amount of public comment what has been commonly referred to -- we refer to this ourselves -- as the priority system. This system is designed to order -- rank order -- the way in which we do our business.

And when you have more petitions than you have resources to handle, you have to make choices about what to do first. And we've discussed our priority system in this meeting numerous times over the years. It's a process that we've always done through public comment.

Coming out of that, the public comment process and subsequent revisions to it, the priority system, which gives priority to reduced risk compounds, methyl bromide alternatives, OP alternatives and then IR-4 submissions as well as company priorities, we have found after the implementation of that process that EUPs with a tolerance have just not gotten priority. They didn't get priority from the manufacturers, and they weren't getting priority because we didn't identify them specifically

either as a reduced risk alternative or an Op alternative. They didn't have their own independent priority.

After several years of working through the priorities using our system, we have found very few -- the results have been very few EUPs with a tolerance. And I think that one of the messages that we've gotten throughout the process, both explicit and implicit, is that there is a greater desire for Section 3 registrations for new chemicals and new uses than there is a desire for EUPs with a tolerance. And therefore you can see that the priority system is delivering what the customers are asking for.

However, that being said, there is clearly a desire on the part of more so the growers than the industry, but the industry as well, for more EUPs with a tolerance, in particular as growers struggle with transition issues. So what we have tried to do in this proposal is maintain our basic overall priority system. But it's not really the priority system we're trying to protect. We're trying to protect the new chemical and the new use registrations that we have historically

committed to and continue to commit to.

As we hear over and over again, although we want EUPs with a tolerance, we don't want you to do fewer new chemical registrations or fewer new use registrations. So we've tried to come up with a way in which to both maintain the productivity of the program for Section 3 registrations while increasing the number of EUPs that will have a tolerance.

And what you'll hear today is a proposal that we -- it's a proposal, and we're going to get not only the comments of the PPDC, but we'll get a fuller vetting through some type of a public process, either a PR notice or a FR notice. We think it is a proposal that meets those objectives.

So with that, I'll turn it over to Rick who will sort of walk through the proposal.

MR. KEIGWIN: Okay, thanks. As Jim was mentioning, we haven't issued that many EUPs for food uses with a tolerance post-FQPA. And in an attempt to address concerns raised by growers, and registrants to a degree, we have tried to create a program that meets the grower's needs for greater utilization of new

technologies under -- or prior to registration. That still allows us to make the safety finding so that we can put a tolerance in place and then allow the food to go out into commerce, while at the same time protecting the new chemical and new use registration resources, and yet at the same time providing us with some flexibility.

So the criteria that we'll walk through today are first cut attempts. Some people might call them -- if a chemical or an action meets these criteria, they are no-brainers. There is probably some room to expand these criteria a little bit, and that's in part what we're hoping to get through the various public processes that we'll be engaging in.

(END OF TAPE ONE, SIDE A)

MR. KEIGWIN: -- requirements we have to make before the agency can issue an EUP, and they fall both under FIFRA and FFDCA. Section 5 of FIFRA requires us to determine that the EUP is needed to gather useful information that can't solely be for purposes of marketing new compounds. It's really to focus on label refinement, efficacy and how the chemistry fits in with the agricultural production process. What is its niche.

What is its fit within the agronomic system. And also we have to make a finding that there is no unreasonable hazardous effects.

On the FFDCA side, this only comes into play where we need to establish a tolerance. It's similar to any other tolerance that we have established post-FQPA, that there is a reasonable certainty of no harm from aggregate exposures.

With that, a great deal of data needs to be reviewed. The regulations call for a very narrow set of data. But as we've encountered with the passage of FQPA, there is a full arrange of data that we need to evaluate in order to make the FQPA safety finding, and obviously a great deal of environmental FATE data in order to properly characterize the contribution or the attempts of the pesticides to get into water systems.

The regs, for example, call for a limited amount of data on developmental and reproductive toxicity with FQPA. We want to look at that more fully. We need to look at aggregate exposures, whereas in the past, pre-FQPA, when we issued temporary tolerances we focused on incremental risk as opposed to full aggregate risk.

And the other aspect of this is that often now when we do receive food use EUPs, the registrants are submitting the chronic studies. And when we receive the chronic studies, we generally at least want to take a look at them to make sure that there is nothing in there that would cause us to be alarmed.

So as with any of our regulatory decisions, we're going to follow a fairly standardized scientific review process, reviewing all the necessary data, evaluating the data through our internal peer review process, conducting risk assessments and making any applicable safety determinations.

So now it's probably at the point where we'll just quickly walk through the criteria. As I mentioned, these are first cut, preliminary, open to suggestions. But in designing the program we wanted to come up with criteria that not only were easy to understand, but that could also be easily applied. We wanted clear criteria where the regulatory staff could make these determinations without a significant or in depth scientific review. Basically, we're trying to rely upon existing risk assessments that the agency has recently

conducted.

Jim touched on some of this earlier in his opening remarks. But the resources to evaluate new chemical EUPs are pretty much identical to new chemicals for registration. Our review times for those have been relatively identical, and I think in large part that's why registrants have opted to pursue registration rather than seek an EUP first.

Even for an older chemical that has not been through an FQPA type of process, there is still a significant amount of review work that we would have to do even to issue a food use EUP. We need to re-look at those studies for, for example, susceptibility determinations. We need to look at aggregate exposures. We need to look at contributions to drinking water.

And for those types of actions, there could be a significant impact on resources if we were to find ways to address those. And maybe through other fora we can come up with ways to address those types of chemicals or chemicals meeting those criteria. But what we'll present are at least a subset of chemicals that we think that we can fairly easily make some safety determinations for and

expedite EUPs through the process.

I think we can just skip over this one, because that's really a repeat. So the proposal that we're presenting today, we would at this point limit it to methyl bromide replacements, reduced risk compounds and OP alternatives, provided they have registered food uses post-FQPA.

And we're even being a little bit stricter in this early phase. What we're saying is not only chemicals that meet that first bullet, but also chemicals that there has been an agency decision since October of 1998. The reason why we chose that is those are the chemicals that have used the more modern or current approaches to how we do aggregate risk assessments and the FQPA safety factor peer review committee had been fully in place by then. So we have very high confidence in those compounds that we can heavily rely upon those previous science determinations to make these EUP determinations.

Also, in an effort to -- because our intention is not to heavily rely upon our science divisions to do these reviews, we want to limit chemicals at least in the

first year of this to those types of application methods or use rates where we've at least looked at that for another crop previously. So, for example, if the registered food use a seed treatment only, and then the EUP was for a foliar application in an orchard, obviously the exposure scenario is very different. And our intention is not to have to redo scientific assessments necessarily in order to issue these EUPs. Obviously a foliar use results in much higher potential worker exposure than a seed treatment use.

A couple of risk cup type issues, and again these are -- we think that there is some room, and we welcome your comment for all of these criteria that we've developed. Dietary issues. We would propose that, again at least initially, that the existing uses utilize less than 50 percent of the acute risk cup and 60 percent of the chronic risk cup. This is using the agency's most recent assessment. And that the proposed new use, or EUP use, would utilize less than 10 percent. We actually think that that third bullet there is very likely to happen under an EUP scenario, anyway.

In terms of acreage, our initial thoughts were

that major uses would be limited to about no more than 2,000 acres. That's actually pretty typical for a food use EUP for a major use. For an aquatic use or a minor use, our initial thinking was more in the hundred acre range. I know some growers might think that for certainly some of the major minor uses, if you will, that that's too limited. And so that's an area for discussion.

Watershed limitations. Our initial thoughts were no more than 100 acres in a watershed. This, again, is so that we don't have to re-look at the drinking water assessment that we've previously done. Now we're not talking about the Chesapeake Bay Watershed or the Mississippi River Basin. What we're talking about is how the U.S. Geological Survey defines -- I think what they call cataloguing units. There are over 2,000 what they call watersheds or cataloguing units, and we would propose to use that as the definition for watershed for these purposes.

This next slide is really what we've generally done by EUPs, both pre- and post-FQPA. These are more on the FIFRA side of things. Counties where we have

significant endangered species concerns, we would either opt them out of the EUP program or try to work with the State heritage programs to minimize or eliminate any impacts on endangered species.

Typically EUPs have been issued for one year with opportunities to renew them on one year increments. We propose to keep that pretty much the same. And then we don't get many EUPs for residential uses, anyway. When we do, they tend to be things where registrants want to do some consumer preference testing, if you will, prior to registration. One of the reasons, again, that we would propose to limit most of them out is so that we don't have to revisit our aggregate exposure assessment.

The next few slides, we'll just quickly run through them. These are the chemicals that have been registered by EPA since October of 1998 that are either methyl bromide replacements for some uses, reduced risk or OP alternatives. It's not an exhaustive list. There may actually even be some chemicals up there that on their face don't meet all of these criteria. There may be other chemicals that were reviewed post-FQPA that should be on this list, and so we would invite that. But

we've delineated them here for this purpose as fungicides, herbicides and insecticides.

Again, our intention is really to be flexible, but we also want to have a program that is going to be useful to growers. If what we've designed here is too limiting, we want to see how we can expand it. At the same time, our most important priority is to make sure that we're being protective. Protective of the food, protective of people, and yet to protect our resources, because we really don't want to be shifting resources to reviewing EUPs and sacrificing new chemical and new use decisions while we're trying to do this.

We're going to have a public comment process. This is obviously part of that process. We're currently drafting some type of either a PR -- a draft PR notice or a Federal Register notice that would go out in the next few months. And then obviously some type of an implementation schedule would be developed as part of that public comment process.

So with that, that's sort of it in a nutshell. I'll take some questions.

MS. MULKEY: We have about 30 minutes for

questions and discussion, so let's hear from you.

DR. BALLING: A couple of questions. One, back on the acreage limitation --

MR. KEIGWIN: Uh-huh.

DR. BALLING: And you mentioned that some of the major minors mights -- some discussion might need to occur, because what is it, 300,000 acres is the cutoff?

MR. KEIGWIN: That's the cutoff for major minors, right.

DR. BALLING: So if you're 3/10, then you can get up to 2,000 acres, and if you're at 2/9, you can get 100.

MR. KEIGWIN: At 2/9, right. So obviously there needs to be some flexibility.

DR. BALLING: Yeah. Maybe some thought about as a percentage of the total crop and the geography spread of the crop? Because those crops that are only in California -- almonds for instance -- probably don't necessarily need 2,000 acres. But apples spread out all over the U.S. are going to need it.

MR. KEIGWIN: Uh-huh.

DR. BALLING: The watershed thing also is a

little bothersome. Again, I'm not quite sure how USGS defines a watershed.

MR. KEIGWIN: Yeah. They're fairly narrow, actually. I was just looking on their web site this morning to get a sense. And the first ones that they do are in Maine, and I think they have about 100 watersheds just in the State of Maine. So, you know, along the Mississippi there are probably hundreds of what they call watersheds.

DR. BALLING: Yeah, hopefully that's not one.

MR. KEIGWIN: Yeah, hopefully that's not one. They don't define it as one. For their purpose it's relatively narrow. What we're trying to avoid is a concentration of EUPs in any one watershed that would cause us to need to reconsider any drinking water assessment that we've previously done.

DR. BALLING: So this is drinking water based?

MR. KEIGWIN: These are drinking water based.

DR. BALLING: If there was no expectation that the chemical -- you've already done 75 percent of the work on it. You certainly have some knowledge whether it would move into the drinking water for some reason.

You have no expectation would you need to maintain that concern?

MR. KEIGWIN: I think, again, the area here, we want to be flexible. But at the same time, we don't want to have criteria that are difficult for our regulatory staff to understand. Generally speaking, we're not intending to have a full science review of the EUP. So if we can develop some criteria that address that point, but are easy to implement, easy to understand and easy to explain to people. And not just to the growers who might be utilizing the chemical under the EUP, but the public generally, then we could try to develop them.

These are the guidelines. They will be rules. And if you were to come in with a compound that had -- we had no expectation of previous reviews, because it's not mobile and it's not persistent, and are they ever getting into groundwater --

DR. BALLING: You can make that argument.

MR. KEIGWIN: Right. Then we could consider going to some higher level in a watershed, yes.

DR. BALLING: And there may not be any need to do it. I just don't want to be bound to those kinds

of --

MR. KEIGWIN: And the other thing on your earlier question, what would be useful through the cup full counter process is to get a handle on -- for those of you who are involved in major/minor crops -- what size of EUPs have you had that you would think would be -- even if you haven't had them. But how big would it need to be to give you the kind of information that you would require to have confidence in how the compound is used.

I mean, I'm not -- it's not clear to me you would need 1,000 acres or 500 or 200. I'm not -- I don't know. But you probably do have some sense.

DR. BALLING: That's a good point.

MR. KEIGWIN: And those of you in the business could sort of feed that to us.

DR. BALLING: That's a good point. We can do that. One other question on -- because we're speaking in generalities. So it's kind of hard to know what the details might be relative -- I'm thinking about this -- you're doing 75 percent of the work for an EUP than you would do for a new chemical.

MR. KEIGWIN: If it's one that is a new chemical

EUP.

DR. BALLING: Right.

MR. KEIGWIN: Right.

DR. BALLING: Is this sort of the first 75 percent, so that in theory when you're that far along on a new chemical, you could actually start allowing EUPs before you finish the last 25 percent, or is it something totally separate that you have to do and that is not accumulative in the new chemical registration process?

MS. MULKEY: The 75 percent was not for a new chemical. It was like 100 percent for a new chemical, if I understand the chart.

MR. KEIGWIN: Right.

DR. BALLING: No, I understand that.

MS. MULKEY: Yeah, 75 percent was a new use.

MR. JONES: We've actually -- we've done them just before a new chemical, because we were far enough along to do an EUP, but not far enough along to register it. But the timing of it has to be -- you have to be very, very lucky in the timing, meaning that you say you hit that point in -- you know, if the use is in May, you hit that point in April. Oh, how fortunate for us all.

That timing rarely works out so beautifully that you can do that.

But it has happened that we have issued -- and we didn't plan on it that way. But either the company or we recognized that it was feasible and therefore we did it. But it's pretty unusual and it's largely because of the timing aspects. The moon and the stars don't line up like that.

MR. KEIGWIN: And remember what we're talking about here is a process for expediting more EUPs through the process. You know, certainly for that scenario, Steve, that you just mentioned, I mean, we have done that before. These are the ones -- you know, FIFRA calls for a 50 day turnaround time on an EUP. And we think that for a lot of the things that meet these criteria we could get closer to that 50 day type of expedited turnaround as opposed to the 12, 15 or 18 month turnarounds for some of the EUPs that might fit the scenario.

DR. BALLING: And presumably you could also look at the opportunity -- as a user at the opportunity of well, we've got this compound that is --

MR. KEIGWIN: Far enough along.

DR. BALLING: -- 65 percent through the system. Maybe we can get the EUP on it this year, because we're not going to get the new registration this year, but at least we can try it out on a commercial level. And that's what's so critically important about these EUPs.

MS. MULKEY: Phil, I think you were next?

MR. BENEDICT: Yeah. USGS numbers uses digit numbers to signify the size of the watersheds.

MR. KEIGWIN: Yeah. These are the eight digit.

MR. BENEDICT: I was wondering where you were. Okay, eight digits. If you just tell people that, it would make it a lot easier in figuring out what's going on.

MR. KEIGWIN: Okay.

MS. MULKEY: And I think Larry was next and then Dan. I may have that wrong.

MR. ELWORTH: Well, one thing that I would want to emphasize in this is that -- and I know this is unintentional. But this is the rationale behind the grower community asking for the agency to look at EUPs. It's not because the growers are interested in more flexibility or want to use chemicals more frequently.

But given all the pressures on growers and not just regulatory pressures, and given the nature of the chemistry that is out there, which isn't broad spectrum but very specific chemistry, there is an incontrovertible need to learn how to use these chemicals before they're actually applied on a wide scale in the field. And without that, it's virtually impossible to make some of the changes that growers have to make, again whether it's because of biological reasons or regulatory reasons.

So whatever the agency does to deal with that problem, whether it's this solution or other solutions in the EUP program -- and that's not the only solution -- the growers and the people that work with them need time to get experience with these chemicals before they take them to wide scale. Or they simply -- number one, they won't be alternatives. Two, they won't be able to be incorporated.

And it's going to take three to five years to get these chemicals to go from beginning to becoming acquainted to them to actually be able to use them effectively in the field, especially since we're talking about chemicals in many cases that have a very limited

spectrum and maybe even a limited spectrum for a limited time during the year.

So that -- I think that's the underlying need here irrespective of -- this isn't a regulatory relief proposal.

MR. KEIGWIN: Right.

MR. ELWORTH: This is a proposal to give the industry the opportunity to do what they need to do. Two specific issues I wanted to raise on that. One is -- and I know there has been some discussion about this -- the issue of the duration of it. If the agency is interested in minimizing its resources, knowing -- based on what I just said -- that you do need some time to do this, looking at more than a one year duration for this especially if the timing doesn't line up, as Jim was saying, would be, I think, a really useful thing for the agency to think of in terms of its resources. And also given the fact that it takes more -- you don't just take something out in the field. You look at it for a year and go ding, you know, we're going to use.

The other issue that you didn't talk much about, Rick, is how this will fit into the priorities set in

with the agency.

MR. KEIGWIN: Yeah, I'm sorry. We think we could handle these without the registrant utilizing a priority. So the priorities are really there in order to help us structure science resources in large part, and we believe that most of these we could handle within RD without significant scientific input.

MR. ELWORTH: What about the duration issue?

MR. KEIGWIN: Yeah. I think we could -- I think that's something that we could definitely work with.

MS. MULKEY: Larry, do you think the only one year might deter people from either seeking EUPs or using them?

MR. ELWORTH: I don't know if it deters. I guess it wouldn't so much be deterring as it wouldn't be a sufficient incentive. I mean, some others may have some ideas on that. Dan may have some ideas on that. But the issue is not so much it would deter. Just whether it would be worth your while.

MS. MULKEY: Dan?

MR. BOTTS: I would like to echo my support for both Steve and Larry's comments and build on them just a

little bit. First of all, I would like to thank the agency for taking a concern of the grower community to heart and actually looking at a system that we think needs to be looked at in some more detail.

And having said that, as a first cut I appreciate the opportunity to look at this. One of the things that I would suggest in this process -- and the priority system having been set up the way it was, even preexisting to FQPA, probably is the major reason for EUPs falling out of favor, recognizing the resource driven issue at the agency and everything else.

I would also suggest that in the eyes of the companies that have developed these products there is no such thing as a product that is not the best and brightest for any particular use. And sometimes the priority system from a grower perspective on what needs to be looked at in this type of context might be different from the list of priorities that you would receive from the registrant. And if these are purely designed to go into implement into a transition discussion period or transition issue, which the way I read the priorities up front, where I would suggest that

you need some type of grower level input in the selection process for those products that might subsequently be able to take advantage of this system.

And going back to some of the other issues on the size limitations -- acreage limitations -- and some other things, I would also suggest that you need to carefully vet this program with those states who have a second tier regulatory program on state level EUP permits and approvals. Because I know at least in the State of Florida, even if it's got a federal EUP, there has to be an approval process at the state level as well.

And rather than do it after the fact, it would probably be a good idea to go ahead and solicit some comments on this proposal, even before you go out with your PR notice or FR notice at the state level.

MS. MULKEY: Very helpful. Thank you. Ray?

RAY: Thank you. Jay Vroom asked me to sit in for a while while he had a conference call to attend to. I have one question and a couple of comments. You mentioned that the -- well, the proposed use would be limited to 2,000 acres and limited to no more than 10 percent of the total available risk cup.

Does the 10 percent apply to the use on those 2,000 acres, or the anticipated use once it is fully registered?

MR. KEIGWIN: Good question.

(Laughter)

MR. KEIGWIN: It's hard to imagine that, you know, a hundred acres, if that's where we ended up with, would represent 10 percent.

MR. AIDALA: And it's not a reduced risk.

MR. KEIGWIN: And so I'm sure they're talking about 10 percent of --

MALE SPEAKER: Potential.

MR. KEIGWIN: -- potential U.S. full registrations. So, again, an area that we can work on and better characterize what we're talking about.

RAY: Okay. We -- our registration committee of ACPA had a chance to look at this presentation I think a week ago. There is a lot of support for that, and we're quite supportive of the efforts to streamline the EUP process. We think it's an important step in getting on the market sooner with greater confidence some of the replacement products for those being lost either through

FQPA concerns or other concerns. We think it's very important that the growers work soon and early in the process with the registrants on the products of interest so that their concerns are taken into account.

Of particular importance is planning far enough in advance for the residue data that would be required for approval, and that you've got to plan on at least a year to get that residue data. So we're eager to work with it. I guess the one concern -- the only concern I've heard expressed so far is the restrictions, which I understand the need for, might severely limit the number of uses that would go through such a program.

MR. KEIGWIN: One of the things that we've -- from informal discussions that we have thought of since we put it together is that what would likely help us sort through amongst them -- you know, we could conceivably be getting a hundred of them in the first year -- is to require that the manufacturers come with a grower as a partner already, so that we know that there is some grower support for any individual one. Which is an idea that we actually got from IR-4, which is that's what they require as they decide how to pursue which residue field

trials, crop chemical and crop combinations, so that you have this combination of the registrant support but there is a grower group that also is saying, yeah, this would be a very important thing for us.

And I think that that's something that we want to incorporate in the ultimate proposal that we make.

MS. MULKEY: We'll call on you guys, but I was going to ask a question related to this. Dan mentioned encouraging us to involve grower perspective. Ray mentioned encouraging growers to work with registrants.

My question, I guess, to Dan is, is there a practical workable way for growers to engage directly with the agency, or is the agency a tool that could be used to facilitate the interaction between growers and registrants, or is this in fact -- is Ray's envision of this, which is basically that collaboration needs to occur, registrant to growers, really the more realistic model?

MR. BOTTS: An easy question to answer. All of the above.

(Laughter)

Just from my perspective and looking at it from

an organized program where we have attempted to have this level of conversation with individual registrants, even in the numbered compound stage, or even sometimes even pre-numbered compound stage, on products that are in development in pushing for our member-growers to get better communication about what's coming down the pipeline, so that we can push to move things up in the registration process, which is probably the same type of philosophy.

There is no easy, simple way to get that level of involvement on an individual commodity group basis. And I would suggest probably that there is no more than four or five organizations in the country that have attempted to formalize this process to the level that we have in Florida. Because we have actually put together a schedule that we try to work with with what we call the basic research companies on at least an every 18 month cycle, meeting with every one of them to see what they've got moving down their process.

We're actively engaged with IR-4 to ensure that the priorities that our growers have established are involved in their system. IR-4's food use priority

system setting probably comes as close as anything to fitting a model. But I have a problem with how that process works, because it's geared more toward the extension level participation and the research level at the university system rather than direct grower participation at that level.

And right now there is not a single sight that that type of level of interaction could take place. And what I was encouraging a minute ago was maybe using this system and letting EPA serve as a facilitator as registrants come together. I mean, we do it on an individual registrant basis from the Florida fruit and vegetable perspective. I don't know that we could do that with all the registrants sitting around the table, for the very same reasons that they get into anti-trust conversations and other things when you start talking about regulatory impacts on other compounds that go across multiple registrants.

So it almost has to be on an individual registrant basis. But somehow that needs to be facilitated, or communication needs to be picked up to ensure that same knowledge base is out there across the

grower community. And that's not happening now.

DR. LYNCH: Yeah. I was going to say that I also think that the EUP program and the expansion of it -- and I really like the way you've laid out the -- you know, the criteria and prioritization, etc. And it has been really extremely useful in the efforts that I'm aware of where focus has been on transition strategies. You know, articulation of priorities of particular chemicals, high risk chemicals, that need to be removed from a system. The EUP process was incredibly important in being able to target the alternatives and figuring out how that they could be incorporated more rapidly in.

A question that I sort of have for perhaps Al, in thinking about the transitions that the USDA has been involved in, etc., I mean isn't that a way to help begin to bring together perhaps the registrants? I mean, we know that we've worked really very well with the land grant university system in order to get those people to be doing their on-farm research and get directly engaging farmers, you know, in that experimentation on their farm fields. You know, using their equipment. How does it all fit into their system.

You know, is there not a way to, you know, try to use that mechanism to more effectively create that communication with the grower community? And perhaps Steve and Dan would have some, you know, comment about that as well.

MR. JENNINGS: Well, I do think the strategic plans reflect grower-driven priorities for new products and alternative products. The problem right now is those exist for only a handful of crops. My hope is we can get them expanded. So I think it is a natural where they exist and where they don't exist, and I think we have to have some alternatives. The ones that are discussed here sound good to me. IR-4 -- again, while we all have concerns about how that priority system works, it probably comes as close as anything to reflecting grower needs right now.

So we would hope to use a variety of mechanisms, and we would hope to get the additional strategic plans in place over the year.

JIM JONES: Just to comment, I think, you know, Sarah, that the last EUP we granted in the scenario that Steve was talking about, where we were 75 percent done

and the timing just all lined up, was pymetrozine potatoes, the one you were working on in Wisconsin about two years ago. It's just the stars and the moon just don't line up like that all the time, but it did in that situation.

(Laughter)

DR. LYNCH: Well, it certainly did. And if you look at the adoption state wide of those alternative risk -- reduced risk products, Wisconsin stands out far -- you know, far in front of all other, you know, potato producing states for that very reason, because they have a very -- all the stars lined up, perhaps. But in addition, there was this mechanism for figuring out how to really integrate it into the existing farming systems and to get, you know, grower adoption and confidence in using that product.

So maybe we all need to get into astrology or something like that.

(Laughter)

MR. ELWORTH: I want to talk about non-ag EUPs, so, Ray, if you want to -- I assume you don't want to talk about non-ag.

(Laughter)

RAY: I'm not avoiding it. I just don't have anything to say about it.

MS. MULKEY: So your suggestion is that we defer to Larry and Ray. But let's be sure we save some time. I think it was Larry and Ray, then. I assume Larry wants to talk about ag, too.

MR. ELWORTH: With all due respect to your wonderful products. Sarah mentioned the test management strategic plans, and actually this issue came up pretty much early and often in all of those discussions. And it was actually -- the first I had heard about it was from the apple industry from researchers that I had worked with for, you know, 15 or 20 years. And they were universal in their concerns about this.

And I guess having said that, my observation would be -- I think this is a great first step. My observation would be that the big fish in this pond is the new AI's. And this really truly does go -- doesn't resolve that problem, and that's where not only obviously the markets are, but it's also where the larger gains are in terms of growers being able to change their practices.

And so I don't want to minimize how important this step is, but that's -- in terms of meeting the need, it doesn't go far enough. And I'm not sure that regulatory programs are the only way to meet that need.

RAY: Yeah. While my charter, ACPA, can't advocate for any specific product used, because we represent all of the companies who are amongst themselves competitors, I think we can play a role in facilitating the interaction that Dan is talking about. And we would be happy to work with the agencies, including the IR-4 program, to find a way for all of the grower groups to get together on a regular or as needed basis with the individual registrants in order to make sure that these -- their concerns and priorities are considered.

MS. MULKEY: I could offer you -- you might not want to refuse, Dan. I don't know. Okay.

MR. BOTTS: I appreciate the bone thrown here to residential use.

(Laughter)

Most residential uses will not be eligible. Rick, you and I have a little bit of history on trying to get an EUP on sort of a non-ag basis for which there is

really no template within the regulation. And I know you probably haven't discussed this much. Could you say a little bit more about what you wrote here, and then I have some other questions.

MR. KEIGWIN: I guess I have two comments. One is the main reason why that most -- or mostly no residential uses were in there was so that we wouldn't have to revisit our residential exposure assessment that we had previously done. Obviously there are some types of low, no exposure residential use scenarios that potentially could come in. I'm thinking immediately of like a below ground termite bait station, for example, that likely could come in under the scenario.

Now I believe RISE is also interested in exploring ways to pursue additional or some type of -- a new type of forum for sort of the residential non-ag type EUPs. And I'm not sure how far along RISE is.

MR. BOTTS: Well, I'm not familiar with their work.

MR. KEIGWIN: Yeah. I know they've been interested in pursuing this concept.

MR. BOTTS: Well, I would encourage the agency

to think fairly strongly about this. And one of the things that I would certainly appreciate is some sort of translation of acreage into, you know, households or other sites -- non-ag sites -- so we can get a sense of an ability to actually either have a R&D exemption or an EUP.

And the other point I want to make about this -- and why I would encourage you to do this -- is similar to the idea of why somebody has -- an environmentalist may want a hunting season on an animal. And that is, sometimes you want -- it's in the agency's best interest not to avoid the issue, but to actually set some sort of priority or some sort of scheme for non-ag EUPs, because the work kind of happens anyway on some levels of some different things.

And so there is a sort of sub-radar kind of activity, and you guys may want to have that become more above board. And that's if you have an ability to actually have registrants get R&D exemptions or EUPs.

MS. MULKEY: Is your concern primarily with products where the active ingredient is also a food use, or are you -- do you think there are a lot of issues in

this area for products where the active ingredient is not also a food use?

MR. BOTTS: We have both. But in our particular instance, we -- there are certainly non-food actives like in the antimicrobial area.

MS. MULKEY: Because that might be tackled in a different way, because it doesn't -- not that it doesn't matter what the aggregate exposure is. But it doesn't trigger --

MR. BOTTS: It makes it easier.

MS. MULKEY: -- an infinity FQPA analysis.

MR. BOTTS: Right.

MS. MULKEY: So maybe we could look into a first cut at thinking about where the active is not a food use.

MALE SPEAKER: And that would go a long way for a lot of products.

MS. MULKEY: Okay. By my count we have five more minutes, if we're going to stay on -- and we have two tent cards, so we're looking good.

J.J.?

DR. STEINBERG: Wearing my scientist researcher hat, I have to say that this program is potentially

exciting. It's not a common word, I guess, one would use in regulations. But as you well know, when the good Hal Varmis came to the NIH and when the good David Kessler was at FDA, they had a crushing need for new drugs and compounds in the pipelines, certainly as it related to age drugs.

A program like this could be a major catalyst to get new compounds in the pipeline. And I think if that aspect is underscored, I think again that could be very exciting. The key to success in the NIH and FDA's approach in getting those drugs in the pipeline, which we, the American people and the world are now reaping the benefits of dozens of new drugs in this area, was really an expedited review where time was of the essence in getting these things through. The NIH and FDA has shown wonderful charts how time to get these things to this pilot project approval dropped. And that was a major catalyst for all the companies to come across on.

Also, I have to admit as a researcher, the size of the application was critically important. Obviously you have to make sure that there is a do no harm mode. And again, here I think using experimental agricultural

labs in universities, the EPA has wonderful sites to carry these things out across the country. And I'm sure if private industry came forward and were to ask for other opportunities to use land or property set aside -- you know, one of the largest land owners in the United States is the Department of Defense. I'm sure they would be happy to loan a few acres for these things, also.

So I think a lot of novel thinking can come across as it relates to this. The SAP may have a view. So I think that's kind of the catalytic view that I would look at this program.

So I end by saying that this could be an exciting program to really push forward a lot of new novel products and to let the community know that this exists and could really be a boon in replacing a lot of old products and getting the next generation out there.

MS. MULKEY: Thanks. Ray, we'll let you have the last word for today.

RAY: I just did. I'm done.

MS. MULKEY: Oh, I see. All right. Well, thank you. We end then on this visionary note, and that's okay, too. We are scheduled for a break now, and we will

take it. We are scheduled for a ten minute break. Now you folks are impossible to do this with, I have learned. But you really need to honor that.

There is an AT&T cell phone in the Washington room, if anybody has lost your phone.

MALE SPEAKER: Oh.

MS. MULKEY: And if any of the members of the public scheduled for public comment at 4:30 are heavily burdened by the timing on that, if you could let Margie know during this break, and we will see if we can work out something so that you don't have to wait until then.

Thank you.

MS. FEHRENBACH: You can just sign up outside at the desk. There is a sign up sheet they can sign up.

MS. MULKEY: Nobody has signed up yet for the 4:30?

MS. FEHRENBACH: No.

MS. MULKEY: So if any of you were deterred by that timing, I guess is what we're saying. And please, ten minutes only. That means you can't hold a half hour meeting.

(Whereupon, a brief recess was

taken.)

MS. MULKEY: Those of you who are here are just toting up a lot of brownie points in my book, I'll tell you that.

(Laughter)

MALE SPEAKER: They're all on their cell phones.

MS. MULKEY: Oh, I know. Well, the next item on the agenda is the rodenticide stakeholder work group presentation. And this includes basically a presentation of the work of one of our work groups that has been active. That is, our -- the PPDC's work group that has been active for quite some time.

And rodenticides do present -- for those of you who are not closely attuned to, they do present some very special challenges in terms of regulatory decision making. And the obvious is not always as workable as you would think. I mean, one of my favorite stories about the obvious is these bittering agents which seemed like a good idea. The baby would go bluu, you know, and the problem was solved. And of course the problem, like many others in what we do, turned out to be far more complex than that. And maybe among other things rodents go bluu.

(Laughter)

And that's my grossly over simplified version in an effort to stall here to try to get some people in their seats.

(Laughter)

Of the kind of work that this work group has done, which is in fact very sophisticated and not that kind of simplistic -- although it seems simple once they've done their work. Some of the issues seem simpler than, you know, when they first embarked on tackling them. So it's been a lot of work. It's been a lot of good work. And it has matured to a near conclusion, right? Is that fair?

Those of you -- the PPDC has always been troubled about what does it mean to embrace the work of a work group. And there has been some struggle with am I saying I agree with everything. Am I saying that I endorse every statement they make. I think we concluded the last time we struggled with this issue that the right way to think about -- the work group exists as a legal entity, and we are a legal entity -- the PPDC. As a legal entity only because of the advisory committee.

It is not its own separate independent advisory committee. So it brings its advice to the agency through the PPDC. But the PPDC doesn't have to operate by consensus. In fact, neither does the work group. So the advice can come to the agency without your embracing it at all. What you do need to do is to decide that it is appropriate to have the advice go to the agency.

You may want the advice to go to the agency unedited by you. You may want the advice to go to the agency with some caveat, like frankly I don't individually have an opinion on whether the agency should accept the advice. You may want it to go to the agency saying we think the agency should receive this advice because they did a bunch of work.

But frankly we're not persuaded that the agency should take the advice. That's okay, too. Or even we individually as PPDC members, or even collectively, recommend the agency not embrace this advice. You do not have to agree with the advice in order to basically make it. Use yourselves as a conduit for the advice to be received by the agency as an advisory committee.

So let's be sure we understand that dynamic.

This doesn't mean that we want you to just rubber stamp the receipt by the agency of work group advice without engaging on it. We welcome your engaging on it. But it's okay not to.

All right. I think maybe now we are ready for the presentation, and they've built some time in for group discussion as well. Take it away.

MR. MCDAVIT: Okay, thank you. My name is Mike McDavit. I'm with the Special Review and Re-registration Division from OPP, and I had the pleasure of being involved with this group from its beginning to what appears today to be its closure. But I'm not going to be doing most of the talking. We're going to let some of the stakeholders speak to you about what the group did and what some of the recommendations are.

And before I do that, though, I want to just lay the stage -- the groundwork a bit more so that you have some context. I think for many of you this is not a new issue, but for some of you it might be. So real quickly just a bit of background.

In 1998 the agency issued two rodenticide REDs, one of which covered six active ingredients which were

primarily anticoagulant rodenticides. And there was another RED issued on zinc phosphide. In both of these documents we outlined a concern we had discovered by consulting with the data from the AAPCC, which is the American Association of Poison Control Centers. It is basically the poison control center data that is collected.

And what we saw was a disproportionate number of exposure incidents involving young children in the home. And we were concerned about that and felt we needed to address it in the REDs. And so we took a two prong approach in both of these documents.

The first part was to have some immediate effect. It was to require the reformulation of products to include a bittering agent, which Marcia just eluded to, as well as a staining agent or an indicator dye into all formulated products that were sold in the home. That was phase one, and that was envisioned as kind of a short term step.

The second part was to convene a stakeholder process of some type. It wasn't specified in the RED. But some type of stakeholder process where all of the

issues could be fully vetted and discussed across multiples of concerns here. And so that's where the rodenticide stakeholder work group comes into being.

We approached the PPDC also in 1998 seeking your support for forming a subcommittee, and we asked for your participants and any other recommendations on who should be on such a group. Bob Rosenberg was a member of the PPDC who also served on the rodenticide stakeholder work group. But most of the membership came from other efforts that we undertook to get a balanced group.

We convened the group. We had its first meeting in March of '99 and it included 26 members. Lois Rossi was the chair, and she would be here today if it weren't for some other pressing matters in the office. So her apologies for not being here, and so you get me instead. And then in July of '99, sort of an interim report or a recommendation was made to the PPDC.

And that recommendation was to basically take a fresh look at the labeling and try to devise labeling statements that would preclude exposure cases involving young kids. And Eileen Moyer, who is with Reckit Van Keyser, will be speaking about that in a few minutes.

But that particular recommendation was endorsed by this body, and so the agency started working on it with the rodenticide community -- registrant community. And again, she'll speak to that.

And one of the things that also came up then was -- it was Marcia's suggestion that basically created the expectation that when this group was finished, we would have a full report. And that's now available, and that indeed is how we concluded the work of this group.

As far as today goes, I'm going to put the mike down in a second and hand it over to Rose Ann Soloway of the American Association of Poison Control Centers. She is the Associate Director and she was an active member on the stakeholder work group. And she's going to discuss the findings and recommendations of the work group.

And then when she concludes -- and I think it's approximately a ten minute or so presentation. Then Michael Nieves of our office, the Special Review and Re-registration Division, who is now the Chemical Review Manager for all of these particular active ingredients, will introduce the next speaker, which is Eileen Moyer, the Director of Regulatory Relations at Reckit Van

Keyser, which is the maker of the decon products in case you don't know the name Reckit Van Keyser, which I think is kind of a disguised name.

But she'll be speaking specifically about the status of that effort to improve the labeling. This has been a joint effort between EPA and the Rodenticide Registrants Task Force to vamp up those labels. So with that, I'll turn the show over to Rose Ann Soloway, and I'm going to flip charts up here.

MS. SOLOWAY: Thank you, and good morning. It's an honor to present the work of such a diverse group, and I thank Mike for agreeing to flip charts so that I don't have to stand up right in the middle of the screen and get in your way.

This work group was convened to assist EPA to address potential problems related specifically to children's access to rodenticides in the home setting. So while there are many uses for rodenticides, the focus of this work group was very specifically children and very specifically the home setting.

The members of the group included not only federal agencies and bureaus, but also representatives of

the general public, representatives of the medical community, public interest groups, as well as industry, and chaired, as Mike said, by Lois Rossi. We met five times. Went on a field trip. Had a number of invited presentations, as well as public comment, both orally and in writing, and a great deal of very polite, but very vigorous discussion.

As part of the groundwork, we were asked by EPA to keep in mind several things as our deliberations proceeded. First of all, the number of times that children gained access to rodenticides in a home setting, and almost by definition, gaining such access would be under inappropriate circumstances.

Secondly, to focus not only on potential toxicity or perceived risks of pesticides, but also -- of rodenticides specifically, excuse me. But also on the public health benefits of rodent control, including the use of rodenticides.

We needed to consider the fact that solutions -- potential solutions -- should not substitute one potential human health hazard for another, that few actions are without costs, both monetary -- actual

monetary costs as well as costs in resources, and that the equity of those costs and regulatory burdens needed to be considered. And finally that any potential solutions recommended had to be economical and efficient. That is, not just a possible solution, but a feasible solution.

We embarked on several meetings' worth of fact finding. And I'm not going to identify them all at this moment, because I will say a few words about each of the items you see on the list in front of you. I'll simply say that we did this by means of presentations by agency personnel, work group members, as well as invited guests from other federal agencies, as well as other outside groups.

The first of these issues was data sources. EPA came to us with a great deal of information from the toxic exposure surveillance system of the American Association of Poison Control Centers. But about immediately the group wanted to find what other sources of data might be available and might be relevant to the issue at hand. And so over a period of our meetings, information from other federal sources and other state

sources were gathered.

Now there is a great deal of information to look at here. The information came from desperate sources with desperate findings. And I will assure you that there was a great deal of discussion about data, about the sources, about what the data meant and about how the data were interpreted. There was a pretty general agreement that little, if any, of the data actually characterized the circumstances surrounding children's access to rodenticides.

But there was agreement on two issues. Number one, a large number of children -- we're talking about in the tens of thousands over a period of service years -- came into contact or presumed contact with rodenticides in the home setting. Given that, this situation could only occur if the product placements were made in a manner which directly violated label instructions about safe use, for placement of dates and any instructions about keeping out of the reach of children. Because whatever else was happening, these were not out of the reach of children.

But regardless of individual thoughts about the

use of chemical rodenticides, there was certainly an agreement that there were significant public health benefits to controlling rodent populations. First of all, protecting the public health. We heard information from CDC about 20 different rodent borne diseases that are found in the United States. And some of those diseases are fatal. For example, in one report period outlined by CDC, 45 percent of victims of hanta virus died.

We learned that rodent borne diseases can be transmitted in a number of ways. First of all, directly by bites. Secondly, by rodent contamination of food, water and residential areas. And thirdly, by other critters that bit the rodents and then bit humans and passed on rodent diseases that way. Rodent borne diseases that way. So that was one issue.

Another is actually protecting food supply. Since rodents eat, they'll eat food wherever they can find it, and if what they find is bulk food supply, they're happy with that. And finally, to prevent property damage. We heard and saw some dramatic information about what happens to residential structures

-- and other structures. But we're focusing on residences.

What happens to residential structures when rodents are given unfettered access. They can bring a building down. They'll chew through wood. They'll chew through all kinds of structural building materials. In their search for water, they will chew through water pipes, which not only affects the water supply, but causes floods. And one of the frightening -- and I think for many people very surprising -- things was how they will chew through electrical wires and cause fires as a result.

We then got to the issue of chemical rodent control, since that, after all, is why we were there, and considered information about the properties and the toxicity of six currently used anticoagulant rodenticides, as well as zinc phosphide. Since we're not here to talk specifically about toxicity, I'll leave that for now unless anyone has questions later.

But I want to compliment that discussion about chemical rodent control by mentioning issues related to nonchemical residential rodent control. Integrated pest

management is an issue that was brought up by a number of constituencies around the table, certainly representatives of the public communities as well as medical -- people with medical concerns and the industry. And it certainly was agreed that integrated pest management is an important consideration when discussing rodent control in general. It's impossible to discuss rodent control without at the very least talking about sanitation and waste management.

But a couple of other issues were raised. Number one, nonchemical means are not going to be effective if there is some reason for rapidly decreasing a rodent population. If there is some need to rapidly decrease rodent population, then nonchemical means are probably not going to do it. And one instance of that might be an acute public health hazard.

Secondly, it was noted that while a number of nonchemical rodent control methods are available, they may not have toxicities, but they may in fact present other hazards. A kid who comes on a rodent caught in a snap trap has access to that rodent and potentially rodent borne diseases. If rodents accumulate in a multi

critter trap that, again, is not removed immediately, then there is access to children. And quite frankly, you know, I have taken calls at the poison center from people who are bitten by rodents who were stuck to a glue trap. Kids can get their fingers stuck in a snap trap and have finger trauma as a result.

A number of potential risk management strategies were discussed, and I'll talk about each of these briefly before getting to our recommendations to this group. First of all, there was some discussion about making these rodenticides restricted use versus general use. And there didn't seem to be much support for that possibility for a couple of reasons, one of which restricted use means exactly that. And so people who need access to rodenticides and are not in a position financially or otherwise to use the services of a professional pest control applicator automatically are disadvantaged. And secondly, the toxicology profile simply didn't seem to indicate a need for restricted use for these substances in general.

Bittering agents. Bittering agents are voluntarily used by some manufacturers in their products.

However, we also heard some testimony that mammals, including rats, certainly have strong reactions to available bittering agents, and that the required use of bittering agents in rodenticides could have the undesired effect of making them unpalatable to the rats and mice in question.

Tamper resistant bait stations. On the surface, that seems like it would be an excellent idea. There are a number of practical considerations. One is that they are more expensive. Another is that they are larger, so they are harder to display. They're harder to market. They have been less readily purchased and accepted by consumers in past situations where they have been marketed to consumers. And there are a number of other technical issues as well. But the bottom line is, with the information currently available it makes them more expensive, less available and less attractive to consumers.

Indicator dyes. Again, at first blush that seems like a simple thing. If we don't know if a child with an open packet of rodenticide actually ate some or not, if there was some dye in that packet that told us

yes or no, that at least would start weeding out the non-ingestions from the actual ingestions. It doesn't address the issue of the youngster got a hold of it anyway, but at least from a medical point of view it would seem that would make it easier.

But the bottom line after all of our discussion was that right now there are no currently suitable dyes available for this purpose. So it doesn't mean it's a bad idea. It just means that right now it's not even a feasible alternative.

There was discussion of reformulating delivery forms and repackaging amounts of pesticides available for home use. Let me talk about forms for a minute. There was discussion of actually embedding the pesticide product in something like paraffin, which meant it wouldn't be scattered. You would have bite marks. If a child got into it, you could guess amounts.

There was discussion about reformulating them into some sort of a hard pellet that would be more difficult for children to get into. But in one case we ran into the issue of decreased acceptance by the rodents in question. In the case of something that would be

harder for a child to chew on, it would also be harder for a rodent to chew on. And the bottom line is, rats have plenty to eat, and if we want them to eat rodent bait, we've got to make it maximally acceptable to them. We want them to eat rodent bait rather than our houses.

In terms of limiting amounts available, many people thought that that was feasible and in fact would be consistent with recommendations that homeowners check product placements regularly anyway to see if the product has been disturbed. To see if there are rodents actually eating the bait.

And then finally consumer education. First of all, we all accept that education is a good thing and that there are multiple potential means of providing educational messages to consumers. But one message that came through loud and clear to this group is that the best time to teach someone something is at the point where they need the information.

And without getting into all of the discussion that led to that point, to the stakeholder work group it seemed clear that in terms of homeowners using pesticides, the best way for them to get that information

is right there on the label of the product that they're buying. And that led to the earlier interim report that this group received and the report that will follow mine.

Finally, recommendations. First of all, labels are the immediate targeted source of information for consumers, and so labels should provide better information about how to place products safely and protect children. Next, that outreach education efforts can and should be adjuncts to existing programs involving products and labelling.

Having said that, it is a recommendation that EPA in partnership with a number of partners develop a web site with basic information on rodent control, which of course could include many means of rodent control other than chemical rodenticides, as well as the safe use of rodenticides.

Next, the EPA should not now require the use of indicator dyes or bittering agents in rodent baits, but that industry should have the option of including these agents on a voluntary basis and that industry should be encouraged to continue research into innovative strategies.

Next, EPA should support registrant activities to evaluate the feasibility of reducing the maximum amount of rodenticide bait per placement. And finally, that EPA should cooperate with industry and other agencies to better understand the causes of rodenticide exposures in children. The group felt that more research is needed for two reasons. Number one, we need to better understand the circumstances that characterize children's exposures to rodenticides, and that number two, without that kind of information, it in fact would be impossible to evaluate the effects of any strategies put into place to reduce those exposures.

Thank you.

MR. NIEVES: Good morning. Can you hear me? My name is Michael Nieves. No, I am not Eileen Moyer. I'm the new Chemical Review Manager for the rodenticide chemicals. Dennis Diesel sitting back there used to be the Chemical Review Manager. He works now out of the front office of OPPTS. So if you have any hard questions, feel free to ask him.

With that said, Eileen Moyer is going to give a presentation on the labelling improvements for these

rodenticide products. Before she starts, however, I want to stress that this is an ongoing process and at this point we haven't finalized anything. It's been a while since the agency has met with rodenticide manufacturers, and based on the phone calls and the e-mails that I've been receiving, I sense there is a bit of urgency on the part of the industry to get this process back into high gear.

So I want to announce that before the week is up, I will be sending out e-mails and calling the RRTF members to let them know that right after the holiday season there will be a meeting and we can look forward to working on this and trying to finalize this process.

With that said, I will move back and help Eileen. Thanks.

MS. MOYER: Thanks, Michael. Okay. I passed around a sample label that was given to the RSW last year. This was not the only sample label. Other manufacturers provided examples of how they could take their current labels at the time and improve them, work with the agency to find new ways to present the information and make the information clearer.

The other thing I want to do before I move on is to just mention the RRTF, which is the Rodenticide Registrants Task Force, which is an industry joint venture that represents either directly or indirectly over 90 percent of the rodenticide products that are on the market. And the RRTF has been working very closely with the agency to find ways for label improvement.

As Rose Ann said, when you look at the incidents with children, children have gotten hold of the product in one way or another. And whether they've actually eaten the product or not eaten it, we're not sure. But when a parent finds a child with rodent bait, everybody things rat poison and immediately they call poison control, because they want to find out what's going to happen to their child. So we needed to find a way to get consumers to place these products so they're not within the reach of children.

The concept that we worked off of as we worked with the agency really came out of EPA's consumer labelling initiative. And we looked at the initial guidance document that came out of the CLI and that was presented to the registration groups to look at what we

could do now. What needs -- what we could do, but may need regulatory changes. But we tried to find ways that we could work right now without having to go through the regulatory process which is a lot more cumbersome and would take a lot longer to see results.

If you look at the labels that I have passed out, I have what we're calling our simplified label on the front and what was the current decon label at the time. You may notice the name of the company has changed. But one of the things that -- one of the concepts that came up in CLI was having more white space. And that doesn't necessarily mean the labels have to be white, but really just more space around the labels.

If you look at the current decon label, at the time it's a pretty daunting label to read. It's difficult enough to get consumers to read a label. But when you have all this information packed together, small type size, it's even harder and it's harder to get someone to even find the information.

If you look at the simplified version, which is the top copy, you'll see that the formatting is very different. We numbered the steps so that people could

easily follow what they had to do in order to place a bait. We used bulleting in the storage and disposal area. It's a cleaner looking label and people can find the information a lot easier.

We have highlighted the key sections of the label. We centered the headings so you can see the directions for use instead of the heading for directions of use being hidden within all the other text. You now have a bolded heading. It's centered. You know, it has the highlight -- the red highlights so there is a contrast. People can find that information. They can find the statement that says important. Place this product out of the reach of children, pets and other animals. They can find the safety information, first aid information and the environmental hazards.

We also worked on simplifying the phrasing that was used. Some of the language that was used on the labels in the past was difficult for some of us to understand, you know, let alone your common consumer. And even in the RED there was a recommendation that a phrase be placed under the environmental hazards that advised consumers not to place the product in intertidal

waters. Well, your consumer isn't going to understand what an intertidal water is. It's better to just say, don't put this near or in water, and put it in language that the consumer knows what you're saying.

Since the problem -- as we looked at this, the problem seemed to be that adults were not keeping these products out of the reach of children. They were not being placed properly. We put more emphasis on keep out of the reach of children. We bolded a statement right on the front panel. We enlarged the statement. We bolded it so people could see it clearly on the front panel as they made the purchase. And again, it goes back to the teachable moment, so when someone is even making a selection, they can see the statement.

We have a lot of repetition on how -- on keep out of reach of children. Repetition is a good way to learn. So maybe if they don't see it in one place, they'll see it in another. And if you look on the back panel of the simplified label, we have keep out of reach of children boxed in a red section. We have it in the directions for use as the first statement in the second and third steps of the directions for use. We have it

again in storage and disposal.

We also have emphasis on read the label first, which was part of the campaign of the consumer labelling initiative. And that is right at the top of the use directions, to read this entire label and follow all use directions and safety information.

Basically, this is our simplified label where, as Michael said, we're anxious to move forward on this. And we've been working with the agency to develop a time line. There are a few things that we still need to work out in language and what items might require a regulatory change versus those things we can do right now. But we really would like to move forward as quickly as possible in improving the labels and trying to get this as one means to mitigate unnecessary exposures or even children having the product in their hands.

Any questions?

MR. MCDAVIT: And that's all I had.

MS. MULKEY: That's it. By my count we have about 30 minutes, right, until 11:50. So we have about 30 minutes for discussion and comment on issues.

MR. BOTTS: Just on the simplified labelling,

this was developed using EPA's consumer labelling effort and guidelines. Have you consumer tested this, or taken this label out to people who actually use the product to see whether they can understand it or read it, or whether they understand -- just reading it and looking through it, having tried to read labels from an agricultural situation, it's a lot more straightforward and a lot more good solid information and a lot fewer words than what you typically see on a label.

And I just -- have you done any testing on whether this does get the message across to consumers?

MS. MOYER: We haven't actually done that work yet, because we're still working on the format and the language that's in the label. But that's something I know that as a manufacturer we would look at the label from that standpoint.

MR. BOTTS: Okay. And one follow up. There are things on this simplified label that if you change them would require a regulatory change than what's required on labels now, or is this --

MS. MOYER: Some of the language. There is a PR notice. It's 94 dash -- Bill, seven or eight? Seven.

That impacts the language that we use on the label. And as you know, PR notices many times are used as a requirement and the states will not allow us to register our products unless we meet the conditions of a PR notice. So there might be some other changes that we would need so that we can get state approvals on the labels as well.

So it's one thing for us to work with the agency and get the agreement with the agency on the better label, but there may be some processes we need in order to gain our state registrations. So we need to address that situation as well.

MS. MULKEY: J.J.?

DR. STEINBERG: You know, this is all great stuff and I love that the label is getting simpler. Unfortunately, I love pictures and I think pictures are really terrific. And I would love to see some place where pictures can be available. I will tell you that in the Bronx if we don't have a working facility with half a dozen different languages, not including English, you know, we would have difficulty with this. And you may need to consider an insert in multiple languages. But

pictures I think are really a clue.

Regarding the very nice presentation of the RSW, I would also say that I've got to believe in this era that there are a few things -- you know, bait stations. Children under the age of three will eat essentially anything. They're in competition with many other species of animals that will just eat anything that comes their way. And they will find out much later that they don't like it. I've got to believe that we can come up with a very clever, novel bait station to keep kids out.

I know Consumers Protection has thought about these things. Also, another good resource to hit, the industry has brilliant engineers. I'm sure they can come up with this and make them look pretty and attractive and cost effective enough that people will buy them. We in the Bronx and in New York are interested in this, of course. We have lost people because of hanta virus. And believe it or not, we have Rocky Mountain Spotted Fever in the Bronx, and we are worried about these emerging infectious diseases. Rodenticides are critical for health.

And the last note is that I still believe we're

looking at the tip of the iceberg type stuff. And in the way of getting money for epidemiology, really counting the numbers of how many people and children are involved, I can't underscore this more than enough. I think the American Association of Poison Control Centers needs a couple of extra dollars to do this. If Jerry Blondell is still working dutifully for you at EPA, he is an astoundingly amazing epidemiologist. He needs a dozen people to help him. And I think you need an accurate count, because an accurate count is how you base your risk assessment.

This is very important stuff. I'm delighted that PPDC has involved itself in this and the RSW and EPA and the industry have moved forward to make this a better product. We all need it. The consumers of America need it.

(END OF TAPE TWO, SIDE A)

FEMALE SPEAKER: We're a very friendly group here.

MS. MULKEY: Yes.

FEMALE SPEAKER: I want to just highlight what J.J. said, because when I looked at this, I was thinking,

who is this for. The language issues are so important. In the community that I live in -- you know, they say that in the Montgomery County schools, which is just a suburb -- a county near Washington, D.C., you have 120 different languages represented at the schools.

So first off, that really has to be addressed. It's so important. And then that gets to, you know, a second suggestion that he just made that I was getting at in a more research oriented mode. But I like moving right to pictures. And that is, how do people get this information. And we know already that there are labels on these products and they're not being followed.

So has any research been done as to why people aren't following them? Now as a consumer myself, I know a lot of times there are reasons why I don't follow the labels. So I'm imagining that with a product like this that -- have you really -- you know, do we really understand, you know, the reasons why people are not absorbing the information that's there, and is there a better way to get it to them? And I think the idea of pictures, you know, is a way that should really be explored.

The other thing that I've been thinking of, have we thought of point of purchase kinds of ways of putting these products in a place that says they are really dangerous to kids if used inappropriately? To really highlight to consumers that you're entering into a different part of the supermarket, or into a different part of the hardware store when you, you know, come into the products that are rodenticides and pesticides, etc., and that perhaps if used according to the label, etc., etc., etc., they don't have impacts. But if not, if those are violated, as we see that they can be, that there are impacts.

So, you know, maybe some other thinking of how that label information or that consumer information can be conveyed is important to think about.

MS. SOLOWAY: I would just add that a number of the issues that you raised were actually part of our deliberations. We did hear some information about pictograms. We discussed issues related to point of purchase information regarding consumer outreach issues and so forth. So they were part of our deliberations, but we couldn't put everything into a few final

recommendations.

FEMALE SPEAKER: Right.

MS. SOLOWAY: But we do have some more information available about those points.

MS. MULKEY: Does your report cover some of these other issues?

MR. McDAVIT: The report touches on the point of purchase issue, but it doesn't go into a lot of detail. Because I think what bogged us down was we weren't sure whether as feds we had the reach to get to the point of purchase, because it probably is more of a state and local -- unless we had expanding labelling -- and we kind of spun out at that point, I believe -- it seemed a little bit onerous to have competing products delivering messages at the point of purchase in a grocery store, where it's hard to get them to even carry bait stations where there is limited shelf space.

So we really kind of spun out on that whole area. We recognize that as a critical spot, but we weren't sure how to get to it.

MS. SOLOWAY: It's very difficult really to get retailers to put documents up in the store and to

maintain those documents. And unfortunately they don't really run under the same jurisdiction, so it makes it very difficult. And that's one of the things we did discuss. You know, that point of purchase. You know, whether we could do plaques or some kind of other information. So with that it's really more the difficulty and the experience that the industry has had in getting retailers to put even documents to help sales in general in the store.

MR. McDAVIT: Marcia, can I respond to one other comment that was just made?

MS. MULKEY: Sure.

MR. McDAVIT: If you notice, I think item three is a good example of progress made. If you look at the simplified label -- I don't have my glasses on, so I'm a little challenged here. But I can make it. It now makes a statement about -- a more descriptive statement about placing it behind a heavy appliance or something. And I don't think that was explicitly -- that kind of language wasn't there before.

And so the label before may have sent conflicting messages. On the one hand it would say, put

the product where you have rodents, but keep it out of reach of children. Well, how do you marry up those two ideas unless you give an example of what we mean. So that was a CLI kind of thing. Well, describe what you mean by doing both of those things at the same time. So put it behind a heavy appliance or something. So that's an example, I think, of the progress that was made on making it more meaningful.

MS. MOYER: But I want to pick up on somebody's point who said -- Dan's, I guess -- the need to do some real in-house -- because I'm thinking -- I'm lucky enough not to have to have a rodent in my house. But I'm thinking how does a person, you know, put it behind a heavy appliance. You know, locked cabinets, etc. You know, I think that's a pretty onerous burden on the part of a homeowner. And if not understanding really the toxic nature of the product might say, oh, well, I can't do that. But the rats are a worse problem than whatever is in here. I'm going to go ahead and just leave it out. You know, I think that really seeing does make a difference in the actual use place.

MS. SOLOWAY: I do want to make one comment

about what you said about the toxic nature of the product. The products fall into the lowest risk category in EPA's Category 4, so there is not the acute toxicity to these products that people think. With the rat poison, if a child eats, you know, one or two pellets that there is this poison that if occurring. And actually when the data was looked at, I do want to point out there were very, very few incidents where there were symptoms from ingestion of the product, which really affects the clotting mechanism of the blood.

So, you know, I just wanted to take that opportunity, just because of the comments that you made.

MS. MULKEY: One more question that relates to comments. Two people have mentioned language and I think three people have spoken. So that's obviously --

FEMALE SPEAKER: Uh-huh.

MS. MULKEY: Now obviously you're not going to put 120 different languages on a label.

FEMALE SPEAKER: Right.

MS. MULKEY: But has there been discussion about the key words. The key warning words in Spanish, which I think is the next most prevalent language after English.

MS. SOLOWAY: One issue that comes up -- this particular package lends itself to a lot more room. A lot of the rodenticides are sold in place packs and small packages. And because you have limited space to even get the required language without making it mouse size, it's difficult to put bilingual or tri-lingual on those packages versus a package like this. And we're looking at some of the -- you know, the place packs having one ounce of product in it. So you are looking at something that is very small.

MS. MULKEY: Okay.

MALE SPEAKER: A couple of comments. One, I do think that this working group is a model for all the working groups in the success that they've had at getting to a joint conclusion that looks like consensus to me. And that's nice to see.

I have a question about the report, and Eileen, maybe you've gotten at this already. But there was some disagreement or a lively discussion about setting a quantitative goal of reduction of exposures to 50 percent and that was abandoned. And I would just like to know a little bit more about that.

MS. MOYER: Do you want to take that?

MR. McDAVIT: Yeah, let me address that. We were -- the group just kind of kicked the idea around, is there some way to establish some goal or some performance standards. Where do we go from here. And I think there was an interest in doing that, but we just didn't know how to get there again. We didn't know where you set the bar. Since we didn't know enough about the cases -- the details of the cases, the behaviors behind the child that resulted in any given case, it was kind of hard to set the bar.

And I think we were hopeful that we could come up with something, but we feel short of making that. That's my recollection.

MS. MOYER: That's exactly right, Mike. And also that's why we felt really for us to do that that we need to improve the data collection that was taking place. Before you can measure something, you need to know -- have appropriate information to measure. And that's why we talked about improving the data collection opportunities. You know, what kind of questions should poison centers ask when calls come in -- other types of

information -- so that we can really sort out the exposure from non-exposure and some of the other calls that come into poison centers.

MS. SOLOWAY: I might just add that none of the data sources available really characterized the circumstances of exposure. We have a meaningful number in terms of reducing exposures. And we have a literal tip of the iceberg number. A call to a poison center -- there are many calls to poison centers -- represents a circumstance, but it's not the goal of a poison center managing a potential emergency to do detailed data collection about the circumstances.

That's one of the reasons why a recommendation is that more research be done. And there are actually many examples of research where data like these have been used to identify a problem and then a structured study conducted as a result of that to get at more issues. And I think that's where -- that's something that we agreed on.

MALE SPEAKER: Mike, you said this is sort of a sunset of this group, and yet there are a lot of recommendations going forward. Who would pick those up?

MR. McDAVIT: Well, my understanding would be that the PPDC should consider these recommendations. And I think as Marcia -- earlier on when we were killing time, she was describing that it's really up to the group to do whatever it sees fit. I mean, the agency will react to whatever the PPDC wants to do as it sees fit.

But I think you've got a full medley -- kind of a full story here, acknowledging that we didn't solve the problem. I don't think we felt like we got that far. But we certainly feel like we accomplished what we set out to do, which was based on what we had what could be recommended as a group. And in that sense it wasn't perfect, but it certainly was progress on a continuum. So I don't know if I'm answering your question.

MS. MULKEY: To be very literal, the agency anticipates some sort of an amendment of the RED to bring to conclusion the regulatory decision making under these REDs. I mean, that's one piece of things.

MR. NIEVES: And I just wanted to add that the RED -- SRRD management is looking to rewrite or schedule a rewrite of this RED sometime for FY 2000 -- 2001. What year are we in?

MS. MULKEY: It's 2001, yes.

MR. NIEVES: I can't keep track. Currently right now we're working under a ecological assessment of the rodenticides, so we're working on three things right now. We're working to -- we're working on this side and gathering these comments and see where we go from here with this information. Then we're also working on the ecological assessment. And then we're also working on the label improvement.

And I guess at this point I'm basically the lightening rod for -- or the contact person -- I'm not exactly sure how you frame it -- for the rewrite and for collecting all these comments. And Dennis Diesel was, as I said, the Chemical Review Manager. Now this is my responsibility, so we'll see where it goes. But right now I'm collecting the information and the rewrite is scheduled for later this year.

MS. MULKEY: Right. We will ask you -- one of the problems we have here is that we have about seven minutes. Two of our public commenters have asked to use this time instead of later, so we may go an extra five minutes before our break. But not much more, because we

need to get back.

We'll hear from Jose and Adrienne. And then we will see if it makes sense to have some sort of PPDC closure here.

DR. AMADOR: Mine will be short, because the two points that I wanted to make have already been made. One was the issue about using another language, using at least a key word, as Marcia has said. We do that in pesticides. You know, some of the key words. We have danger, caution and warning at least.

The other one I have has to do with the pictures, and that point has been made. I just wanted to raise the question, what was the rationale for taking the pictures out? I mean, there must have been a reason why the pictures were taken out other than just space.

MR. McDAVIT: To keep that part short, I would say that there is actually -- there are some differences of opinion within the agency about the value of pictures. And the reason is that pictures can say a lot of different things to a lot of different people. So one has to be very careful that you get the picture right.

And we have been in a bit of a discussion with

Eileen on this very point. So I think they were dropped just for the sake of not having to go to that issue.

MS. MOYER: One of the things to keep in mind is that this is a work product. It's not a final product. And we did, you know, discuss what appropriate pictures may be used. A picture of a refrigerator showing the bait behind it. But to make things a little easier right now as we, you know, are continuing to work on this work product, we figured we would put the things on there that were where we were right now, so that what you have is a status. So that doesn't preclude the fact that in the future there may not be pictures, especially on larger packages versus your small place packs.

MS. MULKEY: Adrienne?

ADRIENNE: Yeah. I'm also going to be brief, because I don't want to belabor the issue of language. But, I mean, even on a small package where the word caution is listed in English, it could be listed in another language or even with a picture. I know that in some pesticide products the agency has allowed some picture use in order to indicate some type of danger.

I don't know how appropriate it would be in this

case, but a simple word directly under caution, for example, on this label might work.

Also, an alternative to that is if -- because it's really unfeasible to provide these packages in two languages as far as use is concerned, it might be that some type of 800 number, or some type of information is available at, might be enough at least for the time being if an insert is not possible. And, of course, we can't have an insert that is available in all languages, so something like -- something along the lines of what EPA does if information is not readily available in Spanish or in Chinese -- or one of the dialects of Chinese. You can contact the agency and they can at least put you in contact with people who can help you or who can get you those materials.

Also, I just want to echo something that I believe Sarah said about the delivery methods and putting the onus not on the homeowner but on the manufacturer. I can see why these pellets would be very attractive to children. Fortunately, I've never had to use these either. But there might be ways of making some of these a little less attractive. And I would just hope that one

of the recommendations is to put a little more research emphasis on that, just because ultimately -- as I believe Dr. Steinberg said -- children will put anything in their mouth.

You know, if you look at the pictures and you see in the little bait box -- which since I've never used these I thought maybe this comes with a little bait box. And then reading more carefully I realize no, it doesn't. The bait box seems like a great idea. So I don't know if something like a roach motel -- I mean, I'm sure that everybody who works in this field has thought about all of these things.

But I just hope that any recommendation really includes an emphasis on that.

DR. AMADOR: Marcia, could I just add one thing to that? It's very short.

MS. MULKEY: Sure.

DR. AMADOR: Another thing you might want to consider is a suggestion to the manufacturer to make boxes with the whole thing in one language. There are a lot of places now where ethnic foods are sold and the whole thing could be done in one language, like in

Spanish. So they might want to consider, you know, having boxes done in English and then boxes done in Spanish, and then that way people can put them in whatever they want to.

MS. MULKEY: Well, we appreciate your engagement with this. What -- the only thing that really needs to happen for the agency to consider this report as advice -- we don't have to adopt it. We're not bound by it. It's for this group to encourage the agency to consider this report.

And so while I don't have to take a vote, what I think might be helpful, is any sitting member of the PPDC concerned about the idea of the agency considering this report in its deliberations?

Yes, Ray?

RAY: A question on that point. It's outside my area of expertise, but the report goes forward? It doesn't close off discussion or outside input or comment on it?

MS. MULKEY: No, none at all.

RAY: Okay.

MS. MULKEY: It's just advice. It's not

significantly different than the comments you all made this morning on the EUP. That was made by the PPDC, so that was advice we can receive from the PPDC. Because this is a work group, we basically need your -- you basically become the conduit. It doesn't mean you agree with it. It just means that you think the agency should receive this as advice that occurred in imprimature of the PPDC.

Any other concerns? Yes?

MALE SPEAKER: Well, no. Maybe this is the inappropriate time to say this. But I just -- you know, I don't know for what reason, but I just wanted to say that it was really a rather extraordinary process. I recall at the first meeting there were people who attacked other people's ethnic heritage and similar kinds of remarks. It was really a very contentious meeting.

And in this process the EPA personnel who were involved genuinely forged a consensus. And maybe it's not, you know, the ideal solution. But I think it produced a very tangible change in the way people use rodent control products, and I compliment the agency and the folks who were involved in it for making that happen.

MS. MULKEY: That's good to hear. One thing all of you should know is that in addition to this exercise there are two related exercises, one of which we've not had a lot of discussion here but you heard mention, which is the so-called consumer labeling initiative which is a major effort. And at some point we may want to engage in that. The other is some things having to do with pesticide use in urban areas, which we are actually going to discuss briefly this afternoon that relate to this topic.

Well, then, I think what I would like to say is that unless I hear dissent, I will assume that we have heard from the PPDC that it is appropriate for the agency to take this report as advice to it.

Very good. Now we will take two public comments. And these are limited in time, as you all know. The first is Sissie Spragins of Rockwell Laboratories.

MS. SPRAGINS: Thank you. I'm actually speaking on behalf of Bell Laboratories. I was a member of the RSW and also a member of the RRTF. Bell Laboratories is a manufacturer of a wide range of rodent control

products.

And I wanted to mention -- just make a couple of points for the PPDC and the agency that in the course of the discussions that the issue was really not the toxicity of the rodenticides but the number of encounters that children had. I think if you spray a liquid insecticide, you know, along your baseboard you don't really know if your child happened to touch it or not, or you're not really cognizant because you don't see it.

But with a rodenticide, because it's a physical, you know, solid product, if you put it out on the floor, then it's picked up and then there is a call. But in terms of the actual number of cases that actually caused any, you know, medical symptoms at all, it was extremely small.

Secondly, rodenticides are truly a microcosm in the grand scheme of pesticide chemicals. It is a very small market. It is a microcosm. And I think the meetings were really extraordinary. I think it was a very good opportunity to educate people on a subject that unless you're embroiled in rodent control on a day to day basis, which is an extremely small number of people that

are, really there's not a lot of general knowledge about that subject.

Thirdly, on the issue of bait stations, I guess I've said it a lot of times and I might as well say it one more time. We manufacture bait stations which are tamper resistant -- or which we claim to be tamper resistant. We are interested in selling these in basically anywhere we can. The market has been limited in the consumer realm for these types of bait stations, and we don't advocate making it a requirement because we feel like the cost of them would prohibit a number of people that need these products from potentially buying them.

We did talk about a number of the issues, you know, and some that were raised in the discussion. It's been kind of beaten to death in a lot of ways. But, you know, we are working on things. Unfortunately, again the size of the market relative to the current requirements to actually show that a bait station is tamper resistant so that you can make that claim on the label is basically prohibitive. And that's basically an issue.

So there is no product on the market, despite

the fact the products are certainly going to protect the bait more than an open placement to actually make that -- that they're able to make that claim because of the cost prohibitiveness.

Thank you.

MS. MULKEY: Okay. Our next public commenter comes from the City of Seattle. I'm sure I'm going to butcher her name. But I did want to tell you that the City of Seattle expressed a keen interest in participating on the inerts work group, and because it had progressed so far when that request came, we encouraged them to be a very active observer, if you will. And they've taken us up on that.

But in general we are delighted to see city governments able to and willing to invest in paying attention to pesticide issues. And so a special welcome to Tracy Diconner.

MS. DICONNER: Actually, Marcia, I was hoping to comment after the afternoon presentations.

MS. MULKEY: Oh, I'm sorry. We misunderstood. We thought you wanted to comment this morning. We're glad -- we're all ready to go to lunch, so we're happy to

have you later.

And we're off to lunch with a return exactly at 1:00. And you pay the price in your discussion time if you don't follow that rule.

(END OF TAPE TWO, SIDE B)

(Whereupon, a lunch recess was taken.)

AFTERNOON SESSION

MS. MULKEY: -- from the other stakeholder work group that has been very active and is a work group of the PPDC. It's dealing with some very important issues relating to inert ingredients and public information relating to inert ingredients. This work group has, I believe, had two extended face to face meetings, and if I've got the number right, seven conference calls. This has been a hard working group. It represents a very rich mix of participants, experience, points of view, passions, concerns and considerations. And I think it is eager to have us know where it stands.

The presentations are to be made by two EPA employees, but they are being made in their capacity as co-chairs of the work group. So they're here to speak for and on behalf of the work group. All right. Cameo is going to do Bruce's --

MS. SMOOT: -- work group management.

MS. MULKEY: Oh, okay. So my notes are wrong.

MS. SMOOT: He changed his mind yesterday.

MS. MULKEY: That's fine. No problem. We can handle this. I think it's going to actually follow a

model more like what the rodenticide work group followed, which is to call more on the talents of the work group members but with a framing presentation from one of our key people, Cameo Smoot.

MS. SMOOT: Thank you. Good afternoon. My name is Cameo Smoot. I work with the Field and External Affairs Division of the Office of Pesticide Programs. The last eight months my division has assisted the inert disclosure stakeholder work group and its activities. And this afternoon I just want to present a very brief status report on what's been ongoing for the last eight months. I left a copy of just a quick summary of the activities in your chair. Hopefully you'll come back and -- if you don't have a copy, let me know. Also, as part of the very small packet is a copy of the four proposals that I'll discuss in just a moment.

In January of 1999 EPA asked this committee to consider establishing a work group to advise the committee on ways of making information on inert ingredients more available to the public while working within the mandates of FIFRA and confidential business concerns. The committee acknowledged that an

investigation into the current EPA policy would warrant constructive stakeholder input.

With the approval of the committee and after a formal solicitation period, in July of 1999 EPA established a diverse work group of members from public health, environmental, industry, academic and state government organizations. In March 2000 EPA sponsored the first face to face meeting of the inert disclosure stakeholder work group. Over the last eight months, the work group has held two face to face meetings and seven conference call meetings.

EPA's charge to the work group is to consider potential measures to increase the availability of information about inerts to the public. EPA also asked the work group to factor into any work group recommendations informational needs for a variety of stakeholders; current agency processes and policies related to inert ingredient information; commercial considerations regarding the disclosure of inert ingredient information; barriers and constraints in existing law and policy, and relevant principles and benefits of right to know.

The work group -- over the course of the work group activities, the work group agreed on some evaluation criteria for any proposals that might be introduced by work group members. Questions such as who are the audiences, what are their informational needs, how can their needs be met effectively, how can commercial interests be protected, and what other regulatory policies and schemes may be relevant.

Over the last eight months, the work group members and EPA have coordinated in a series of discussion papers to help answer some concerns. Some of those questions that we've tried to answer are how information about inerts is provided to health care providers? How does EPA disclose information about the inerts to the public? What is the role of patents in protecting industrial proprietary rights? What are the regulatory requirements for ingredient disclosure for other products such as cosmetics, over the counter drugs and/or prescription drugs? What types of barriers or restraints for sharing inert ingredient information exists between the federal government and the states or within the states? What are the informational needs of

sensitive and vulnerable populations such as people with multiple chemical sensitivities? To what extent can ingredients in a pesticide product be reverse engineered? To what extent is there standard nomenclature and/or common names for inert ingredients?

Yesterday for the first time the work group introduced four proposals which they had an opportunity to critique. While there have been no formal decisions as to which proposal may or may not be considered -- further considered for work group activities, the work group did spend about six and a half hours yesterday. And I'm going to turn over the mike to a number of the work group members. Each of them has introduced proposals to the work group, so they can briefly give you an overview of what the discussions were about yesterday.

And the first person up is Carolyn Cox. And a copy of that proposal is the second page in your packet.

MS. MULKEY: The second page? Oh, the petition.

FEMALE SPEAKER: It says the Cox proposal.

MS. SMOOT: Yes. It says the Cox proposal on the top of the page.

MS. COX: Good afternoon. I'm Carolyn Cox and

I'm here from the Northwest Coalition for Alternatives to Pesticides. We're a regional environmental group based in Eugene, Oregon.

The proposal that I want to outline for you today is based on a rule making proposal that was requested by a petition that my organization submitted to EPA back in January of 1998. That petition has been co-signed by 260 local, regional and national environmental, health and labor organizations. In addition, a parallel petition was submitted by the New York Attorney General and seven other Attorneys General. Those petitions were one of the reasons that you all acted to form the inerts disclosure stakeholder work group.

The proposal that I'm outlining is probably the most conceptually simple of the four proposals that you'll hear about this afternoon. It would simply change current labeling requirements so that labels on pesticide products would list all the ingredients in that product, much like the label on a box of cookies. It has several advantages. It probably requires the least amount of EPA resources in terms of evaluating what needs to go on the label.

We tried to address concerns that registrants have a way to protect the pesticide formula, which for many products they would like protected as confidential business information. So our proposal does not require labels to actually identify what I would call the recipe for the pesticide product. That is to say the actual amounts or percentages of a particular ingredient. It just lists the ingredients.

Of the four proposals that you'll hear about, this one I think comes closest to meeting the full needs of all the audience groups that the work group has identified as needing information about pesticide ingredients. So for state regulators, for health professionals, for the exposed public and for pesticide consumers it would give all of those groups the most information of any of the four proposals about what is actually in the product.

And I'll be happy to answer questions, but should I wait until --

MS. MULKEY: Why don't we go through the four.

MS. COX: So I would be happy to answer questions.

MS. MULKEY: If you have clarifying questions.

MR. ELWORTH: Yeah, actually I do. Who are these proposals to?

MS. MULKEY: These are proposals within the work group, as I understand it. They're not to us. They're not to -- well, this one was filed as a petition.

MR. ELWORTH: Right.

MS. MULKEY: But with the exception of that, I believe these were all just internal. They're in the midst of their work. They're not finished and this is just an internal stage in which they've developed four proposals.

MR. ELWORTH: So are these proposal presentations informational just for discussion?

MS. MULKEY: Yeah, I think so. Yes.

MR. ELWORTH: We're not being asked -- okay.

MS. SMOOT: Just one thing. I mean, it's primarily informational. On the other hand, if any or all of you have, you know, brilliant insights or ideas of things that the group should think about when we get back together in January, it would be helpful to hear those.

MR. ELWORTH: Okay, thanks.

MS. COX: Any other questions I should answer at this time? Okay. So I'll be happy to --

MR. AHADOR: These proposals from the group are from four separate people from the group, that each one makes a proposal, or are these proposals of the group?

MS. MULKEY: They're not of the group. They are within the group, for lack of a better word. One or more members of the group have put them forward for consideration by the group. They may or may not have been massaged a little bit after their initiation. None have been adopted. They've not been thoroughly -- the group hasn't come up -- the kinds of things we heard about the advantages of this, I think at this point are her opinion and not the group's opinion.

These are just proposals that have some degree of activity within the group, I think. Right? Have I got that right?

MS. COX: So if you have more questions, I'll be happy after the other people --

MS. MULKEY: Well, why don't you save them, so you can --

MS. COX: -- finish their presentations.

MS. MULKEY: Yeah. So we can get everybody together.

MALE SPEAKER: Do you have any more copies of this proposal?

MS. MULKEY: It's the whole package that had included it. Do we have some -- Cameo does have some. You need to understand. This group met yesterday to prepare for this -- in part to prepare for this session after that. So that's why it's in a little less cooked form than the other things we've heard.

JULIE: And I think each of these proposals was discussed yesterday, too, so we're really basically giving you what we gave to each other yesterday. The proposal that I have put to the work group is -- and I think it says Proposal for Consideration by the IDSW Regarding Ingredient Information on Labels. And this proposal is based on the recommendations that came out of the Phase 2 of the consumer label initiative research and the partners and task force recommendations from the CLI, and also partially from EPA's interim guidance that was issued on implementing the labeling changes.

As a result of that, you know, we did try to

implement some of these changes, and through that process found some of the barriers -- encountered some of the barriers. So part of this proposal is also to address some of the barriers that we encountered.

The proposal basically is that EPA would issue a PR notice indicating that registrants would be allowed to portray their ingredient information on their labels in whatever manner seemed most appropriate through a number of options, you know, considering what would be appropriate for that type of formulation as long as it wasn't false and misleading.

And to facilitate that disclosure that EPA would also include in that PR notice specific criteria for allowable label placement of the ingredient information. And this targeted particularly on the current requirement that all ingredient information be located on the front panel. This kind of is a barrier to putting a lot of additional information on labels.

So that on packages that are small enough that can be turned around easily, that the ingredient information can be on the back or side panel, as long as it is -- there is a referral statement on the front and

the ingredient information is easily located and easy to read. And then on larger packages, basic information would be found on the front panel with additional information located elsewhere on the package.

More importantly, that subsequently EPA through the CLI or other appropriate task force or group would conduct further research on what needs may not be met on labeling through this and what may be the most appropriate manner for including ingredient information on labels. And that the research should also -- you know, should examine the way that consumers expressed that they want to see label information.

And then based on, you know, the conclusive results of research that indicated how label information should mostly appropriately be placed on labelling, EPA could then initiate rule making procedures to require such label information.

The last component of this proposal is that EPA extend their current consumer education program, which is the Read the Label First campaign, to include providing consumers information about ingredients, such as the meanings of the terms and the functions of inert

ingredients in formulations. FDA has done similar type programs with explaining -- there are materials explaining the purpose of food preservatives, food additives and with cosmetic ingredients.

So in conclusion, this proposal -- and I'm going to pass around -- I'll have one go each way -- a couple of packages that have implemented this proposal, just so you can see in, you know, real life the types of ingredient information that would be provided. In both of these the ingredient information is located right under what's called the Quick Fax box on the back panel.

I think the advantage that we see for this program -- or for this proposal is that it is something that could be initiated immediately, you know, as a first step. Even though it is voluntary, it would at least be able to be initiated immediately. And with the consequent research, we can ensure that we find the most appropriate way of putting ingredient information on labels so that we don't have kind of the unintentional consequences of, you know, putting information on labels that would actually be less likely to be read and kind of run counter to our whole proposal to increase label

reading.

And I can answer any, I guess, immediate questions and then I guess we'll answer more questions in the discussion.

MS. MULKEY: Any clarifying questions for Julie? Okay. Do you want to move to number three?

MR. SURGAN: Good afternoon. I'm Michael Surgan. I'm from the New York State Attorney General's office, and I'm going to sacrifice 30 seconds of my time to explain that the proposal that I submitted along with others to the work group was submitted with my work group hat and not with the hat of a petitioner. That petition is in front of another forum where it's more appropriately considered.

A group of seven of us representing diverse interests got together and put forward a proposal that is based on a recognition of the need and the right of those who use pesticides, and those who may be exposed to pesticides even though they didn't use them, to know the precise composition of the products to which they've been exposed.

And I think that it also reflects some of the

thoughts of the rodenticide work group that you heard this morning. I heard that the rodenticide work group found that the label was the best time to -- the best part to educate the consumer and that the moment of purchase was the teachable moment.

The proposal as it is set forth in the memo that you have is, I think, also fairly simple and straightforward, although not as neat and simple as the proposal that was put forward by Carolyn Cox. It is based on current practice for cosmetics. It's a practice that is in use by federal regulatory agencies today. And it is based on a presumption that EPA will require the disclosure of all ingredients on the labels of pesticides unless there is a specific finding to the contrary.

The proposal includes, as does the regulatory statutes within which FDA works -- it includes provisions as to what the content of a petition by a registrant would be. The petition process would give the registrant the opportunity to make to EPA its case for any competitive advantage or economic distress that would be caused by revealing the inert, and EPA would then consider that against the presumption of disclosure and

EPA's understanding of the toxicity and adverse effects of the pesticide and the inert ingredients.

As far as time, we proposed a time line that would require that registrants present the petition at the first instance when they may be re-registering a pesticide, when they may be filing for a label change or in any case within three years from the passage of promulgation of enabling regulations.

The proposal would give to the public much -- most, perhaps, but not all of the information that we believe they should have. Obviously to the extent that EPA decides that the information could be held confidential, the public would be denied that quantum of information. And in making that information available to the public on the label, it would also certainly similarly serve the needs of all the other audience groups that we have identified.

And like my colleagues, I'll be happy to answer questions.

MALE SPEAKER: Can I ask a clarifying question? You're with the Attorney General's office in New York?

MR. SURGAN: Yes.

MR. ELWORTH: And on Carolyn's proposal it lists that this is an excerpt from pages 18 and 19 of a petition. Is that right, that New York has a pending petition with the agency?

MR. SURGAN: Yes. I said -- I clarified that at the beginning. Although New York is one of the petitioners, I'm a member of the work group and I proposed this as a member of the work group.

MR. ELWORTH: And is that -- is what you're proposing substantively different from --

MR. SURGAN: Yes, it is.

MR. ELWORTH: Yeah, it is.

MR. SURGAN: Substantially different.

MR. ELWORTH: Why are you all doing that?

MR. SURGAN: In the spirit of cooperation in the working group, we put forward a proposal that we thought might address the needs of everybody around the table.

MR. ELWORTH: Okay.

MR. McALLISTER: Musical chairs without the music. My name is Ray McAllister. I'm with the American Crop Protection Association. In your packet you have a two page proposal. Each page is entitled Draft Proposal

on Non-confidential Pesticide Product Summary. This was put together by an informal coalition of trade associations representing companies who are registrants of FIFRA registered products.

By way of background explanation, over the last few years EPA has received a large number of requests for product ingredient information under the Freedom of Information Act. To respond to those, EPA has prepared a list of -- I think it's 12 or 14 questions which go out to the registrant of each product for which there is a request. And in responding to this, the registrant must answer the 14 questions about each of the ingredients in the product, justifying the reasons why that individual ingredient should be retained as confidential business information. This turns out to be a considerable burden for both EPA in processing these FOIA requests and for the registrant in responding on a product by product, ingredient by ingredient basis.

So the origin of this proposal was to assist both the EPA and the registrants in responding to these types of proposals -- or these types of requests. As such, it addresses only a limited aspect of the concerns

which have been expressed over disclosure of inert ingredient information.

What this proposal does is it proposes that the registrant prepare a releasable summary -- a pesticide product summary -- outlining the ingredients in that product. The releasable product summary would have information which would identify the function of an ingredient in the formulation. It could identify the chemical or common name or a generic chemical classification. The means of identifying the ingredient would be at the discretion of the registrant.

If you look on the page that has a table on that with boxes numbered one through four, the active ingredient in box one is already required on each product label or the number of all of the active ingredients. In box two the registrant would identify all other ingredients through one of those means of identification: purpose, actual chemical or common name or the generic chemical classification.

In box number three the registrant would identify any ingredients of toxicological concern now on what EPA calls its List 1 of inert ingredients. If these

occur in a product, they already have to be identified on the product label. In box four the registrant would identify other ingredients associated with specific physical or health hazards. This is the type of information that now occurs on the material safety data sheet for each of those products.

Depending on how such a proposal were implemented and whether it is strictly voluntary or through some regulatory means, the other page gives three possibilities for submission of that information, whether it's a releasable product summary, a phrase which already occurs in the regulations and could be modified slightly to accommodate this type of submission. Whether it's a non-confidential formula description form, which would accompany and not replace the current confidential statement of formula that is submitted to the agency. Or a new type of form, a pesticide product technical data form.

As such, this proposal -- or this type of information could be provided by EPA to any requester for the ingredients information on a product. Another possibility is to make this information available through

some clearinghouse, such as an Internet web site where anyone can go look to find this information. It is strictly the information that the registrant chooses to disclose about his product. It is not a full disclosure unless the registrant so chooses.

We expect that this type of information would satisfy a large number of the requests that come into the agency, and could dispense with a lot of the bureaucratic effort required to respond through the Freedom of Information Act.

MS. MULKEY: I have one clarifying question.

MR. McALLISTER: Yes.

MS. MULKEY: Do you have any sense of how many inert ingredients or other ingredients would have to be disclosed under your proposal because they are required to be listed on the MSDS?

MR. McALLISTER: I don't have a good feel for that information. Some of the others might.

FEMALE SPEAKER: I think it varies, you know. The types would be the products that have physical hazards, such as flammability. So if you've got a propellant it would probably show up on there. If you

have a hydrocarbon propellant. You know, many solvents because of flammability or other reasons. Anything that would be required through HAZCOM to be on an MSDS would be included. So fitting the hazard communication criteria for what is a hazardous material, either by toxicity --

MS. MULKEY: Did the work group discuss this proposal enough to focus on that item four and how much disclosure it carries with it or doesn't carry with it?

MR. McALLISTER: Yeah, we discussed it. Now it's nothing new in terms of disclosure, because the information is already made available on the MSDS sheet. And this is not placing that type of information on the label. It is simply a separate avenue for disclosure of the ingredients information.

MS. MULKEY: But I think I heard you say it might be on a web site.

MR. McALLISTER: Well, that's a possibility of taking this entire form, whatever form it takes, and making that available publicly, so that an individual or an organization interested in getting that information could get it directly and not go through the bureaucratic

process of the Freedom of Information Act.

MS. MULKEY: Okay. Any other clarifying questions?

MALE SPEAKER: I have a question. Ray, to the point about the label, why -- was putting this information on the label considered by your group, and if so, why was it rejected?

MR. McALLISTER: Well, putting this type of information on the label is basically the proposal that Julie described. They're companion proposals. They're not separate. They're not -- no. You know, you don't do one or the other. You could do both of them together. This is a central repository for this information. It's probably easier to implement in the short run. And what Julie described was putting exactly this type of information on a label.

MALE SPEAKER: Okay, thanks.

MS. MULKEY: Phil?

MR. BENEDICT: Yeah. Is just saying that there is an emulsifier in the product good enough under part 2? It says one of the above, and one of the options is to say that it's a surfactant or an emulsifier. It doesn't

tell me what that is.

MR. McALLISTER: That's correct. This is up to the discretion of the registrant to choose how he identifies that product, and the limitation being that it not be false or misleading. Now one registrant is going to choose to disclose more information on this type of form. Another one will disclose -- will choose to disclose less. As I said, it's intended to facilitate provision of this information which is now going to the Freedom of Information Act. It doesn't preclude anyone who says this isn't enough from going ahead with a Freedom of Information Act request.

MR. BENEDICT: And I can't figure out who this piece of -- who this form is going to be filled with. Does it accompany the label, or is it part of the registration packet, or where does it go? Because that really doesn't help the states much, at this point, unless it's out there in some other format.

MR. McALLISTER: Well, yeah, it would be filed -- those details certainly haven't been worked out, because it's just an initial proposal. But it could be filed with the registration package with EPA. EPA could

take on the responsibility of making this available in a readily assessable form or avenue to states and others having an interest.

MR. BENEDICT: If this thing came to pass where you've got provisions about CBI in your law, would that work around those issues for us or not from a state perspective?

MR. McALLISTER: This is not intended to disclose CBI. Unless the registrant chooses to put all of the ingredient names on there, you would not see that type of information. It's not a replacement for the confidential statement of formula. It would accompany or be in addition to the confidential statement of formula that EPA now receives.

MS. MULKEY: We have about 15 minutes. I'm sure that this group has opinions about disclosure. It would be good if anybody wanted to share any particular suggestions for the work group about where to focus. So if anybody has any advice that is either with respect to a particular proposal -- I think you saw, as I saw, there are two proposals that go in one direction and two proposals that go in another direction in terms of

mandatory or voluntary, scope and so forth.

So if people want to talk about direction rather than details, but let's try to use that time to help the work group because they're not done.

Bill?

MR. ROSENBERG: Yeah, thanks. I sat in yesterday on the group as a member of the audience and watched them go through their work, which I think is pretty difficult because people are coming from very -- as he stated earlier, very different places on this issue. And one of the things that I thought was encouraging was this preamble to the proposals in terms of asking a series of questions.

And I would advise this group to take a step back. I think they went to solutions fairly quickly. I know that there has been this eight month period. But they went to solutions without really setting a common -- I think coming to some sort of concurrence in answering these preamble questions in a way that might lead them to some commonality.

Because right now it's very polarized. My sense is that they can't come together in the process that has

been set up now. And I would encourage everyone to maybe model themselves after the rodenticide group, find some areas of commonality and then work toward solutions. Because right now this group will -- the way it looks to me will not come to any kind of a fruitful conclusion as a group.

And you're saying, you know, we can pass over these differences and there doesn't need to be concurrence. But we'll be faced with full disclosure or not and that's it. And there's no marriage there.

MS. MULKEY: Convergence is always better. Larry?

MR. ELWORTH: Well, my question is a little different, but it has the same issues that Bill does. And actually I'm interested in the answers -- what answers the work group has to these questions here. I mean, it's not clear to me whose purposes this serves. I mean, if this were -- for example, in my life this would have an impact on me. It's presumed that in the middle of either going to Lowe's or Wal-Mart I'm real interested in having more information in front of me when I have to stand in line or something. The last thing I want in the

store is any more information.

So I'm really -- which isn't to say that you should or shouldn't be doing what you're doing. But I'm real interested in what the group considers the answers to these kinds of questions. Who would use this information? What would they use it for? How would they use it?

So I don't know how we get -- how we could hear about here from the group what you all are thinking about that, but it would be real helpful to me.

MS. MULKEY: Cameo, can you do anything? Or anybody?

MS. COX: Could I take a few minutes? I think my organizations and many of the other organizations that signed the rule making petition to EPA started from a perspective of public right to know that we're all exposed to pesticides and that that gives us a right to know what we're exposed to. And I think that's a sentiment that has strong public support, but is certainly controversial and not something that everyone subscribes to. It is something that I believe very strongly.

And then when you look at the specific audience groups, I think you see specific needs. Health care providers may be the most obvious group with specific needs. If they have a patient which they need to treat and need to treat that patient quickly and efficiently, they need to know what substances are that they're dealing with.

When you talk about pesticide users or pesticide consumers, some of those are people standing in line at Wal*Mart buying a pesticide. But some of them are school districts, city parks, county road maintenance crews and other public agencies. And many of these public agencies feel a responsibility to consider the particular impacts of their management practices on local specific problems.

I come from the northwest and saving salmon is a big deal in the northwest. A lot of the public agencies in the northwest are committed to trying to change their practices in a way that will protect salmon to the maximum degree possible. Many of these agencies are not able to fulfill that job, because if they're using pesticides, they don't have the information about what is in that pesticide in order to evaluate what its potential

impact in their local area might be on, you know, Coho salmon or whatever.

So there is a variety of different audience groups. If you're a parent and you have a child who you know is allergic to a particular substance, you would want to avoid using a pesticide product in your home that contains that substance. Right now you have no way of knowing whether that's the case or not.

And I guess I could go on with more examples, but I've probably taken too much time. So I'm going to pass the microphone on. But if that didn't clarify it, please ask more questions.

JULIE: Just looking specific to labeling, you know, I did base the proposal -- I put forth on the consumer labeling initiative. So it was looking primarily at consumers -- you know, consumer products and consumer labelling, although I think some of the aspects go to all labelling.

And I know Marcia made some mention earlier to the CLI and maybe at some point some more information can be provided on that. But the CLI based on the -- we had done some initial research in phase one and also got a

number of public comments in phase one specific to ingredient information. So ingredient information on labels was one of the particular topics and particular focuses of the research that was done with consumers in phase two.

And these are both quantitative and qualitative phases. The quantitative phase involved a survey sent to about -- we got responses back from almost 3,000 consumers in three product categories, about a thousand in each category: outdoor pesticides, indoor insecticides and household cleaners. And different ingredient formats were put forward to consumers. The most preferred was more this generic description with also the function of the product or the purpose of the material. Full disclosure was one of the options that was given to consumers, but was not favored.

So I think the question was not so much to disclose or not to disclose, but how to disclose and what to disclose that would be most useful. And even though the proposal I put forward the initial phase is voluntary, I think the more important is that the recommendation from the CLI partners and task force which

was made up of a lot of agencies -- various agency personnel as well as the company partners, was that we needed to get more information on the specific kind of formats, or how specific we should get on what type of information we would put on ingredient -- for ingredient labelling.

And so I think my thing is let's not -- let's walk before we run. That is, I guess, my opinion in a nutshell.

MR. ELWORTH: Well, what I am struck by is that if -- just, for example, two of the possible audiences are the consumer on one side and a health care provider on the other. The level of information to health care -- the kind of information and the level of detail -- or technical detail that a health care provider might want would be very, very different from what a consumer might either want or be able to use.

Did the work group talk about being able to accomplish the same thing through different formats in any of the proposals?

MR. SURGAN: If I may, I would like to answer your question and also supplement what the two previous

speakers have said. One of the problems that I see in the way that the work group has been progressing or in trying to differential these groups is that there is a tendency to pigeonhole some of these categories. There is a tendency when we talk about state governments to think in terms -- in limited terms of the needs of the agency that regulates pesticides, and there is a tendency when we talk about consumers to think about the average housewife or house husband at Lowe's. And I think that those are both very dangerous over simplifications.

State governments incorporate a variety of agencies and offices who have an interest in protecting the health of their workers and protecting the health of the people who come to do business in the office. And they don't have access to the information that may be available to the regulatory agency in that state who may or may not possess a CSF.

For instance, the Attorney General's office. My office is in New York City. We are in rented space. Pest control is the province of our landlord. Our landlord cannot provide me with information that I would offer I'm qualified to evaluate. The landlord makes

enough money to hire a consultant to advise him, but he doesn't have the information.

In other places in New York state, the Attorney General's office is located in state owned and operated buildings operated by the Office of General Services. They do not have access to the detailed ingredient statements that may reside with our State Department of Environmental Conservation. The same goes for other agencies of state, county and local governments who are well qualified to evaluate the information, who are taking upon themselves perhaps substantial responsibility and perhaps even liability in the use of pesticides and the exposure to people who use the properties that they own and manage. And I think that these aspects are too easily overlooked when we pigeonhole populations.

And as for the remaining -- as for the average housewife and house husband, I think that there is a great deal to be gained by first providing them with the information that will enable them to take part in their own health care, and whether or not they understand it, whether or not they are readily able to provide their doctor with that information. Not just for emergency

health care, but for health maintenance care throughout their lives.

And then also to inform them and perhaps stimulate them to learn more. If those ingredients were on the labels, even those people who were not aware might now become aware of it and might invest the effort to find out what the importance -- what the significance of that bit of labelling is.

MS. MULKEY: We have three minutes on this topic, and more than three tents. We will take everybody. But part of what you're getting the flavor of is how much there is to be said on this, which is why there have been two full meetings and seven conference calls. And we will not get, and you will not get as the PPDC today, a good thorough flavor of what the dialogue is. But we probably have some means to help facilitate that, including the fact that the stakeholder meetings are public and one can either personally monitor them or ask.

Now of the PPDC members who are on the work group -- anybody?

(END OF TAPE THREE, SIDE A)

MS. MULKEY: -- and Sheldon. So you also have some people. So you may be able to take advantage of those relationships.

FEMALE SPEAKER: And Jay.

MS. MULKEY: And Jay. Okay. Of those relationships for other opportunities to have these discussions.

But having said that, we'll take the remaining tent cards and then we'll think about our next step briefly. And I paid no attention to the order in which they went.

MALE SPEAKER: I have some clarifying questions for Michael, though.

MS. MULKEY: All right. Well, why don't you do that and then we'll go.

MALE SPEAKER: Two things, Michael. When you're talking about sort of an occupational exposure issue, have you tried getting material safety data sheets on these products which are supposed to list the hazardous ingredients, and has that been helpful at all?

MR. SURGAN: In rare -- well, in some occasions there is information on the MSDS which goes beyond what

is available on the label. But that is certainly not uniform and it's certainly not widespread. And without commenting on the validity -- the value of MSDS's, again they are information that is prepared by the company and done by people who have the interests of the company and their confidential business information in mind.

MS. MULKEY: J.J.? Oh, I'm sorry. I didn't mean to cut you off.

MALE SPEAKER: One other question just to wrap up on your proposal. With cosmetic labelling there is sort of a provision for catchall, nonspecific terminology. Are you comfortable with that?

MR. SURGAN: I provided that -- I used that as a model. I'm not saying that we can lift it without modification. I am sure that my friends on the other side will also have modifications. I think that that's something that we can look at. Yesterday at the work group meeting there were questions about fragrances and a recognition that we may need to deal at greater length with fragrances. And I'm sure that several of us on the working group have thoughts about the role of fragrances in pesticide products.

MS. MULKEY: All right. J.J.?

DR. STEINBERG: I think there should be no doubt that consumer labelling has been one of the great success stories in the '90's. I think the industry has done a spectacular job as it relates to consumer labelling. I think they did that with the FDA. And though it was a costly process in the beginning, you are clearly selling more food, and Americans are clearly eating more food, based on consumer labelling.

(Laughter)

And I have to admit, we know that because as we all know now -- and I apologize for this. America now leads the world in the weight of the Americans. We are a weighty country.

(Laughter)

So as I said, consumer labelling is clearly a success. There are obviously leaders in industry that did this with the FDA. The FDA has a great deal of experience in this. I know that EPA has been keen on trying to set this up. People like AnnE Lindsay have been working on this for a long time. I think it would be good to make sure that we can keep this committee

invigorated to try to come to some conclusion on this, because this will be good for everyone.

MS. MULKEY: All right. Are we going to endorse that?

(Laughter)

MALE SPEAKER: Well, I think the group is continuing the work on the area of labels. I think we were also able to identify a couple of other areas dealing with medical and medical emergency situations, and also with states -- state officials, state governments and state operations. And I think in both of those areas there is an opportunity to try to look at an array of potential information, whether they be 800 numbers or educational programs or databases or web sites or any other kind of additional information.

And the real question is, how can we get important pertinent information to people who are, first of all, caught up in a medical emergency. Whether we're talking about an emergency room or a clinic or a doctor or a nurse or some kind of health care professional or a poison control center, how can we get pertinent information to immediately address that particular

problem.

And then the other issue that we just briefly talked about was the whole issue of state and state governments and the ability to share information with different parts of state government. I think those are all difficult and thorny issues to work with, but I think they really have an opportunity to try to make some progress or to come up with some specific solutions in each of those areas.

And I think we made a lot of progress yesterday in getting our arms at least out and around some of these topics. We've got a long way to go. But I think we made some progress, and I think we can make further progress in January and down the road.

MS. MULKEY: Jay?

MR. VROOM: I've long been an advocate of more information and disclosure, respecting the fact that there are commercial considerations and some of those can evolve also on the commercial side. So I guess I would like to sort of react to what I've heard from the presentations in saying that I have a sense that there is some convergence. But maybe what I heard Bill say also

seems to be apparent to me, and that is that the movement probably has been incremental. And maybe we're focusing too broadly on these issues when, as I think Warren just said, you know, just to call all of these products pesticides in the context of understanding inert disclosure issues, both commercial and scientific and medical interests, probably need to be looked at differently in some cases, and that compromise doesn't always need to be straight down the middle between the two polarized positions.

And the more we can look at policy and an approach that perhaps reflects the fact that the disclosure that might be helpful and important that could be on a package of rodenticide may be different from what is necessary for atrazine that farmers use. And I don't have a sense from what I've heard today, and what I've sort of gleaned in monitoring the Internet communications, and the written record from the work group that that kind of detail has been addressed yet. And so I would encourage you to think about that.

I'm going to ask a question, I think probably for the agency. And I'm afraid I'm going to regret

asking this. But in looking at the samples -- the label samples that Julie sent around, I was reminded that there has been some discussion around whether the term inert, you know, was viable or not. And I can't remember kind of where that is, except for the fact that I guess these are actual labels, Julie, and they don't use the word inert. They use the words other ingredients.

So where are we at on that?

JULIE: There was a PR notice issued in 1997 that allowed the use of the word other in place of inert. So that's kind of where we are at with a lot of the recommendations, that there were things that were being allowed -- changes that were being allowed to be made and in some cases encouraged.

MS. MULKEY: Right. I would say we've encouraged the use of the term other, but the word inert is still in the statute. It's still in regs. It's still in -- so we work with both terms.

MR. VROOM: But that discussion is over, so we don't have to worry about that.

MS. MULKEY: I wouldn't say it's over.

(Laughter)

There's room for more. But I don't think there is any --

MALE SPEAKER: There's still time for a recount.

(Laughter)

MS. MULKEY: I don't think it's -- always. Always time in our business. But I don't think it's controversial to use other, and whatever controversy is left is with the continuing use of the word inert. But that is sort of constrained by some remaining legal context.

Well, I've been watching the clock assiduously on your behalf, and we have one public commenter remaining. It's the womAn I introduced you to this morning from the City of Seattle. Her interest is in talking about inerts. And it's the only one, and we have 30 minutes allocated. So I would suggest -- not for her to speak in as a public commenter.

But I suggest we hear from her and we wrap up this topic, and that we will only be 15 minutes behind after having done that. So other than timing of the break, we should be in good shape in terms of going forward. So you would think after she helped me --

Diconner?

MS. DECONNER: Deconner.

MS. MULKEY: Deconner. Oh, boy.

MS. DECONNER: Well, thank you. And again I'm Tracy Deconner. I'm here representing the City of Seattle. And pesticide issues, and particularly today, inert disclosure issues, are very important to the city. People think of city government as, you know, picking up garbage and whatnot. But we're also stewards at the city to over 110,000 acres of public land. That land is in parks. It's in rights of way. We have ornamental beds. We have golf courses. We have zoo exhibits. We own an entire watershed that our water supply comes from, and it tastes a whole lot better than your water, I have to say.

(Laughter)

We also have several production greenhouses. So we face a pretty wide array of pest management issues. We implement IPM in all cases, and sometimes that involves use of a chemical control.

And as Carolyn pointed out, we are very concerned about the impact of all the chemicals that the city uses, be it on janitorial uses, fleet maintenance

and pesticides. And we're concerned about what the impact on a residence, our employees and the environment is from those chemicals.

We do a lot with communication in the city, and we go far beyond legal requirements in both our pesticide application signage protocols, as well as our posting protocols. We do a tremendous amount of outreach on pesticide issues both about what we do internally, as well as trying to help our residents to make informed choices through our natural lawn care program, salmon friendly gardening program and other programs. And the effect of those and the ability to meet all of the questions of our residents is limited by not having full information about inerts.

It is important to us that we can make informed choices, and particularly with the pesticides that we use. So what we've done is a hazard assessment on all of our pesticide products. We've looked at about 12 different human health and environmental criteria. But that assessment, again, has been very limited by not having access to all of the inert ingredients in order to do that.

Again, we go far beyond the law. We've eliminated use of many perfectly legal products in the city because, you know, as Carolyn, again, pointed out, we are concerned about the salmon, the pollinating insects, and making sure we provide safe habitats to as much wildlife as we can attract within our city.

We also want to make sure that our residents can make informed choices about whether they want to enter a park area that has been treated, for example, or come to a festival on the Seattle Center grounds. They need to know about the applications, which is why we have increased our requirements for internal operations on posting. But we also feel that they need, and they feel that they need, information about the inerts so they can make those decisions. Some of our residents have multiple chemical sensitivity or otherwise immune suppressed and really feel that they need this.

There is a third category that we feel is a fundamental right to know for our residents. Sometimes the state government -- not the city, but the state -- has to come in and treat for gypsy moths. We completely support the need to protect our urban force by

controlling these invasive destructive pests. But in this case, when you're applying pesticides to people's homes, their personal property and their yards where their pets play and their children play, it is important that they have all the information that they need to be able to protect themselves and to comment on the process of applying pesticides for control of those insects.

So in conclusion, the city supports disclosure of inerts, but we also appreciate the need to protect the business interest. We hope through our purchasing practices, and the information that we give our residents in their purchasing practices, will encourage industry to research and bring to market safer alternative products. And it is important that any action taken on inerts not inhibit or impair the ability of manufacturers to do that.

Also, we've been really encouraged by the activity on the work group. I think we feel that they have brought forward the issues. They've really flushed out the issues and that they're ready to take the next step. The interest of industry and the environmental groups has been described as very polarized, but it's not

mutually exclusive. And we feel that it is EPA's responsibility to kind of focus that group as they move forward and facilitate that in a way that it's going to produce some outcomes.

Thank you.

MS. MULKEY: Thank you. Jay, is your tent card still up or is that left over? Well, I will hazard a very brief attempt to summarize what I thought I heard from the committee and its advice to the work group.

I think I heard at least some members of this committee saying think about looking for partial or intermediate successes. Now not everybody said that, and I suspect not everybody said that because there is a fear that a partial success will be latched onto and that nothing more will happen. And so I thought I also heard a sentiment that says be assured that we're with you for the long haul.

So maybe it's possible to combine those two messages to say it's alright to look for partial and intermediate successes, because we will not abandon the effort to try to go further in the face of some limited or partial or intermediate successes. So I'm only trying

to summarize. I'm not trying to substitute my own judgment.

I am torn personally between the grab a few successes and the desire to sort of get all the way as far as we get can while there is the impetus behind it. But I thought I heard those two sentiments and a way that possibly could put them together as guidance from what I heard out of this committee.

Does anybody else want to amplify that? Because otherwise we're just sending them off to work more, and I think all of you did that in your various ways. Does anybody want to correct or modify my summary?

All right. Well, we are scheduled to move into a very expansive discussion of residential pesticide issues. One of the earliest things you will learn is what we mean by that. We don't just mean inside a person's private home. This is sort of a catchall term that really includes everything that is not agriculture and isn't the occupational part of the issue.

We have a set of presentations scheduled to last about an hour, and then we have about an hour of discussion scheduled. So what I suggest we do is that we

really monitor the presentations so they only last about an hour. And that will be hard, but that will take us until three. And then we have a discussion, we break at some point, and we complete the discussion, so that we have at least a full hour of discussion on this vital set of topics.

So, Bill, do you want to lead us off? I know you all are all eager for your break, and you've got to wait a hour and a half for it. But, you know, we haven't been back that long. Okay. I'll give you a minute to -- I'm afraid to encourage you to get up. I'll loose you all. But let's get going and try to keep people from drifting on us, as it were. I want to avoid that drift problem.

MALE SPEAKER: You would make a good cowboy, Marcia. You don't let the herd mill.

MS. MULKEY: Don't let the herd -- what's the word?

MALE SPEAKER: Don't let the herd mill.

MS. MULKEY: Mill. Oh, okay. I spent my career managing lawyers.

(Laughter)

MALE SPEAKER: They're all the same, cowboys and lawyers.

MS. MULKEY: That's what I thought.

(Laughter)

All right.

MR. KENT: Good afternoon. My name is Ray Kent of the Health Effects Division. We appreciate the opportunity to talk to you about exposure assessment -- residential exposure assessment. There is a common theme to several of the presentations you're going to hear, and that is that our residential exposure assessments are data based.

In some instances the data are actually on the chemical we are assessing. In other instances we may use surrogate data, which are data on other chemicals with similar use profiles. Even our so-called default assumptions have their basis in actual data.

Since we have a lot of material to cover, without further ado I'm going to introduce the speakers. The first presentation will be by Bill Wooge of OPP's Health Effects Division, who will present an overview of the process currently used to assess residential exposure

and risks. Bill's talk will touch on the types and sources of data available for residential exposure assessment and how we make use of this data to assess residential risk.

Kathy Davis of OPP's Biological & Economic Analysis Division will present a brief overview of the types and sources of use and usage data for residential exposure assessment.

Following Kathy, Chris Saint of the agency's Office of Research and Development will present a talk which will focus on how the agency seeks to identify important residential exposure pathways and how to quantify exposures that may occur via these pathways.

Claire Gesalman of the Field and External Affairs Division will have a short presentation on the urban initiative and education and outreach program to inform children and adults about proper storage and use of pesticides in and around the home.

Kathleen Knox of OPP's Biopesticides & Pollution Prevention Division will briefly discuss OPP's efforts to promote integrated pest management in our nation's schools. OPP is also focusing on reducing the public's

and the environment's exposure to pesticides that drift from the application site during or shortly after application.

In our last presentation, Jay Ellenberger will provide a summary of how OPP is addressing this area of residential exposure.

Following Jay's presentation, we will open the floor for a general discussion of the residential exposure topics presented.

MR. WOOGE: Hello, everyone. I'm Bill Wooge from the Health Effects Division of the Office of Pesticide Programs, and it is indeed a great pleasure to give you a little overview of the residential risk assessment, and specifically the exposure characterization. Unfortunately, given the time constraint it's going to kind of have to be fast and furious. And I'm going to give you key concepts, but if you get confused, there's always questions. And I'm going to have to do yoga to get this started.

Okay. Before I go into the exposure part, I want to ground it in the overall risk picture. And I'm going to take you back 500 years to the Medieval German

Scientist Paracelsus, who made the statement the dose makes the poison. And he was right on the money with this, and we still use it today when we do our risk assessments. And we believe that risk to a pesticide is a function of the pesticide's toxicity and a person's exposure to that pesticide.

Well, when we do a risk assessment, we use the National Academy of Sciences risk paradigm method, which is in this flow chart in the next slide. Oh, there's Paracelsus. Okay. I'm going to concentrate today more on the exposure side over here. This is the toxicity side, which is pretty well understood. It's the same for dietary, occupational and residential. It's the same battery of toxicity studies that we use for all of these risk assessments.

So, as Marcia was saying earlier, sometimes the term residential can be confusing. A better term is non-occupational and non-dietary. And these can be exposures in the home, schools, day care centers, parks, other public settings, institutional settings and such. And here is a great graph that I'm very proud of.

(Laughter)

Okay.

MALE SPEAKER: Mine's not moving.

(Laughter)

MR. WOOGE: I'm sure everybody is familiar with FQPA. In 1996 Congress passed the Food Quality Protection Act, and it fundamentally changed the way we conduct residential risk assessments. First of all, we're required to do an aggregate risk assessment. Then we're also -- there was increased emphasis on children and vulnerable sub-populations.

Okay, let's change gears now. Another key concept is how do we calculate residential exposures. Well, first of all, we use data, and we rely on pesticide specific data whenever possible. If that isn't available, we extrapolate from pesticide specific data. But we have a lot of other tools, including the pesticide handlers exposure database, which Jeff Dawson will talk about more at length tomorrow, but we do use it in our residential assessments, residue dissipation data, transfer coefficients, label and use information, and the last thing on the list which I left is an acronym. SOPs for residential exposure assessments. SOP stands for

standard operating procedures.

And we rely on these standard operating procedures only when pesticide specific data are not available. We do rely on data first -- as our first -- whatever the word is.

MS. MULKEY: Approach.

MR. WOOGE: Approach. These were developed shortly after FQPA as a response to FQPA, and they add consistency and transparency to the risk assessment process. The SOPs contain over 40 individual scenarios, and they've been recently updated and reviewed by EPA's Scientific Advisory Panel in September of '99 -- last year. And we're currently in the process of including all of the SAP's comments, all of -- this also went out for public review, and we're incorporating the public comments, and also other agencies' comments and internal agency's comments. And we're trying to get that out very shortly.

Now we rely on the SOPs when we do not have specific -- chemical specific data. But I want to assure everyone that the SOPs are grounded in data as well: compound specific data, published scientific data and

generic data. So relying on the SOPs is also a data based approach.

Now I want to break up these concepts -- oh. I got out of order. So the scenarios in the residential risk assessment can be a person spraying a liquid pesticide, a person working in a home garden, a person living in a house treated for insects, a toddler crawling on a treated lawn, a person swimming in a swimming pool and such.

Okay. Now I want to break it up into manageable chunks. First of all, we think of a person applying a pesticide, and we're concerned with the exposures that that person might come into contact with. And then we're also concerned with the exposures to residues that a person might come in contact after the initial application.

So let's go to the first one. And if you think about it, it is applicator focused. But if you really think about it, it's applying a pesticide in your home is very similar to say applying a pesticide in an occupational setting. Using a sprayer in your home is very similar to using -- as a professional using a

sprayer. And because of the pesticide database, we have extensive information in order to -- there is parallelism. And we use this information to conduct our applicator exposures.

We also recently received information from the Outdoor Residential Exposure Task Force on residential lawn applications which has greatly improved the way we have conducted residential applicator exposures.

Okay. The second one -- and the slide didn't work -- is post-application. This is very involved -- involves many roots of exposure. And we have to think of the activities as repetitive or simple, such as working in the garden and pulling up, and it's easily monitored and characterized or more complex. And the only thing that I can give you as an example is I have two five year old nephews. And when they're playing on the lawn or playing on the carpet, for every five minutes they're doing something different. And it's very hard to characterize what they're doing. But that's our job as the agency. We do characterize that risk.

So --

MS. MULKEY: You skipped one.

MR. WOOGE: Oh, okay. I'll go back. So what does a risk assessor ask? He asks where are my slides.

(Laughter)

First of all, a risk assessor would ask how much residue is in the environment. And that can be determined in the risk assessment by pesticide specific residue data. It is also related to the label use rates.

The second question that a risk assessor would ask is what activity is happening in that area, and how much surface area will a person come in contact when doing this activity in a given time period, and what portion of residues will be transferred to the person.

And a third and final question would be what is the duration of the activity. Now if you take the two middle bullets there, that comes into a key concept called transfer coefficient, which I'll go into in a little bit.

Now I said this was going to be fast and furious, so here it is. This is a dermal exposure example. And you have to think of these risk assessments in kind of a three dimensional way. Because if a child is playing on the lawn, he may be -- or she may be --

exposed dermally by inhalation or orally by incidental ingestion. Now one of these might occur, two of these might occur or all three. But we do add these together. And then we also have to add the other third dimension of time. There is short term, intermediate, long term, life time and cancer risk as well. So it helps to think in these -- if you could think of it as a cube or three dimensional.

Now this is a dermal example, and this is kind of a simplification of the equation. But each transfer coefficient, which is the -- actually comes down to surface area for a given unit of time, residential -- environmental residues and duration of the time spent in the area.

Okay. Now when dealing with transfer coefficients -- and these are equally important and I didn't know which one to put first on the slide. But they're equally important. First of all, transfer coefficients are derived from scientific studies. Reproducible, repeatable scientific studies.

The second and equally important one is a transfer coefficient is related to the specific activity.

There is a transfer coefficient in playing on treated lawns to sitting on lawns. And if you think about it, a transfer coefficient for a child playing on a lawn would be a lot higher than, say, a transfer coefficient for an adult sitting in a lawn chair on that lawn. And that's why the transfer coefficient is specific to the activity.

We're very proud of the work that has gone in to develop these residential risk assessments and the exposure assessment characterization. And this work has involved partnerships with other agencies -- USDA, HUD and HHS -- and registrants. As I mentioned earlier, the outdoor residential exposure task force. There is the residential exposure joint venture. We work with user groups and public interest groups. And the whole point of this is to improve and refine the way we do residential risk assessments, and as I speak specifically today, the exposure characterization component.

As I said earlier, we're revising the residential standard operating procedures. We went to the Scientific Advisory Panel in September of 1999. And we view this document as a living document, and as we get more information and more data, it will continue to grow

and we will continue to refine and improve our risk assessment methodology.

There are millions of dollars in research, and actually one of the next speakers, Chris Saint of ORD will discuss the millions of dollars that are being spent in research. It is the fastest developing exposure science, and really our goal is a more refined, non-occupational and non-dietary exposure assessment.

And that concludes my comments.

MS. MULKEY: Okay.

MR. WOOGE: Are there any questions? I tried to give you key concepts.

MALE SPEAKER: Just a quick clarification. The scenarios or the specific activities --

MR. WOOGE: Uh-huh.

MALE SPEAKER: How many specific activities are there that you have to have measured for?

MR. WOOGE: Well, the -- Jeff Dawson here is --

MALE SPEAKER: Yeah. There are a lot of activities that could go on in residential exposure. There would be hundreds. And they've done that work for all of them? Is that --

MR. DAWSON: No. What we've done is we've taken selected ones that we thought would best represent certain segments of the population. And what you're really hitting on is a major research question. So we want to start looking at a variety of different kinds of activities and filling in those blocks.

But what we're doing now that we feel is very adequate and protective is to have selected specific exposure data from the literature that we believe represents, let's say, the behavior of a three year old child, or somebody who is, let's say, a youth age kid ten to 12 years old working in a garden, or adults doing whatever on the lawn. So we just pick selected kinds of activities.

MALE SPEAKER: Presumably you pick the most conservative for a kind of activity or something, so wrestling on the lawn in a pair of undershorts or something would be --

(Laughter)

FEMALE SPEAKER: Naked.

MALE SPEAKER: Well, naked, too. That would be more fun.

MR. DAWSON: I think we pick numbers that we feel are protective. The numbers that we -- the kinds of data that we pick, they're all empirical or measured data, and the values that we're using are within the ranges of those data sets. So we believe, you know, that they do represent some segment of the populations out there. So that's how we kind of viewed it.

And, you know, we recognize that this is an area that needs more research, and frankly that's where a lot of the research money is being spent. It's a big focus, for example, the ORETF, which is the registrant task force group that is looking at residential exposure, and also frankly a big focus for the Office of Research and Development. So that's an area, you know, where we feel we can make some big improvements over the next few years as well.

MALE SPEAKER: Well, then as a follow up question -- and if I'm getting to detailed, cut me off. But how does this get plugged in? How do you know how many times someone wrestles naked on a lawn that has been sprayed three days ago or five? I mean --

MR. ELWORTH: I really missed something.

(Laughter)

MALE SPEAKER: You shouldn't leave, Larry.

MR. WOOGE: You should have seen the slides I took out.

MR. ELWORTH: The iterations are unbelievable. And I've just got a sense of how complex this is.

MR. DAWSON: It is incredibly complex. I think the way we've handled it so far is -- for example, we've been dealing with the organophosphates and some of the carbamates first. We've done those particular classes of chemicals. So in some ways we haven't had to deal with that issue for those chemicals because, you know, on the day of application, for example, when the kid goes out and plays that day, you know, that's what we're really concerned about in making sure they're not getting too big of a dose on those particular days and then looking at it over the short term.

So that kind of probability issue goes away with the kind of risk assessments. But, again, that's another area that is a big area of research for us. And some of the -- I would say the next stage approach is like the calendar based models, for example, that are being

developed. CARES is one that is being done through ACPA, and ORD has one called SHEDS. And there are other ones called Calendex. And we funded one called Lifeline. They're all building in a component to address that kind of calendar based probability. So that will be the next phase for us to look at.

MALE SPEAKER: Do you have the equivalent of a 99.9 percent eater?

MR. DAWSON: With those new approaches we will be able to more accurately look at percentiles. With the way we're doing it now with more simplistic means, it's harder for us to characterize specific percentiles like that.

MS. MULKEY: It might help to put it in perspective. Except for OPP's dietary risk assessments and a few super fund risk assessments -- I think I'm right -- that there is almost no probablistic risk assessment going on in the agency. Almost all of the agency's risk assessments are what are called deterministic, which is you take a scenario and you say -- and what you want is a reasonable high end. That's the magic word under the risk assessment paradigm. So that's

what we try to have.

And you may remember the big debate over 99.9. We pointed out that the reasonable high end for deterministic at 95 percentile was actually more protective than the 99.9 probablistic. And that sort of gives you some flavor. So I don't know that this is 95th percentile or even -- but it's the deterministic. I don't know. I probably confused you more than I helped.

(Laughter)

MALE SPEAKER: Well, you tried. That's all that counts.

MS. MULKEY: We have the 20 minutes and we can move onto the next one. We're on track here. Thank you, Jeff.

MR. DAWSON: You're welcome.

MR. WOOGE: I hope I didn't confuse everyone too much. That's Kathy's job.

MS. DAVIS: I'm Kathy Davis. I am with the Biological & Economic Analysis Division. And I'm going to cover real quickly use related information. You'll remember, I'm sure, back in slide two of Bill's presentation he mentioned label and use information as

some of the components that go into exposure assessments. And our first stop on that trend is to take a look at the label, which Bill mentioned.

The label is going to have things like the use sites on it. It's going to have application rates. It's going to talk about formulation that is important to the risk assessment. It may include things like the number of applications for a residential use, or it may not. It may include things about application method and the type of equipment that you might use in applying that pesticide in and around your home. And those are all very important pieces of information for the risk assessment.

I want to remind everybody that there is quite a range of the number of labels involved in this kind of development of information from these labels. And it can be really simple. It can be one product or one active ingredient that we have to assess, or it might be up to a thousand products that have these homeowner uses on them that we have to put together and pass to the Risk Assessment Division. So sometimes it's not as straightforward as it might seem. But that's our first

stop.

On the next slide, we go to the use related information. And this is more the quantitative and qualitative sorts of information that we get from other databases. On the quantitative side the kinds of information we might get are things like how much of a particular active ingredient is actually applied to a residential use scenario. Now the pounds of active ingredient may not be used directly in the risk assessment, but it provides a measure of how much of the relative volume of use is going on compared to other chemicals. So it sort of puts it in a series for us.

The next one is average use rates, and that's a much discussed term, average. In this particular scenario I would say that average is reported average use rates. Our sources of data on residential use are not as robust as they are for agricultural use. And in some of these reports, we actually do get average use rate. We don't have a whole lot of definition about exactly how that is calculated, and oftentimes it's a range which doesn't help us out a whole lot. And sometimes there are sources -- the information is provided on a regional

basis, which can be very important when you're understanding the exposures.

We also get information about percent area treated, so we might know approximately how many homes might be treated across the United States, how many lawns and what size of lawns. Those kinds of pieces we might get from these sources.

On the qualitative side, the questions that we're looking at are how and where is the compound actually applied and what is it intended to control. And an excellent example of that is a lawn application where you're going after managing fire ants, where there is a spot treatment, versus a white grub control that you're going to broadcast across your entire lawn. So those fellows wrestling are more likely to encounter, we hope, the application for the white grub as opposed to the fire ant treatment.

(Laughter)

MS. MULKEY: For several reasons.

(Laughter)

MS. DAVIS: Many. Very many. Then we would like to talk a little bit about how we characterize the

use related information for risk assessments. So we thought we would walk you through an example of white grub control, because we know that's a common problem.

Starting with label information, we identify use instructions that might be like application rates, the application equipment and maybe some regional specific information about timing. When to expect white grubs to be around and big enough for you to treat, but small enough for you to control. This gives us sort of a sense of where the application is going on and how much. The size of it.

For the risk assessment side of the program, understanding the actual products used is of interest. Average or more typical -- depends on what you're looking at -- application rates might be considered and whether there are differences occurring between a homeowner use versus a professional application. So those kinds of pieces of information are important.

And some of our information actually does exist in our sources, such as with Kline and Company, one of our proprietary data sources. And they provide average -- they report average product use rates broken out by

homeowner and PCO. So that's pretty valuable.

Questions might also arise about whether or not differences in usage occur based on geographic location. Regional use data is provided by some of our proprietary sources, and we have some state and local information, some surveys. They're very sporadic in nature, so we'll have one from 1992 in Michigan, and one from 1996 in Wisconsin. Maybe one or two from Arizona.

So you can see that it is relatively difficult to put these together and understand the whole picture. It's very limited. So sometimes we're asked to try to extrapolate and infer from the available information, and that, of course, makes us a little bit less confident in the information that we pass to the risk assessment division.

For some of the more obscure, non-agricultural uses, things like crack and crevice treatment, pet treatments and uses in schools or in public areas, our sources of data are less specific. These data might be pieced together from one or more of the sources that we have. But our confidence in those, again, is not as high as we would like it to be.

Some of the challenges associated with the non-agricultural data sources, there is a limited number of sources. You'll hear me say that again and again. Some of the data are proprietary, so they're not releasable to the general public. There is limited time series data, so trends are very difficult to ascertain. Sample sizes can be very small, and that makes us very -- somewhat uncomfortable with how reliable that data is.

It's very difficult to collect this data, and I'm sure that CSMA, if somebody is here from them, with the residential exposure joint venture would speak to the -- they're doing a survey right now and it's quite expensive and it's difficult. So we're understanding of it. We just would love to have better data. There is limited detail in --

(END OF TAPE THREE, SIDE B)

MS. DAVIS: Crack and crevice treatments are rarely broken out.

My next slide gives you a flavor, not an exhaustive list of the data sources that we have for non-agricultural information. And we look forward to whatever additional information. We know that there are

some surveys going on and some that I think are wrapping up pretty shortly, and we're looking forward to hearing about those and what kind of information they can provide.

Are there any questions?

MS. MULKEY: Thank you. I think we can move on, then.

MR. SAINT: Hi. I'm Chris Saint from EPA's Office of Research & Development. And I would like to discuss the ORD's various programs related to residential pesticide exposure assessment. First, some context and a few definitions so that at least I'm clear about what I'm talking about.

Human exposure to an agent can be defined as a process by which the human comes into contact with that agent. It's a relatively simple definition. In a human exposure assessment, sources are usually considered to be environmental media which contain the agent of interest, such as a pesticide. And that includes air, water, food and beverage, surfaces, soil and other things that are -- well, those are examples of the kinds of things that we consider sources.

Exposure can occur via various pathways. You've heard that term before. In terms of the research we're doing, we consider that there are three basic pathways: inhalation, dermal contact and ingestion. Ingestion can be either dietary or non-dietary. Today we're going to talk mostly about the non-dietary.

Besides determining simple exposure or contact with a chemical, we're also interested in determining what the internal dose is for risk assessment purposes. Therefore, we wish to be able to predict these internal concentrations by understanding the processes that govern the distribution of chemicals in the body. And for those of you who don't know, this is usually called pharmacokinetics. So I'm going to talk about all of these things today and some of the research that we're doing related to these.

Okay. The ORD program in residential exposure has three major objectives. First, it's to identify chemicals, pathways and activities that represent the highest potential for human exposure. Secondly, we wish to determine the factors that influence these exposures, both the frequency and duration of them. Factors include

human behavior, the chemical stability of the compound in the various environmental media, movement of chemicals in and around the body and human physiology. Thirdly, the program is aimed at developing methods for quantifying both aggregate and cumulative exposures to pesticides and other chemicals. And dose.

Aggregate has been discussed before, but I'll reiterate. It means exposure via multiple pathways. So what we would term total human exposure. And cumulative means in the FQPA terms and in other places exposure to multiple chemicals or stresses.

Our approach towards this rather complex issue is threefold. We are sponsoring and conducting a series of exposure field studies aimed at collecting data on exposure and related to exposure. And that includes chemical concentrations, human activities and related data. and analysis of that data in terms of assessments or the development of various factors for use in assessments.

We also have a number of studies looking at the exposure factor in pathway analysis. These are usually experimental studies and involve sometimes methods

development.

The third major area is exposure modeling. This is a broad sense of modeling. Not simple -- not just mathematical deterministic models, but statistical approaches, metda data analysis, relational database development and various statistical techniques.

In terms of field studies, we have -- the major emphasis of the field studies is currently on children's exposure to pesticides and a number of other toxic chemicals. However, the first study I'll discuss here is the National Human Exposure Assessment Survey, which has currently just completed three pilot studies and are essentially surveys of exposure in a specified population. And I'll discuss all of these in a little more detail in a minute.

A second major study is a new one which we've recently initiated called the Children's Total Exposure to Persistent Pesticides. It also includes some non-persistent pesticides as well. And it's a similar survey, but focused on children -- mainly preschool children ages 18 months to three years.

The third group of studies is a series of

children's exposure studies on organophosphate pesticides, which was funded through the Science to Achieve Results or STAR program, which is a new EPA grants program. These are essentially surveys of exposure of children in farm and urban communities, and the age ranges on these are mostly two to six years old.

Thirdly, we recently in a joint venture with NIEHS, the National Institute of Environmental Health Sciences, funded a series of children's research centers, three of which are targeting pesticide exposures and effects.

The first field study -- major field study was Nexus. As I said, these were pilot studies intended to design a national survey which may one day be implemented. They are population based. It includes two population based exposure studies in Arizona and the midwest, and a two year long longitudinal study which involved multiple samples over time. These studies are currently -- the study is currently developing a set of interactive databases, including both questionnaire and chemical measurement data, and these will be up on the web sometime this year. Up on the Internet.

The second is the so-called C-TECH study, a children's pesticide study. It's a survey of 300 preschool children in six rural and urban counties in Ohio and North Carolina. It will measure concentrations in environmental media and biological samples, mostly blood and urine, and will also collect location and activity information. We will also video tape a subset of these children to address -- I think it was your question about how are you going to get all this information on this stuff. Well, we're actually going to take pictures of them and try and figure it out. There are several studies which are video taping, so hopefully we're going to have quite a library of them soon.

I talked about some of those techniques.

MALE SPEAKER: Excuse me. You're going to video tape what?

MR. SAINT: We're going to video tape the children as they're playing around the home and in the day care centers. We have some --

MALE SPEAKER: Be careful.

(Laughter)

MR. SAINT: -- development projects.

MALE SPEAKER: Are they not going to notice that you're video taping them?

MR. SAINT: Well, that's an issue.

MALE SPEAKER: You can video tape my kids.

MR. SAINT: Yeah. I'm going to talk about that a little bit more in just a minute.

(Laughter)

MALE SPEAKER: That's the one that's in college.

(Laughter)

MR. SAINT: Well, as a quick aside, yeah, we did actually have a two year old tear the camera apart.

(Laughter)

But I think we've solved that problem. Another set of studies is the STAR grants. These were funded in 1996 and are in the final stages of completion. They are a series of studies along the U.S./Mexican border in California, Arizona and Texas that are looking at children's exposures mostly in farm worker communities. There is a study looking at the exposure of urban and rural children in Minnesota to pesticides, which is linked to the Nexus study in the midwest. And we hope to do some comparisons of children versus adult exposures.

And there is a longitudinal study of children's exposure to OP pesticides in the Yakima Valley in Washington state. And a school based study of complex exposures in children which is looking at multiple chemicals, including pesticides, has a longitudinal component and is jointly implemented with the Minnesota Department of Health. It includes pesticides, PH's, volatile organics and metals.

And lastly, there are three research centers which have exposure components. One at the University of Washington, which is investigating the take home pathway in a farm worker community. Pesticides being brought home by the farm worker into the home. The exposure assessment involves a survey of children in the Yakima Valley and the collection of exposure related data.

There is a study at the University of California at Berkeley in the Salinas Valley, which is looking at exposures in another farm worker community. They are actually cooperating in their methodologies between Washington and Berkeley. Berkeley is going to characterize OP levels in urine, determine OP levels in and around the home, and describe exposure from behavior

in children using video tapes.

There is a third study at Mt. Sinai, which is in an urban community in New York City. It's studying pesticide exposures and PCB exposures in an urban population.

All of these centers also have an epidemiology component and an intervention study, which is looking at methods for reducing exposures. But I'm not going to talk too much about those today.

Okay. Another major effort besides the field studies looks at exposure factors in pathway analyses, and there is a whole series of efforts going on in that area. The first one is the consolidated human activity database, which is an effort to consolidate data from a series of human activity surveys which are essentially time, location and activity information collected through telephone and other questionnaires and surveys. It contains about 17,000 person days of data.

To answer an earlier question about how many of those scenarios you have, in this one there are about 14,000 of them. There are 140 activity codes and there are 114 location codes which can be combined in any one

of those combinations. It provides time, location and activity information, such as eating in the kitchen for 30 minutes, as an average, or there are distributional data in there as well.

So we feel it's going to be a very useful tool for exposure assessments in the future to develop scenarios and interrelational databases. It is also currently available on the web and the web site is up there. And I think I can get some copies of this.

MALE SPEAKER: Can I ask one quick question? How is that information collected to go in that database/

MR. SAINT: Telephone and questionnaires and surveys, but it's basically questionnaire data. It's personal recall. You know, what did you do today kind of thing.

MS. MULKEY: Like USDA dietary.

MR. SAINT: It's like the dietary survey. Another effort is looking at non-dietary ingestion. We are trying through video taping and other techniques to quantify a series of activities related to exposure, such as surface to skin contact, skin to object contact, skin to mouth, object to mouth, surface to mouth and things

like this. Essentially the aim of it is to develop a series of transfer coefficients for a lot of these activities.

In addition to that, we're also doing some gastrointestinal absorption modeling, which will help us to extrapolate that to dose.

The dermal contact research is essentially looking at kind of activity -- using activity data to predict dermal exposures through whole body dose symmetry. Wearing cloth suits and doing certain activities, taking the suit off, cutting them up and analyzing the data, trying to see where this stuff goes. We also are looking at florescent tracer analysis using the same techniques, conducting a series of surface sampling in and around the home, looking at where the pesticide goes after certain types of treatments, and video taping of preschool children again to look at activities that would lead to dermal contact.

The idea is to develop protocols for collecting transfer coefficients under certain scenarios, or actually publishing certain transfer coefficients, and developing dermal transfer coefficients for children.

MALE SPEAKER: Chris?

MR. SAINT: Yeah.

MALE SPEAKER: I have a question. What do you do with the video data? Are you like transcribing it in some manner?

MR. SAINT: Yeah. Yeah. There was a technique developed by Jim Lackey at Stanford to -- well, Jim Lackey and Valarie Dartarian, actually, who now works for us. It involves a very laborious screen based touch -- touch screen based system where they are quantifying particular activities. They're not taking the whole run of the video taping and timing every single thing that happens. There is a battery of about, I think, 80 activities that they're trying to capture.

And they run it on slow motion when one occurs. There is a time index thing. They push it. When it stops, they push it again, and then it's automatically time indexed in there. It is rather laborious and it burns out a lot of graduate students.

(Laughter)

MALE SPEAKER: That's what they're for.

MR. SAINT: Pardon me?

MALE SPEAKER: That's what they're for. I was one and I did it.

MALE SPEAKER: It sounds like an Andy Warhol movie to me, you know.

MR. SAINT: Pardon me?

MALE SPEAKER: it sounds like an --

MR. SAINT: Not having ever seen any Andy Warhol movies, I don't know what you're talking about.

MALE SPEAKER: Well, there's 12 hours and the guy's sleeping.

MR. SAINT: Oh.

(Laughter)

There is another effort we have ongoing looking at exposure via pets. There are two small projects. One is looking at, you know, is there a potential for pets to track in pesticides from lawns after lawn care treatments. It's a very small project. They're just trying to determine some preliminary data to see if it's worth doing anything more on.

There is also a similar -- my particular office is funding a study looking at the transfer from pet fur onto hands -- children's hands. And that study is just

about completed, and I think has published a couple of papers, which she hasn't sent me yet, which I'm kind of annoyed about.

MALE SPEAKER: Look them up.

MR. SAINT: Well, the trouble with grants is you have no hold over them.

A major effort in the agency -- in ORD is the Exposure Factors Handbook, which some of you may have run across. This essentially is trying to develop distributional and other types of data for various factors using exposure assessments, particularly physiological factors, physical factors and some chemical data involving transport, FAPE and those kinds of things. You know, an example would be the dreaded soil intake by children and that kind of thing, as far as a big controversy. There are currently three volumes of the Handbook up on the Internet, and we are currently working on developing one for children.

And lastly, there is a small project going on in one of our labs in North Carolina looking at pesticide use patterns -- from what I know from what Kathy talked about -- but mostly trying to get all the data from our

various questionnaires that we do in our field studies and some other studies and trying to pull all of that together so that we can hand it off to OPP.

And lastly, we have a program in exposure modeling, one of which has already been mentioned, the SHEDS model. These are mostly what we call data rich models or relational databases. We have three main efforts. One is new exposure models, one is looking at a modeling framework called Mentor, and the third is kind of a series of small projects looking at modeling methodologies.

SHEDS is the main effort right now on pesticide modeling. And it uses a two stage Monte Carlo, which is a statistical technique, for sampling exposure data from various databases and combining them. The nice thing about the technique is it produces distributions as opposed to point estimates, and it combines distributional data as opposed to combining point estimates as a deterministic model would. It combines demographic human activity and concentration data. It predicts distributions of total personal exposure for a particular population, so you get a distribution for a

population.

I had some really nice pictures of the distributions, but I don't have time -- I didn't have time to show them all. But that is going to be published soon, so you'll be able to see some of those for yourself.

The second area is looking at dose estimating models, which are essentially what I talked about before as the pharmacokinetic models. This is very difficult, because, you know, basically you have to have a PK model -- a pharmacokinetic model -- for every chemical. And what we're trying to do is to say, okay, can we somehow simplify that to try and develop tools for risk assessment to use instead of having to go out and collect all the animal data necessary to do a reasonably reliable pharmacokinetic model, and then have the problems of extrapolation to humans, and then de-extrapolating to the children. So it's an effort that is really looking at all the incremental things we can do to make it easier.

One area that is not specifically related to pesticides but does have some, I think, relevance is this idea of developing a modeling framework. It is kind of a

tool that risk assessors and others can use to go and find models and tools that can be used to build models. Kind of a clearinghouse for modeling to help people who want to develop certain scenarios -- a model for a particular scenario that doesn't exist yet, and if there is one out there, to help them use it in a consistent framework. And if you want to, I can tell you more about that at some time if you want to give me a call.

Lastly, there is a large series of projects looking at modeling methodology. This includes new statistical techniques. We're looking at improvements to Monte Carlo sampling to try and make it more robust. We're looking at techniques such as bootstrapping and other statistical techniques. Also, looking at model validation. What is the best use of the data we're collecting in our field studies to help us understand how the models work. We're looking at new techniques for understanding uncertainty and variability to understand how well our models are working, and looking at techniques for packaging the model better so that they are more easy to use, similar to Mentor.

And that's about it. Any more questions?

MS. MULKEY: Well, we do have -- we're going to go a whole hour.

MR. SAINT: Okay, that's great.

MS. MULKEY: So unless there are some clarifying questions -- believe it or not, despite the volume of this material, we still have about 12 minutes for these brief, additional snippets. And we will take our break before the discussion. It's clear -- and I'm also going to separate you two.

MALE SPEAKER: Bill and Warren are being quiet.

MALE SPEAKER: I have a question.

MS. MULKEY: Yes.

MALE SPEAKER: Is it possible to get copies of this presentation?

MS. MULKEY: Margie? Yes, we'll arrange to get you slides. We're arrange to get you that. Okay. Claire?

MS. GESALMAN: All right. I hope everybody is still hanging in there. We have been talking a lot about the scientific aspects of exposure to pesticides and assessing exposures and so on. And I would like to talk about something completely different.

We're trying to help educate people to reduce exposures to pesticides, in addition to our work in assessing what they are exposed to. And the program that I'm working with to do this is something we're calling the Urban Initiative, which doesn't necessarily have only to do with urban areas, but is mainly non-agricultural kinds of things.

This program originated in 1998 to help increase the attention to pesticide use in the non-traditional kinds of settings. You know, the fact that a lot of pesticides are used in homes and that sort of thing. It includes both enforcement of increased inspection activity in urban areas to retailers as well as other kinds of things, and the education and outreach kinds of things that I'm involved in.

Basically the situation as it stands is that people don't really like pests, and they want to control them, particularly in their homes. But they've also for one reason or another misused pesticides in a number of situations. For example, there were some more widely publicized incidents involving methyl parathion several years ago that EPA spent a lot of time and money cleaning

up. We have problems in some urban areas with something called insecticidal chalk, which is dangerous because it looks a lot like blackboard chalk and has no child resistant packaging and it's not registered. And some other pesticides that have been used in -- used illegally and not for their registered use.

Some of the causes of misuse of pesticides are that sometimes people can't afford appropriate pest control services, or they don't have the kind of information they need to make appropriate choices. We have unscrupulous pesticide applicators who have offered low prices and big guarantees in terms of the effectiveness of their techniques, and people may not be aware of what's really causing their pest problem, that they can do some simple things to solve it themselves.

So to reduce this kind of problem, we're trying to do a number of things. We're trying to inform people about the dangers to their families of misusing pesticides. We've done workshops in some regions, doing outreach to community groups and that sort of thing. There have been a lot of articles in magazines and health provider newsletters and that sort of thing. Posters in

public places.

We have been informing the public about sources of information. For example, we have some truck ads going on right now that are designed to promote the National Pesticide Telecommunications Network. And I have a picture of one of those a little later on. We're developing educational materials in addition to the ones that we already have on appropriate methods of pest control. And I think probably pretty much everybody probably knows the Citizens Guide, which has been around for quite a few years. We're right now developing some handout types of sheets based on this information that are a little bit easier to use if you want just a small bit of this information.

We recently did an activity book for kids -- I think you may have picked this up out front -- and a small poster that gives some pest control tips for around your home or in your home situation. And we have a few other things that are going on that we're trying to do in that line as well.

We're educating various people that are not necessarily the users of pesticides directly about their

roles in preventing misuse. We're developing a tool kit about these materials that will be available to some of our partners such as the Extension Service and states and others who are active in this effort.

There are several programs within OPP that relate to trying to reduce pesticide exposures. The Urban Initiative, which I've been talking about, involves a lot of education and outreach and a communication strategy that we've developed. We're coordinating with the regions and trying to incorporate the work that they're doing. We've done a lot of grants to partner organizations through the regions.

The Consumer Labeling Initiative, which most of you probably have heard of, has the Read the Label First campaign with several brochures and a big display and other types of things that they're doing. That's another heavily -- a heavy involvement of partners in terms of getting the message out.

The truck ad is also -- that's going across the country in certain areas right now. It's actually going to be here on Monday, if anybody is in the D.C. area. It's going to be at the different EPA buildings on Monday

at different times. So if anybody is interested, we can let you know what time that's going to be. But that's going to be going in different cities. It's also in Spanish on some of the trucks. And they either have or are going to do some small, like delivery truck type of trucks, as well as the over the road truck that this is an example of.

And finally, I'll just mention the IPM in Schools program. We published a pamphlet in 1993 called Pest Control in the School Environment Adopting IPM. And now the next person on the agenda is going to talk a little bit more about that, because there is sort of an increased emphasis on that aspect of controlling -- or reducing exposure to pesticides.

MS. MULKEY: All right. Kathleen and Jay, you have to share about six minutes. So I'm sure you'll figure out how to do that.

MS. KNOX: Okay. Sharing isn't really a problem. I don't have overheads, and Claire just gave me a good head start into my presentation.

Integrated pest management in schools is not a new activity at EPA. The brochure did come out in 1993.

We've issued over a million copies of it since then, and the information in it is still relevant. In addition, many of the regional offices are very involved with their states and with local school districts on integrated pest management activities. In addition, our voluntary Pesticide Environmental Stewardship program has a lot of partners who have worked on integrated pest management in schools issues over the years, and in fact has some really good success stories.

Because of all these various activities going on in EPA, a little over a year ago we formed a work group in the Office of Pesticide Programs that included regional participation. The topic wasn't really limited to IPM in schools. It was -- we tried to look at it more broadly as a pesticides in schools issue, looking at data needs, looking at data we had from states and looking at how could we improve the exposure data, etc.

The outcome -- and we looked at it not as reinventing anything, but trying to identify existing materials, existing activities and trying to do some coordination. The work group consists of people from most of the divisions that had worked with pesticides and

several of the regions. In addition, we work with other programs in the agency that are working on school projects. We've had contacts with the Department of Education and various state components.

Our main purpose really is to try and identify issues, try to coordinate and facilitate information transfer, and like I said, collaborating with other EPA projects. One of the things -- we did get a little bit of budget money in fiscal 2000. We've put a small amount to looking really at the feasibility of data collection. It is a small amount, and we know that actual data collection of pesticide use data in schools would cost a lot. It would take time. It would be difficult to design, etc.

So we're really doing sort of a feasibility of a feasibility study, looking at potential surveys -- ongoing surveys from the Department of Education or other kinds of things to see whether it would be possible to get that kind of data in a cost effective, timely way. In addition, we've drafted up a communication strategy. Again, we don't want to reinvent materials that already work. But part of it is what is it that -- what role can

we play.

Most importantly, though, we've put out a request for proposals. The Federal Register notice came out, I believe, two weeks ago. The proposals are due in by December 15th to actually try and identify and fund a pilot technical resource center for IPM in schools. Our vision is that it would be a regional center. It would be there to -- again, not reinvent information. But try and coordinate and pull together existing information and help the states within that region to try and develop programs, etc.

So we're quite anxious to see what kinds of proposals we get in. We expect to get probably a dozen or more. The process then will be review of the proposals, face to face interviews and then final proposals.

So that's basically what we're up to right now. Like I said, we're just trying to build networks and get the right people together and be aware of what's going on.

MALE SPEAKER: Can you tell us the magnitude of that -- of the grant or the money that is available?

MS. KNOX: We have $100,000.

MALE SPEAKER: And how many regions?

MS. KNOX: This is a pilot. It's just one.

MALE SPEAKER: Oh.

MS. KNOX: Yeah. We really just want to figure out if this would be a valuable kind of activity, something that would really have some return on the investment and if it's the direction we want to go in in terms of further investment. It would never be that we would anticipate funding these things forever. The idea is get things up and running. Ultimately, we would like it if the school districts all got sort of into fully IPM kind of programs and didn't need that kind of center any more.

MS. MULKEY: Okay. Jay?

MR. ELLENBERGER: I'm Jay Ellenberger, OPP's lead for pesticides spray drift issues over the last few years. I thought I would use this opportunity to tell you about a few initiatives that are happening in relation to residential exposures.

As we all know, public and as well as EPA have a great deal of interest in pesticide exposures from

pesticide spray drift from all types of applications, whether they be aerial application, ground application and in fact backyard and home and garden applications. Each year regulatory enforcement agencies from the states receive thousands of complaints that they investigate from all different kinds of application methods, all different pesticide types and uses and a wide range of effects from phyto toxicity to human toxicity to environmental problems.

And I think this is becoming exacerbated as the residential areas are moving in more and more each year to the agricultural areas. Over the last decade through a series of DCIs -- data call in notices -- that OPP issued to registrants, a flood of data have come in. We have a very robust set of studies now that characterizes pesticides, spray drift, how it happens, why it happens and what are the most critical variables that influence drift for each of the major application methods.

We also have all the published literature, as well as some European databases. So we have a very robust set of information that allows our scientists, risk assessors and exposure assessors to have a much

better characterization for any pesticide that will be used, particularly in the agricultural setting, and how that application method may or may not drift to particular sites and sensitive sites, such as residential areas and people's backyards, as well as other neighboring crops or sensitive environmental areas. So this robust data set now can be used to infer, if you will, what drift deposition may occur at any site downwind from an application site. We use that information in risk assessments.

An additional initiative that OPP is involved in is drafting a new PR notice and a Federal Register notice of availability. The PR notice to provide registrants with guidance for new product labeling that we think will be a great improvement over current product labeling that will provide applicators with a much more comprehensive set of instructions of what they should do or must do to control drift from the off target sites.

We think that will raise the bar, if you will, of applicator behavior, and a better use of developing technology to really get at many of the problems relating to drift. We're hoping that that PR notice will go out

soon. It will be a draft PR notice for public comment. So we look forward to comments that you would file with us, as well as other folks.

And then lastly, OPP continues with its support, financial and otherwise, with continuing education of applicators about drift, how it happens, why it happens and what they can do to control drift. For the C&P programs, working directly with aerial applicators, ground applicators and so on and so forth.

With all of these initiatives, the bottom line is to significantly reduce drift, the number of incidents, the amount of drift, bring way down the exposures to people and the environment.

Thank you.

MS. MULKEY: All right. By my calculation, if we take a 15 minute break and are really, really back in our seats, you can still have a full hour discussion and we can finish our business at the time. Use a little bit of this 15 minutes to think about how you want to frame up a discussion of these issues. There is an incredible amount of material that you've been hit with, and we're eager to hear about your reactions, your questions, your

concerns and where you see the gaps in what we've demonstrated and so forth.

So enjoy your break and get back on time.

(Whereupon, a brief recess was taken.)

MS. MULKEY: -- speakers and we've asked Donna Davis and Mike Metzger, who are in our Health Effects Division and have supervisory responsibility for a lot of the work -- the risk assessment work you heard about, to join us at the table, too, so that we can maximize our capacity to answer questions. But we're eager to hear not only your questions, but your comments, your perspective, your suggestions, your complaints and your compliments, etc.

We must really harass Bob, if he doesn't come back, since it's his topic, right. Okay. Larry, do you want to lead us off?

MR. ELWORTH: Well, I had a couple of questions. One of them is -- and I understand that this is going to be answered. That was an impressive set of researches being done that people pointed to. What is the public investment in that research?

MS. MULKEY: Federal dollars?

MR. ELWORTH: Federal dollars.

MALE SPEAKER: Meaning how much money did we spend?

MR. ELWORTH: What? I beg your pardon?

MALE SPEAKER: I don't know off the top of my head.

MR. ELWORTH: It would just be -- I mean, it would be interesting to know.

MALE SPEAKER: It's spread across three -- that particular program is spread across three different labs. Well, a lab and two centers in the Office of Research & Development. I can tell you what the grants program is spending on it. The grants program has an investment of approximately eight million dollars. I think the lab program has got to be around the same, if not a little bit more.

MS. MULKEY: There are -- I have seen a budget breakdown of what portion of ORD monies is FQPA, for example, which, of course, is not just this work.

MR. ELWORTH: right.

MS. MULKEY: But all sorts of other work. So I

think Joe could help you after he gets here. We'll see if he knows anything off the top of his head. But if not, we can help you get some data on that.

MR. ELWORTH: Okay. That would be interesting.

MALE SPEAKER: Certainly for 2000 there is numbers available.

MS. MULKEY: Yeah, right, on an annual basis.

MR. ELWORTH: Because there's obviously the cost of developing and maintaining a database and things like that.

MS. MULKEY: Right.

MR. ELWORTH: Which would be in the grants program.

MALE SPEAKER: The Nexus database, for example, is funded at about $800,000 to get it up and running and maintaining it.

MR. ELWORTH: And the other question that comes to mind, with all those different databases, how are you coordinating the quality of data and things like that?

MALE SPEAKER: There was a program developed in EPA called IAMS, which is -- I can't remember what it stands for. But that's their job. They are -- they are

kind of the data police there looking at not so much making sure the data is of a particular quality. But making sure we know what the quality is.

MR. ELWORTH: Right. Right.

MALE SPEAKER: So Nexus is being coordinated with the IAMS program. The data that we're getting in from the grantees will be transferred to the IAMS people, along with the papers and documentation that goes along with that.

MR. ELWORTH: I would like to see the dollar amounts at some point.

MS. MULKEY: Okay. We'll try to get an answer.

MR. ELWORTH: On the school IPM stuff, apparently California just had a program funded, too, in school IPM. How -- what connection is --

MS. GESALMAN: Region 9, California, is very active in our work group.

MR. ELWORTH: Okay. But this is a state program.

MS. GESALMAN: Right.

MR. ELWORTH: This is a DPR program.

MS. GESALMAN: Right. And the people in EPA's

Region 9 are involved with the state people as well. So there is a lot going on in California in L.A. and in Marin and a variety of places in terms of IPM.

MR. ELWORTH: Uh-huh.

MS. GESALMAN: So, again, like I said, we're just trying to get a handle on all the things that are going on and make sure that people are talking to the right people.

MR. ELWORTH: Uh-huh.

MS. MULKEY: Yeah. A big focus of our effort is a clearinghouse, the left hand knowing what the right hand is doing, rather than doing things ourselves.

MR. ELWORTH: Okay. And can I get a copy of the Fun with Cockroaches pamphlet?

MALE SPEAKER: Activities with Cockroaches.

MALE SPEAKER: You can't kill them. You've got to play with them.

(Laughter)

MS. MULKEY: All right. I think Bill was next.

BILL: I just want to echo Larry's sentiment here. I was astounded at the amount of work that is going on in this area. I had no clue. And I know some

of the joint venture work that is going on in the trade associations, but I thought that was sort of almost primary and above. And really that's a small part of what's going on. So I'm very impressed with what is happening.

A couple of questions about that. To what extent are these grants -- have you scripted sort of the data gaps and the things that you need and know that this will fill them? That's one question. And the other one is, I would hate to see this amount of effort put forth and then have it sort of criticized and shot down or, you know, industry or academia sort of maybe take potshots at it. Is there any sort of oversight or sharing beyond this kind of scope that is assuring that once these data are collected and might be used in modeling that it's not going to be criticized?

MR. SAINT: There are two levels of -- there are two types of research that we're doing. We have a grants program and then we have our own researchers in the labs. In all cases, the work is published in the -- to become official, it's going to be published in peer review literature.

In the case of our in-house studies, the studies are peer reviewed before they're implemented. Likewise, in the grants program we issue RFAs -- requests for applications -- which specify the type of research we would like to have done. They're not as prescriptive as an RFP, which is asking for contract work. But they do lay out the priorities and what we would like to have done. A peer review panel reviews all those proposals against that RFA and the best ones -- the most highest quality science are considered for funding and then we fund as many as we can given the budget.

They obviously publish through the normal publication channels in the peer review literature. And we have several efforts encouraging them to publish more and sooner. That is the main peer review process and the results stand up to that -- if they get through that process, they'll stand up to criticism in a scientific community.

Now things can always be misused. But given what's published in the literature, you always have a touch tone to be able to go back and say, well, you know, the paper said, you know, it can be used for this, but it

can't be used for that. And you're using it for that, so you shouldn't do that. So there is a reference there.

We do not have a specific program designed to kind of ensure the quality of the publications. Each project we have has a Q&A program related to the data collection activities, and there is a series of steps they have to go through, including review by me and other project officers on their Q&A, site visits and other things like that. But that's more of the nuts and bolts of the study rather than the publication of the results.

Did that answer your question?

MS. MULKEY: Buried in your question is something more basic, which is how much of this research is specifically designed to meet the needs of the pesticide program's risk assessment and risk management challenges. And that question is not -- could be posed to the agency with any of its hats on, whether it's the Recker program or the AIR program. And there is an extent to which the work of our Office of Research & Development is very closely meshed with programmatic needs, and there is an extent to which it is deliberately maintained somewhat independently of programmatic needs,

so that it is the scientists deciding what science questions are most worthy of pursuit and most needy.

So it's a mix, frankly, of research that is very carefully calibrated to address a data gap, or a data interest that we've identified and surfaced, and research that may serve that purpose, but may have been designed and pursued because of some fundamental questions that we believe we need -- we, collectively, larger EPA believes need to be answered. Some of it is primary search. You know, really -- so there is a -- the dynamic of how agency sponsored research fits with agency programmatic needs is a constant and tricky dance that involves a lot of different competing considerations.

MALE SPEAKER: Marcia, a quick question, sort of a follow up. You've got all these different levels, it sounds like, of research gaps. Yet at the end, presumably this is all going to have to be plugged into a model that helps you determine residential exposure -- or residential risk. I guess that would be the more -- I would be more worried about the ability to merge all these studies together to try to form a single risk assessment that has meaning and equivalence.

MS. MULKEY: Well, I think we think of these data -- and maybe the scientists could help me -- as another very valuable source of data, just as registrant sponsored data and sometimes general public literature data. And that as these studies become available, we use them as best we can. And we don't wait for all of them.

Do you want to elaborate on that?

MIKE: Yeah. There are various parts of the -- various things that ORD does are already interwoven in the risk assessments that we do. And as we get new data from them, we incorporate it in the risk assessments. An example would be the new transfer -- transfer factor for movement of pesticides from children's hands and the saliva extraction factor is something they have been working on for a while. That is a new piece of information which we got recently, and really it will help improve our risk assessments tremendously and make them more accurate for children's hand to mouth behavior.

Some of the behavioral data -- some of the stuff that sounded funny earlier with the picture taking -- that's very useful information, because you know how many times a kid might pet the dog during the day, so you know

how to do your risk assessment.

MALE SPEAKER: By the way, we had an idea on that camera and the video taping. Use a catcher cam, you know, in the off season. The little cameras that the catchers do for Fox.

(Laughter)

MALE SPEAKER: I never noticed it.

MALE SPEAKER: Yeah, it's funny. And you could do an ump cam like they do in football.

MALE SPEAKER: They have a single recorder and they have several little cameras in different rooms.

MALE SPEAKER: Oh, okay. Sorry.

MALE SPEAKER: But a two year old really did tear the first one apart.

MALE SPEAKER: But there is all the information that is in the Exposure Factors Handbook that we incorporate into risk assessment, and the draft kids -- Children's Exposure Factors Handbook that we would use. And then -- that's some of the stuff that we're currently using in the risk assessments that we've been doing, plus there is all the work that they're doing for us in the future. Work related to our doing distributional

assessments for residential. And a lot of that we'll be able to use in the future.

So there is stuff that we're able to use now that they've been doing over the past several years, plus the stuff that we'll be able to use in the future.

MALE SPEAKER: But they're being designed so they're mergeable into the databases you currently have?

MALE SPEAKER: Yes. Chris and I have --

MALE SPEAKER: So it's not apples and oranges.

MALE SPEAKER: Yeah. Chris and I have met several times and had arguments.

(Laughter)

But generally a lot of the work they're doing is very useful for us, not only giving us what we need to do our risk assessments, but also pointing out where the specific problems might lie. For example, the STAR program, dealing with farm worker kids exposure and showing us that we really need to focus on that area.

MALE SPEAKER: Yeah. The idea is to provide data sets of tools in our program. We're not set up to do the risk assessments for anybody. We do have an assessment center which does risk assessments as

requested, but that's not really our job. Our job is to provide things that can be used by the people to do risk assessments.

MALE SPEAKER: Well, that's the critical point.

MALE SPEAKER: Yeah.

MALE SPEAKER: It can be used.

MALE SPEAKER: Yeah. So what we try to do is to negotiate beforehand with the program offices as much as possible on their needs and then implement things that we hope will get what they need. Sometimes they don't, because they either fail, as they do sometimes, or, you know, through the vagaries of the granting process we don't actually get what we ask for. And then we either don't fund it or we think, well, that's still interesting so we'll pursue it at a lower level or whatever. So, I mean, there are other things that happen, you know.

But the idea is to provide small and large tools and lots of data. I mean, because that's -- the NES came out very early on in '93 or so and said there's not enough exposure data, particularly in this area. So we said, well, let's go get some.

MS. MULKEY: Bob?

MR. ROSENBERG: Is this like the question time or the comment time or both?

MS. MULKEY: Either and both.

MR. ROSENBERG: Okay. Well, first of all -- well, then -- well, I don't have any good questions.

MS. MULKEY: We'll give you two rounds, if you want them.

MR. ROSENBERG: But I've always got opinions.

MS. MULKEY: And you don't have to feel like you have to use all of them.

(Laughter)

There is another half hour.

MR. ROSENBERG: Well, here's a couple thoughts. One is, first of all I would like to just tell you just how grateful we are to have had this discussion here today. I think, if I'm not mistaken, it's the first public discussion of these issues, with the possible exception of the SOP discussion before the Science Advisory Panel. And I'm grateful for that.

I couldn't help but be struck by a couple of things. One being the incredible complexity of doing residential risk assessments. The enormity of the task.

What I wonder is this. I've always thought the genius -- maybe it was intentional and maybe it wasn't. But the genius of the TRAC process was prior to the inception of that process. There were lots of questions and lots of uncertainty about how dietary risk assessments were conducted.

And through that process, by the development of science policy papers and discussions of data and papers about what data are available and how those data are used, it accomplished two important things. One was, I think, it de-mystified the process. And secondly, I think it made a considerable contribution to building stakeholder confidence in the process. I think people sort of understand how you do it and accept it and, you know, are grateful that you do it.

I don't think those things have happened yet on this side of the equation more or less. This is a great start. You know, it's the first discussion and a lot of good stuff -- I had no idea a lot of this stuff was going on and the research that was going on.

I guess what I would like to see is some kind of a process where we could do those same things for

residential exposure that the agency already has done so well for dietary exposure, which is to de-mystify and better communicate to the public and stakeholders what this process is all about. And I would suggest -- you know, I know everyone hates work groups. But I would suggest that it might be useful to the agency to convene a work group around this issue of folks -- you know, more than just sitting at this table who are involved in this question, who could maybe meet a couple of times and talk about ways to accomplish those two goals.

So just in summary, you know, this is great. I'm glad we're having this discussion. I would love to see a continuation of discussion to the point where the folks I represent, for instance, have a high level of confidence in the regulatory decisions that the agency is making. And I think it's best accomplished through a work group.

MS. MULKEY: Do you think this topic lends itself -- not necessarily instead -- to a workshop? In other words, this was an hour. You could have a three hour version. You could have a five hour version. And it could be interactive, but working through how it's

done. Is that part of what I hear you asking for or not?

MR. ROSENBERG: Maybe, Marcia. I think my -- it depends on -- you could call it a work group or workshop. I think it would depend more on interactivity more or less. I think there are questions that in my mind -- I mean, much of what was said was way over my mind. My only science that I had was political science. I didn't understand a lot of that stuff.

(Laughter)

How does all this stuff fit together. You know, there is a lot of stuff. I mean, all this data and all the science and a lot of stuff. I mean, how do you bring it all together and come up with a single number that says that, you know, this product poses an unreasonable risk or does not.

I think that could be accomplished in a workshop. I think it could be accomplished in a working group. But I think the agency really needs to try to identify some kind of process that would allow for the de-mystification of this process.

MS. MULKEY: Okay. Any --

MALE SPEAKER: Can I weigh in on that?

MS. MULKEY: Yeah, if you would like. Dan is the next person, but I think he'll let you go ahead.

MALE SPEAKER: I just -- I think a work group might be a more productive event or series of events, because I think there is some complication here. I think having a single workshop may convene in a richer way what we heard today, but not much more than that. And even if it were interactive, I think this connect piece is missing here a little bit. I mean, there is a lot of data generation. How is it going to be used. How does it hang together. Seek outside input so that it's sort of -- at least assures some immunity to criticism later on.

I think a work group with stakeholders would be a better way to go.

MS. MULKEY: Dan?

MR. BOTTS: Just to reinforce the previous two speakers, I saw the notice of the grants that went on on the farm worker children's study and some other things. And I started asking questions then about what was the purpose. Where was the focus. This is the first time I've had a real good discussion of how the whole process

interrelates. And a lot of the things that you talked about today are going to be the bedrock of taking the very conservative assumptions out of the SOPs on residential work as it goes forward.

And I guess one of my questions is, is there a time line in your mind as far as when you'll get through whatever process, of either internal peer review or external peer review, of the information in the data set to where we start seeing some of the results of this process showing up in the risk assessments that are leaving the regulatory decisions to the re-registration process or in the existing program on the OPs that are out there now.

And that's probably a question, Marcia, for both you and our friend from ORD. But I guess, how is that process going to work and how is it going to be transparent. How are we going to know that all of a sudden there is this huge new database that's been inserted into the program that Mike is using to do his risk assessments to come up with the numbers that we deal with on the user side from a regulatory impact standpoint on the products that we use.

I guess -- I don't know whether that's a fair question or not. And then I've got a question for the spray drift issue.

MS. MULKEY: Do you want to start?

MR. SAINT: Sure, I'll start. Well, the things I talked about today didn't all start at the same time, so some of them are ongoing and some of them haven't even gotten in the field yet. C-Tech has only just started out in the field, for example, and the children's preschool. The other children's studies are finished in the field, and we're hoping to get their data by next September to get it all packaged and in our hands.

Nexus, which is a broader set of data from two regions of the country. We just have funded a project to consolidate that into an Internet useable database, because it's a much more robust data set because it's population based. It was proportionately sampled from populations. And that was supposed to be up next month, but there have been contracting problems. But it will be up this year. So very soon for some of this data.

Some of the children's data, the C-Tech which is a more -- which is looking at very young children

probably won't be available for several years. The information that they're developing in the children's centers in the farm worker communities probably won't be available for at least a couple years, because they only just got in the field last spring.

So there is a whole series of kind of milestones that we've laid out through the -- do you know what GPRA is?

MALE SPEAKER: Uh-huh.

MR. SAINT: The government monitoring program?

MALE SPEAKER: Uh-huh.

MR. SAINT: We use to call it deliverables in the old days. You know, we've laid out these milestones and we're trying to stick to them as close as possible. But, you know, research is a pretty big thing. You know, when you go out in the field and all the monitors breakdown, or as we had this year, all of our phlebotomists quit so we couldn't get all the blood samples. You know, it happens, but we're trying to get this stuff.

And the other thing is, under grants we have no legal means to make them give us the data, thanks to

Congress. So we're -- so we are now trying to look at the new Executive Orders on data availability to force our grantees a little bit harder to make their data available. And that includes OPP, obviously.

MR. BOTTS: Are they excluded from using your data in the interim --

MR. SAINT: No.

MR. BOTTS: -- if there are things that, gee whiz --

MR. SAINT: If we can get it, they can have it right away.

MR. BOTTS: Then my question goes to Marcia. How do we know that you have made these changes, like the things that were mentioned earlier on the transfer of factors and those kinds of things. How do we know that those things have been added to the process?

MS. MULKEY: I think you asked a very fundamental question about how do we keep the world aware of every incremental change in science as we internalize it and begin to use it. And, you know, we're working hard at that, and as you know, we try to make individual risk assessments public. We try to make our

methodologies public periodically. These SOPs into which a lot of these data are fed -- I mean, the SOPs, as you know, are not just made up things.

We are updating that so that you'll have when we do what we call finalize, but as you know, we've never said these things are truly final. They will reflect the most up to date -- on any given day there is likely to be something in transition that isn't yet reflected in a risk assessment that is in the public domain.

But we're open to ideas about ways to be more transparent. But our goal is to let it all hang out. You know, to have no secrets about what data we're using and what methodology we're using. This is why we have all -- we've infused so much of this public process into what we're doing. I think we're always open to suggestions about whether there is a better, more efficient way to do that.

I was interested to hear how much ORD -- I have learned today how much ORD has gone to a web based approach. And one of my thoughts was, can we do some better linking between our web site and their web site and things like that.

Mike, do you --

MIKE: Yeah.

MS. MULKEY: Do you have any thoughts on this?

MIKE: Yeah, a couple comments specific to what -- to what we're talking about today. All of this stuff, we use it as it comes in. As we get this information from ORD, we start using it after we evaluate it and make sure it's the proper information to use and it makes sense to us.

But we do take it then to the SAP. All the stuff -- the saliva extraction factor I think has already been to SAP, hasn't it? Some of that stuff -- but it will eventually all go through SAP. So in that forum, it will be announced that, you know, we're going to -- that we've looked at it and we're considering using it, or that we're going to be using it.

And I wanted to throw in another comment in response to something you said about the conservativeness of the SOPs. The comment is that the SOPs aren't as conservative as people generally think. The data in the SOPs is real data and it needs to be updated. It needs to be improved as we get additional information. But

some of the information we're getting from ORD is showing us that these SOPs aren't conservative necessarily in some cases at all.

So I think we want to be careful in thinking that when we get all of this new data in it's going to change things radically and all of our risks are going to disappear or whatever. I don't think they will.

DR. BOTTS: Well, I don't know that I meant to imply that I thought that, but that's -- I was going by what the SAP said when they reviewed them and said that they didn't need to add the extra safety factor because they were conservative enough. If you loaded them all together, you didn't need the extra factor.

MS. MULKEY: Also -- they also criticized a lot of them internally for what they regarded as inadequate conservatism.

MR. BOTTS: Yeah.

MS. MULKEY: So their input was a real mixed bag on that issue, too.

MR. BOTTS: But to the spray drift issue, and this goes to a presentation I had from the spray drift task force relative to some potential labeling changes or

what's starting to show up on labels, because evidently everything seems to be driven by droplet size and potential for movement off site more than anything else. And what we were provided with was some information that there was going to be some very specific nozzle pressure combinations to ensure certain droplet size for certain ag uses.

And our concern with this -- and I don't know whether it has made it out to anything other than the ag community yet, and it's going to be bad enough there. But for the very same reason people don't read rodenticide labels, if you start specifying label types and pressure levels on homeowner's pressure one applications and those things for drift potential applications, I don't think you're going to be very successful.

And I have a real concern for the ag side that we're going to end up with compound specific spray rigs before it's all over with the way some of this appears to be headed. And if you think you've got problems now from an economic standpoint, just wait until you hear that conversation when it gets started.

MALE SPEAKER: Let me address that. One of the things we -- OPP strives to do in drafting new label language is to stay away from specific technology. So it's more -- our goal is really applicator behavioral change, quite frankly. We know that technology for nozzle types and spray rig design is constantly changing, and we didn't want to lock companies, or applicators particularly, into using nozzle type S-103 that is going to be outdated a year later and then they would be misusing the product if they didn't use that.

So OPP's goal is to not go in that direction at all, but rather to tell applicators to do some very basic things regarding how high to set the nozzles above a crop canopy, for example, wind speed restrictions and things that are very, very simplistic to follow, that the robust database we have says these are the things that make 90 percent of the difference. We don't want to get into fine tuning.

Now it's not to say that our guidance -- I mean, it is guidance to registrants -- a PR notice. It's not a regulation. And it does allow room, if you will, for any company to come in to us and say, well, for this product

that we have, we would like some real specific -- we want to go beyond what you're recommending on the label, because X, Y and Z is a real factor for this kind of product, whether it's the toxicity, it's formulation type or whatever.

And we'll look at that. But we -- you know, our approach now is to stay away from specific technology to put on labels. We think that creates a whole set of problems.

MR. BOTTS: I've seen two labels.

MALE SPEAKER: I know. But there is -- they're probably older. I'm not aware of which labels. But I'm just saying that the direction that we're moving in, that we're going to propose, stays away from that approach. And we're going to be asking companies to re-look at all of their labeling on spray drift and take off what we think is not appropriate any more. Take a look at what our guidance says in the PR notice and come back to us.

MS. MULKEY: It's also important to remember, Dan. We are going to ask for comment on this major guidance document. And if you see issues with what we're looking at, we definitely want to hear from you.

MR. BOTTS: Well, I haven't seen your guidance document. I'm working off of a reference in the slide presentation that had two new labels just been approved and both had very specific labels -- or brand name type labels and pressures that would be required to be used for that product.

MALE SPEAKER: One of the things we do want -- we would want companies to think about in their labeling is specifying spray quality droplet size without getting into nozzle type specifics and left up to the applicator by putting in the SAE new spray quality guidance that has been approved, say, use, you know, a medium droplet according to SAE. And then that allows them to pick all kinds of nozzles.

MS. MULKEY: Sarah?

MS. LYNCH: Yeah. I just had a general comment. This is not my area of expertise at all. I'm just really sort of amazed at the complexity of the issue that you all have tried to address looking at the residential exposures and how important it is to do what you're attempting to do. So I really, you know, pat you on the back, encourage you and say that I think this is really

an important, you know, missing link. Something that has had so little attention in the past.

And the complexity of, you know, the various routes, methods of exposure, modes of exposure, etc. -- venues that people can get exposed to these chemicals in the real world, you know, makes me think about what we don't really know about chemicals. We don't really know about some of these exposure routes. And yet, you know, our registration process sort of assumes that we have a certain knowledge base that perhaps we don't really -- we really have.

I think that underscores the importance of what the FQPA does in telling us to try to bring all of these together. And while I, you know, understand Bob's point of view that we really do need to know a lot more before we perhaps should be taking these regulatory decisions, I think that the precautionary principle needs to be really thought of here, because there is enough information to make us think that there are these issues that have to be addressed. The science is -- all the information will not be available to us, you know, to the nth degree.

So I hope that we will really think carefully

about the -- you know, to take the necessary precautions, too.

MALE SPEAKER: Yeah. One of the things that we're trying to do in looking at pathways is -- and partly in the modeling -- although using models is a way to do this -- is to look at how important the various pathways are to the total exposure given the particular scenario -- or a set of scenarios. Kind of a sensitivity analysis, to use a statistical term.

You know, in an assessment framework, you know, you sometimes -- and we've done this already, because we've picked scenarios that we felt would probably be the most likely to produce the highest exposures in certain assessments. If we were able to have tools that would allow us to do that quickly and efficiently and be reasonable -- reasonably certain or within bounds that we're correct, that might help us short cut a lot of these things. And we could actually make decisions at that stage rather than go to a full assessment. But that's not my decision.

So we're trying -- like I said before, we're trying to develop tools that people can use to make

decisions, not necessarily trying to make the decisions. And that doesn't -- and we're trying to make them so they're not compound specific so we don't have to do another one every time a new compound comes along. We can have techniques that are robust.

MALE SPEAKER: Just one quick comment. Can I do that?

MALE SPEAKER: No.

(Laughter)

MALE SPEAKER: No. I just wanted to respond to Sarah.

MS. MULKEY: People have been waiting, but if it's directly connected.

MALE SPEAKER: It'll take 10 seconds. I just wanted to be clear that I was not necessarily questioning the caliber quality of the science or the regulatory decision. What concerned me was the very fundamental question of how do I tell a PCO that I represent that EPA made a good decision in a way that they can understand.

MS. MULKEY: The form of the transparency issue.

MALE SPEAKER: Yeah.

MS. MULKEY: We'll go Jay, Jose, Adrienne and

J.J.

MR. VROOM: I have three questions. Could you give us kind of a beginning to where we're at today and project an end on the SOPs for residential exposure? Are we done? Are we midway?

MS. MULKEY: Do you want to answer that? Margaret Stasikowski is the Director, as you know.

MS. STASIKOWSKI: We are just finalizing making the final -- incorporating the final comments that we've received, and we expect to go out with the revised SOPs in very early winter.

MR. VROOM: Okay.

MS. MULKEY: But they're always a work in progress.

MR. VROOM: Right. So they would be published in the Federal Register?

MS. STASIKOWSKI: Right. Early 2001.

MR. VROOM: As final?

MS. STASIKOWSKI: Right.

MR. VROOM: Okay. And how long has that process been underway? I'm just trying to understand how much effort --

MALE SPEAKER: It's been underway for about a year now.

MR. VROOM: Okay.

MALE SPEAKER: Since the last SAP in September of 1999. It's also going to include the SAP comments. But previously the provisions had gone through public comment through a Federal Register notice as well. The complexity was trying to incorporate not only the SAP comments, but the public comments. And also we received comments from USDA and also from other -- from ORD. And that's been the complexity.

And also along with revising the SOPs, we have to produce a comment and response document which describes all the comments and our reaction and how we incorporated them into the document.

MR. VROOM: And how much --

MALE SPEAKER: It takes a lot of work.

MR. VROOM: Yeah. And how much change has resulted from all of that effort, would you guess? Not to pin you down here in terms of what will be revealed when the Register notice is published.

MALE SPEAKER: I honestly -- I don't know how to

characterize that.

MR. VROOM: Okay.

MALE SPEAKER: They'll be changed for some specific risk -- types of risk assessments. I think Jeff can --

MALE SPEAKER: I'm just wondering, do you want specifics? We can talk about some examples. For example, we modified how we do dermal risk assessments for children. And we modified some other factors like the saliva extraction that Mike was talking about earlier, and also some of the approaches for pet exposure.

So really across the board there were modifications here and there. Some were more major than others. But, you know, they do reflect the new changes that Bill was talking about. They do reflect the most recent data from ORD and whatever other sources we had at this point.

MR. VROOM: Okay. A specific question with regard to estimating children's exposure to some pesticidal compounds that might also have exposure from non-pesticidal routes. Like, for instance, treatment for

head lice in schools certain OP compounds and pyrethroids might be used.

Have you found a way to sort of anticipate that, and is that part of the overall SOP process? Can you accurately set that aside and segregate that from exposure from normal, other traditional kinds of pesticide -- pesticidal uses -- treatments?

MALE SPEAKER: To me that's --

MR. ZAGER: In one specific case, which we dealt with recently we did not include it in the aggregate exposure assessment. It was regulated by FDA and we did not include it.

MS. MULKEY: I mean you're asking -- I couldn't tell whether you were asking a science question or sort of a science policy question. Will we be aggregating those sources?

MR. VROOM: Right.

MS. MULKEY: Was that the question?

MR. VROOM: And as you're developing some of the models, are you using those kinds of exposures to build the exposure models?

MS. MULKEY: The only time I can think that

would be implicated is if you were using body burden data that might reflect some of those sources. And I don't know if we've faced that issue.

MALE SPEAKER: I'm not aware that we have.

MS. MULKEY: That's the only place I can think of that it would be a confounding variable, if you will.

MR. VROOM: Well, in the process of gathering data to develop the models, have you taken blood samples from children that might have been -- might reflect exposure, for instance, to treatments for head lice that would not be regarded as a pesticidal treatment?

MALE SPEAKER: We haven't taken blood samples. We've taken a lot of urine samples.

MR. VROOM: Okay.

MALE SPEAKER: The pesticides that we're worried about don't show up in the blood.

MR. VROOM: All right.

MALE SPEAKER: But we are in one study collecting data on pesticide use in the school for, you know, body pests. And that, as Marcia pointed out, has a compound factor, because we have an inherent problem that our exposure assessments do not adequately predict the

urinary output of the metabolites and haven't for some years. That's one of the reasons we're doing all this data collection, is trying to figure that out. So we do have to collect a lot of data on compounding factors for that reason, trying to figure out where all this extra pesticide is coming from in the urine.

MR. VROOM: Uh-huh.

MALE SPEAKER: But that data is basically being provided by the school districts in Minneapolis where we're working, and then we're getting anecdotal data. As we get a child into the study, we find out if they have had -- from the nurse if they have had a lice treatment in the last -- I think it's the last seven days -- or whatever days. But nothing -- nothing has been designed to collect that data for a specific purpose.

MS. MULKEY: As far as I know, none of our current risk assessment methodology -- and you can straighten me out -- relies on data or models based on data from body burden. We do look at those data when they're available to help us understand what they may tell us about our other risk assessment methodology.

But I don't think we based any risk assessment,

and certainly no regulatory decision making, on any of these kind of body burden data.

MR. VROOM: Okay. My question was the acronym NHANES, and I think, Chris, this is out of ORD. Could you speak to that?

MR. SAINT: (Inaudible).

MR. VROOM: Okay. How does that data from NHANES impact any ORD activities, and then ultimately what does OPP do with that? How does all that get coordinated?

MR. SAINT: NHANES is basically a big epi study -- epidemiology study. I mean, it's a health --

MR. VROOM: Can you provide me with what the acronym stands for?

MR. SAINT: National Health and Nutritional Examination Survey. It's a large health based study run out of the National Institute for --

FEMALE SPEAKER: The National Center for Health Statistics.

MR. SAINT: Right. The National Center for Health Statistics at NIH. And we are sponsoring part of it in terms of collecting some exposure information. But

as a traditional epi study, it's not a robust exposure study like Archer is. The only real chemical data they have relating to exposure are body burden data, which is, you know, body related: blood, urine and some other body fluids and tissues.

MR. VROOM: So it would only be regarded by OPP as something that is kind of a reference database, then?

MS. MULKEY: That part of it. I mean, it also gathers some information that might -- somebody else help me. Some exposure related information. I don't mean body burden. I mean behavior information, for lack of a better word.

MALE SPEAKER: There are some questions on the questionnaire about exposure related behavior which we added to the design.

MR. VROOM: Behavior of?

FEMALE SPEAKER: Diet. Dietary.

MALE SPEAKER: Pesticide use. Some consumption of some types of foods. Those kinds of things. I mean, they have a whole nutritional survey part which talks about food consumption.

MR. VROOM: right.

MALE SPEAKER: Which is useful data. But there is dietary exposure. Jeff, are you familiar with --

MR. DAWSON: We have done some work. I think it's been a while since I've looked at this. But I think NHANES-4 has gone in the field or whatever it is, and we've asked them to collect more kind of germane information about residential uses as much as we could, like how much they use or is there some come of a use event connected with this health assessment or whatever it might be. So we have tried to work with them to get as much of that information as we could.

MR. VROOM: Well, not to let Al off the hook, but what about USDA, then, as far as NHANES is concerned? Since there is a nutritional element there, is there some kind of full circle coordination?

MALE SPEAKER: Yeah. And it's becoming even more full circle. Our food consumption surveys, which used to be independent stand alone surveys, are no more. We will be collecting food consumption data as part of NHANES from this point on. So when the people are in the trailer, in addition to all the other information they're being asked, they will be asked what they ate that day.

And of course there will be a follow up that will probably be a telephone survey.

There are certain weaknesses in the design of the NHANES. For example, they follow the sun. So you won't find them in North Dakota in January.

(Laughter)

They're very clever there. And, of course, what we're trying to gather is what is a picture of typical consumption. We try to capture the full year, because people's food choices change throughout the year. So we are trying to figure out how to compensate for that. So we'll take a summer day in North Dakota in person and then try to do a telephone follow up in January or something along those lines.

(END OF TAPE 4, SIDE B)

MS. MULKEY: Anything else? Jose?

DR. AMADOR: One of the advantages of being one of the last ones is that somebody either said what you wanted to say or made the comments already ahead of time. But I have some concern, too, like Don said, about getting too specific on the label when it comes to spray drift recommendations. Once you put it on the label, you

kind of get hamstrung in what you're going to be able to do and not do. And I can see how that could be a problem and would open a lot of additional questions, particularly in the cases of litigation.

And on the slide that he presented, on the second slide where he got the improved drift control measure on product labels and the continued support and education program to train the applicators, I think maybe most of the efforts should be put on the training of the applicators, rather than trying to put a very specific recommendation of what kind of equipment or how it should be used for specific chemicals. I think that could open a lot of problems, like I said.

And there is kind of a question that I was asking Jay before the break. Maybe I can get a sense from the other people. At least in my part of the country, it seems like the complaints about drift into residential areas have been reduced a lot in the last couple of years because of maybe the right to know, or maybe the farmers are more aware of the problems, or maybe the regulations are a lot more strict.

I don't know if this is the feeling that people

have from other parts of the country. So if somebody could tell us, you know, in the case, you know, where you get a complaint. I don't have an official figure from the Texas Department of Agriculture. But just what it used to be in the past and what I hear now, it seems the complaints about drift from the agricultural areas to residential areas seem to have gone down quite a lot.

I would just like to hear some comments on that to get a feeling on it.

MALE SPEAKER: Again, as I was addressing Dan's concern, our interest is to keep the labels as simply as possible as far as this. We don't want to get too technical. That leaves a whole host of problems. You know, the applicators won't be able to follow the directions, or they won't make sense to them, given that we're trying -- given that we're doing national labels as opposed to regional labels.

We know that some of the difficulties we've had in trying to craft some draft label language is just the wide variations going from Maine to New Mexico on crop types, crop geometry, weather patterns and things that really effect drift, and trying to simplify this as much

as possible without getting too detailed in a lot of algorithms, if you will, on the label.

So we took a look at -- our scientists sort of factored out from this very large database what are the three or four things that make a world of difference in reducing drift. Sort of the generic kinds of things. It doesn't matter --

DR. AMADOR: Not specific to the chemical?

MALE SPEAKER: No. It's not related to the chemical. So very generic. Very important things that we think applicators -- many of them are doing now, because we've talked to a lot of applicators for all the different major application methods and got a sense of what they're doing, what they're capable of doing and what they're willing to do. And by putting that on a label, it obviously has an enforcement piece to it.

So we do want to keep it very simple. We think simpler is better. It makes more sense.

DR. AMADOR: You also have an enforcement piece in the recertification program that most of the applicators, you know, have to go through.

MALE SPEAKER: Right. Right.

DR. AMADOR: So the effort is on the education program.

MALE SPEAKER: That's right. And so our labeling effort blends in very nicely to a lot of the initiatives that are in the C&T program, as well as the private section -- the applicator sector -- on training applicators about drift. And that is -- those training efforts have just mushroomed greatly over the last three or four years, I would say. I know that I have been involved with two new training videos, as well as some CD-Rom training and education things. There are new web sites that are being done by Extension personnel that would be used nationwide.

So that's expanding tremendously. And I think that supplementing the label with these training programs is really the way to go, because you're really telling the applicators, here's what you need to do to get away from this drift problem. I mean, here are the things you've got to do -- the real basic kinds of behavioral changes, frankly -- and just be willing to say no, I'm not going to make the application if the weather conditions are very unfavorable.

So we are a big supporter for sort of the education outreach for applicators on this.

MS. MULKEY: Jay, do you have any sense about the spray drift incident?

MR. VROOM: Oh, yes. And I can get you the reports from Texas. When I look at the -- there is a survey that was done by AFTCO between the years of -- I want to say '90 -- '92 to '98. There is a six year period in there where the number of incidents -- the total number -- really didn't change very much from year to year. There was about 2,500 reported incidents nationwide looking at all different parameters and variables, sort of the hot pesticides that were the most common pesticides involved in drift, application techniques, kinds of effects, etc.

Some of those parameters changed over time, but the total number really hasn't. And so I can take a look and get back to you about Texas.

MS. MULKEY: Okay. Adrienne?

ADRIENNE: Yeah. I just had a brief comment on all of the research that Chris was talking about and the concerns that were being expressed around the table.

I think that we -- what we're forgetting here is that we're dealing with a science, and EPA is dealing with a science, and it has to be malleable. And it's constantly changing and new information is coming to you every day. And I think we have to recognize that the agency needs a certain level of flexibility in that area, and that while I'm sure a lot of people would like to see this go to a work group and have the opportunity to comment on every single study, I don't know if that's -- I'm all for transparency and we would like more of it.

But I also recognize that if we want these decisions to be made -- and I guess that may be what's underlying a lot of this. Maybe we don't want to move these chemicals to be looked at under the new data. But if we want these decisions to be made, and we want EPA to continue to do its job, we have to allow for some type of flexibility to consider these and incorporate them into the -- I'm sorry. I'm not using a microphone. I hope everyone can hear me. I'm loud enough.

Anyway, so I don't know that that's really necessary or really a solution to the questions that people have expressed, which is really, well, when is EPA

going to be using these. I mean, that can be made clear through the message that was described by EPA. And I think that through the risk assessments maybe adding a little more information as to what data was used may be enough.

But putting this through yet another level -- and every time one of these studies is ready, that would mean one of these work groups, or one of these workshops, or something else would have to be had. And, yeah, it would be great. It would be really interesting. But it might delay the process. It might delay even further the re-registration process and the reassessment process. And that is what, I think, we want to avoid at all costs.

So we need to recognize that this is being gathered in order to avoid our reliance on models which has been so severely criticized. And it's a give or take. We're going to have the information. Not everybody is going to like the information. Yes, everybody should be able to have access to the information at some point. But I do think that we need to keep in mind that there needs to be a certain level of flexibility in using the data as it comes in.

MS. MULKEY: All right. J.J.?

DR. STEINBERG: We are yet again staring down another amazing opportunity that I think would be a great gift to the American people and everyone sitting around this table. In the City of New York, we've had great difficulty in trying to get a number of government and other organizations to make available on one common site all the environmental and environmental health information we can get. We've struggled with this for now over a year and a half with very, very, very little success.

If we have to suggest yet another working group, clearly between EPA, the rich data at ORD, USDA and FDA and anyone and any data available from industry we can make a common repository site, just like TRI, to get all this information so that the data can be reached easily. And then, of course, everyone can end up building their own models.

I mean, I have to tell you, the first day a few years back when I typed in my zip code and retrieved all that information from TRI, I got goose bumps. And I think if we can get that same level of information

centrally, that would be a wonderful thing to see. And I think you are in the precipice of doing that. You have all the representation here. We should see a beautiful web site. We shouldn't have to hunt for it. And to get that data would be just spectacular, and I think would lead to a lot of clarity in the future.

MS. MULKEY: Larry?

MR. ELWORTH: Can I ask Chris -- this finally registered with me. We pay -- taxpayers pay for data to be developed that we can't get to be used for risk assessments? That you can't get from the contracts -- from the grants you fund? I just want to make sure I'm understanding you.

(Laughter)

I'm not being critical of you. I'm just trying to understand.

MR. SAINT: The Grants and Cooperative Agreements Act, which was passed many years ago, specifies what we can use what's called government assistance for. If we are purchasing something for the exclusive use of the government, we can not use an assistance agreement. We have to use a contract. Under

a contract, we can get whatever we specify in the contract. They have to give it to us or they're in default.

MR. ELWORTH: Uh-huh.

MR. SAINT: We are barred under the Grants and Cooperative Agreements Act from using a grant or a cooperative agreement to fund anything that is for the specific use of the government only. It is supposed to be for a public purpose. There is an Executive Order which says that anything funded through a government grant -- any data -- has to be made publicly available.

Now the interpretation -- it's in the interpretation of that where the problem is.

MR. ELWORTH: You said the data has to be made public?

MR. SAINT: Uh-huh.

MR. ELWORTH: Okay.

MR. SAINT: All information from the public -- from a government funded grant has to be made publicly available. And I say -- it's not that we can't get it. It's the interpretation of that rule that is in the Grants and Cooperative Agreements Act, and the subsequent

Executive Order has been somewhat varied. And it's basically related to intellectual property rights of the individual investigators in the universities.

Because you've got to remember, their lives depend on publication rates, and they get tenures for the number of publications they get. And if someone else publishes their work, you know, they're SOL.

MR. ELWORTH: Well, you said you can get it. Does that mean you do get it, or like theoretically you can get it?

MR. SAINT: Sure. We are experimenting right now with RFAs that state flat out in it, you will provide the data within a certain time at the end of your grant. And we have had relatively good success with it. Everybody is -- nobody has said, oh, I don't want your money.

MS. MULKEY: In my experience, the difficulty is less about whether than more about when.

MR. ELWORTH: Yeah.

MR. SAINT: Exactly.

MS. MULKEY: And a lot of times we're very eager to see and use these data, and the researcher is very

proprietary about maintaining the confidentiality of the data until she publishes.

MR. ELWORTH: Right. Right.

MR. SAINT: And the problem is, the laws don't specify a time frame.

MR. ELWORTH: Okay. But do you actually in these grants or cooperative agreements or whatever they are provide funding for publication costs?

MR. SAINT: Yeah, for them to publish.

MS. MULKEY: Are we understanding --

MR. SAINT: And they do publish.

MR. ELWORTH: That's fine. That's fine.

MS. MULKEY: I mean, I had a comparable reaction myself on this.

(Laughter)

MR. SAINT: What we don't do -- however, what we don't do, which has become a real problem, is we normally do not fund as part of these grants database development costs.

MR. ELWORTH: Right.

MR. SAINT: The universities usually eat that out of their indirect costs, which is a cost we pay, but

it's not a definite cost for database development. So the problem is, you know, you can call anything a database.

MR. ELWORTH: Yeah. Yeah.

MR. SAINT: You can put a Lotus spreadsheet up on the web with no labels and just a big batch of numbers and say, yeah, there's my data. It won't be any use to anybody. So, you know, the difficulty lies in getting the documentation that goes with it so the people can use it.

And, you know, there are as many database systems as there are researchers out there, so it's a difficult problem.

MR. ELWORTH: Well, is this -- is this an annoyance that you can fix with the FRA process, or is this an endemic thing that is required by statute?

MR. SAINT: We're trying a couple of avenues. We're trying the RFA process. We're trying to work through the Federal Demonstration Partnership, which is an organization of government agencies and universities, to try and standardize rules for granting across all institutions.

MR. ELWORTH: Uh-huh.

MR. SAINT: And we're working with them to come up with terms and conditions for the grants that would allow us to get the data after specific time frames and allow for publication. There are a number of efforts going on to try to clarify this issue. I mean, this is a big hot issue with us right now.

MR. ELWORTH: Yeah. It does seem pretty important to you folks.

MR. SAINT: But, you know, the other problem is, if we do specify we want the data, you know, when the big pile of CD-Roms comes into our office, I don't know what I'm going to do with them.

MR. ELWORTH: Right.

MR. SAINT: So we also have to work at our end with IAMS and other programs within EPA to find a home for these and try and get them available in the most efficient manner.

MR. ELWORTH: Uh-huh.

DR. STEINBERG: You know that to some degree -- you know, when the NIH decided they were going to get the genetic code, what they did is, they changed the ground

rules. And part of the ground rules was that it was to your advantage to get that information on the web as quickly as possible. And that was proprietary publishable information. Hal Varmis, the former Director of the NIH, said that's a publication.

And I think if you -- if you can move your scientific clientele to do that, that is a very important goal standard to the point that you can also exercise some kind compliance. For example, you can list their project and if there is no data, then you just say that there simply is no data, and that usually is cudgel enough to get people to move along.

MALE SPEAKER: The one difference is a majority of the NIH -- of the actual sequencing is being done in-house at NIH. They have to do it. They're employed by the government.

MALE SPEAKER: No. I'll have to -- I'll have to say that that's not completely the case. I mean, the extramural grant funding program has paid for a lot of that. There has been private organizations also. But there has been an overwhelming -- the ethos of those organizations has now turned from waiting those one to

two to three years to get that publication out to actually getting it on the web. Because you want it out, you want priority, and if there is a mistake, you want correction.

And I think you need that type of --

MS. MULKEY: Well, maybe part of the point is that maybe there is some benchmarking we can do, and see whether other parts of the government who obviously face this problem have some interest.

Well, we've used our hour and a couple of minutes.

MR. TINSLEY: Can I --

MS. MULKEY: Oh, I'm sorry. I'm very sorry, Ian.

MR. TINSLEY: That's no problem. I was going to make a question -- or not a question. But a comment in defense of university people.

(Laughter)

Because it's been our experience, and it was quite a few years ago now when I -- and I don't remember the exact details. But there were some studies that were going on and data were being collected. And then I

believe there were some special interest groups that became aware of what was being done and were requesting the data from -- you know, from the faculty member.

And I recall that our -- you know, our legal people on campus sort of protected us from releasing that data, because the faculty member at that point was not comfortable in actually releasing that data because he didn't feel that he could -- you know, he had confidence in it at that point.

So sometimes, you know, there may be sort of extenuating circumstances. And I don't know that that's necessarily a justification for them being tardy in providing the information to the granting agency. It is a little bit -- or can be a little complex in terms of it's not just the agency that might be looking over the faculty member's shoulder on occasion. There are other people who want to use the data or misuse the data, depending on how you want to look at it.

But I'm not sure where all that is right now, but I think it relates to this issue.

MALE SPEAKER: Well, just a quick comment. The issue is not, you know -- the issue is really one of who

the data belongs to. And the data belongs to the public. It does not belong to the researcher, although you would get a lot of arguments. I mean, when I was on the other side of that, I probably thought pretty vehemently for, you know, don't you dare touch my data.

But, you know, the problem is that the regulations haven't kept up with the needs. So we are in the process of trying to back fill, I think. And, you know, the researchers have to be given time to analyze their data and to publish the correct papers and get them in the literature, because they're the ones who know it best and they're the ones who can interpret it best. But the public does have the right to have access to that data because they paid for it.

MR. TINSLEY: Well, that's not the issue. I mean, it was a timing issue.

MALE SPEAKER: It's a timing issue.

MR. TINSLEY: Yeah, it's a timing issue.

MS. MULKEY: All right. But often timing is the essence of the issue. Well, this has been, I think, quite a terrific discussion. It is evidence that you thought that at least the content, if not the glorious

presentations, were -- and maybe that, too -- were pretty terrific, too, in terms of scope and breadth and depth. This represents another step in our ongoing effort to make this information more accessible and more transparent.

It is certainly not the only step. As you know from the discussion of the SOPs, they went through a public comment process. They've gone through a SAP meeting. They will go through a very extensive documentation of how we responded to the comments and how they have evolved. And we will obviously need to look at the question of further additional, appropriate levels of effort on our part.

I would say that your work here and your continued work has to be a part of it, too. It can't all be about things we host and the amount of hand holding that we do to make these things accessible, that there has to be some real mutuality and some real investment. And I recognize that that represents a burden to anybody attempting to invest in it, whether it is by their own science resources or otherwise.

Joe Merenda is here and has available the

information that we hope you are interested in regarding our budget situation, as well as our budget processes, which Larry always pays attention to, and I always enjoy that element of what he does.

MR. ELWORTH: I'm the only one who understands it.

MS. MULKEY: But frankly, it is as important a part of your understanding of what we do. Now I'm mindful that it's getting toward the end of the day, and there's going to be a tendency to want to drift out. I'm equally mindful that this subject matter is not -- not because of Joe, but because of the subject matter -- the most lively available for a potential discussion.

What I would ask you is, if you really don't want to hear it, let's just say that and we'll cut it out of our program. And that's okay. We're cool with that.

MALE SPEAKER: I object.

MS. MULKEY: You want to hear it?

MALE SPEAKER: I want to hear it.

MS. MULKEY: Well, let's try to be patient. We don't have a public comment remaining, so we will end on time and probably ahead of time. Joe's an efficient man

and hopefully this will be a useful part of your program.

MALE SPEAKER: He's smiling. That's a good thing.

MS. MULKEY: Joe, you missed my remarks this morning about what a vital role you play in our ability to keep OPP running. I won't repeat that now, but you should know that we did acknowledge it.

MR. MERENDA: Well, thank you. I apologize in advance that this was not in your folders, but let me pass some copies around. And I'm sure we have more than enough for everyone at the table, as well as there are copies for folks in the audience to pick up later.

I put these items on some overheads, but I think given the layout of the room, it's probably a lot easier, since we'll all in a moment have the piece of paper. It's only a single sheet, so there is not -- we can certainly work from the piece of paper, or those who are positioned in a way that you can readily see the overhead, you can glance at it there.

I was asked to give in an overview update mode a little discussion on three areas: strategic planning, performance measurement and budget outlook. Let me start

with strategic planning.

Chris Saint in the last session mentioned -- he called it GPRA, G P R A, the Government Performance and Results Act. Under this statute all federal agencies are required to develop and then to update on an every three year basis an overall strategic plan.

EPA did its first update of its strategic plan over the course of this past year. In September of this year, after considering public comment on a draft that was made available earlier in the year, EPA published its strategic plan for fiscal years 2000 through 2005. And shown there is the EPA web site where that full strategic plan is available if you wish to peruse it.

The strategic plan does not reflect any major structural changes from EPA's previous strategic plan. There are still ten goals. The ones that are of interest to the pesticide program are goal three, safe food, and goal four, which has a longer title than I'm going to use, but it's basically safe homes, work places and communities. The pesticide program activities are split between those two goals. And if you want to take a look at the strategic plan, those are the two sections that

you will most want to have a glance at.

What sort of changes were made with respect to the pesticide activities in the strategic plan? I've highlighted three areas here on the slide. First off, there is a change in the goal statement for goal three. It's an expansion. And this is a result of comments that EPA has received from a number of external parties who were concerned about whether we were paying attention not only to infants and children as sub-populations of concern, but also other sub-populations who may have higher exposures to toxic chemicals.

Particular interest was to Native American tribes who have subsistence life styles. And so we have broadened the language of goal three to make clear that our assessments and our concerns under goal three include those groups as well as infants and children. Of course, infants and children are explicitly spelled out in the Food Quality Protection Act for special attention, and we continue to give that same special attention.

We also made some adjustments based upon our experience to date under the Food Quality Protection Act to the language of the objectives. Under GPRA jargon

there are goals, there are objectives, there are sub-objectives and there are annual performance goals and annual performance measures on and on. The published strategic plan discussed this only down to the objective level. That's the first level below the broad goals. And the kinds of changes that you will see are primarily date changes that take into consideration some of the things that we've learned since we did the previous strategic plan.

I'm not quite sure, since I wasn't involved in the process when the previous strategic plan was developed, exactly how we arrived at the statement that we were going to complete our dealing with existing pesticides and ensure that virtually all would meet the FQPA health standards by 2005. But we realize, as we've dealt with many of you, through TRAC and other forums that have helped us deal with the close interrelationships between the re-registration program and tolerance reassessment, that we're not going to get re-registration done any sooner than we get tolerance reassessment done. The statutory schedule for that is 2006. Once we complete active ingredients, it will take

us a couple of more years to complete product re-registration.

So if you look closely at the changed objective language for the revised strategic plan, you will see that 2008 is now in there as the time when we say that we will be done with all of that process. So basically we've tried to catch up the language to what we see as our actual schedule.

The last point which I will talk a bit more about in the next slide has to do with one of the core elements, at least in the concept, that GPRA and GPRA watchers use as a watch word, which is outcome oriented. We are constantly told that under the Government Performance and Results Act we should be looking at what are we accomplishing in the real world in the environment with respect to public health, not how many widgets did we produce in a particular year.

This is a major challenge for all sorts of organizations, and our organization is at least as challenged as others in that regard. One of the things that we have attempted to do in this updated strategic plan is to make some incremental advances toward more

outcome oriented measures. And I will talk about those as we turn to the next slide.

I already mentioned this is a challenge with which we continue to struggle. And I've listed on this slide just three of the examples -- and there are a few others in the updated strategic plan -- that are changes. Ways in which we have tried to incorporate data that are available from various sources, but not counts of things that the pesticide program has specifically completed to look at our progress.

The first instance is that we have proposed a goal that is based on using the USDA Pesticide Data Program data for residues on foods to look specifically at the detections of residues of cholinesterase inhibiting pesticides and also carcinogenic pesticides on children's foods, with the idea that as we establish our annual performance goals, we will use those data to see how those frequencies of detection of residues are changing over time -- are they in fact going down -- and as a further look at whether the things that we have done through the tolerance reassessment process and through re-registration -- whether the impact is actually being

seen out there in the data.

This is -- as I say here in quotes, these are experiments by the Office of Pesticide Programs. We are working with at least the understanding internally that we are trying these. We don't know which will succeed and which will fail, because we find that the data really don't show us what we're looking for. We think if we pick ones where there are data sets that will be available over the period of time we're looking at, it will give us some meaningful measure. But time will tell as we begin to look at these.

A second one that we've used is a little bit less outcome oriented, but certainly a step beyond what we included in the previous version of the strategic plan. We previously counted -- in terms of our efforts to encourage the greater use of reduced risk pesticides, we basically were counting how many reduced risk pesticides did we register each year. Well, we're going to continue to count those and report those, and I can assure you that the budgeteers within the agency, as well as the Office of Management and Budget and others outside the agency, still ask us, how many are you going to

produce each year. How many did you produce each year in terms of registrations.

But we've added to that an effort to look at, are reduced risk pesticides actually being used more widely in agriculture. And we've gone through some discussions. If you look at the language in the strategic plan -- I've condensed it here -- we actually talk about the change in the number -- or the percentage of acre treatments that are from reduced risk pesticides and biopesticides, the idea being that we think if through various efforts that EPA and USDA and others that are engaged in, if we're successful in transition in encouraging the use of reduced risk pesticides, then this percentage will go up over time and this will be a measure of success in that part of our program.

We are hopeful that we will see such changes, but these sorts of data on the use of pesticides are, first off, somewhat hard to come by on a national basis, and secondly -- at least at a fairly fine level of desegregation, and secondly they are certainly subject to forces that have little or nothing to do with what we have done at EPA. They have a lot to do with weather,

with pest pressures, with economics and a variety of other things.

So this is one of the issues that those of us who have been challenged with talking about and trying to apply the GPRA goal, more outcome oriented measures to the pesticide program, have been trying to remind people, is don't expect to see constantly increasing values of these measures. You may well find that in a particular year we seem to have regressed in our progress. That does not necessarily mean that people are any less safe, that the economy or agriculture have turned backwards and are falling into evil ways or anything of that sort.

(Laughter)

They may simply be --

MALE SPEAKER: Recidivism.

MR. MERENDA: -- the result of -- recidivism. That's the word I should have chosen. They simply are going to be changes and we need to look over a period of time. And this is something that I think the whole GPRA process needs to think about -- those who review it -- to look at progress and get beyond the annual reporting cycle. But this is what we're trying.

The last example I've cited here has to do with one that is even more illustrative of that, which is the frequency of detections of pesticides in surface waters as reported by the U.S. Geological Survey's Nocqua Program. The very design of the Nocqua Program, if you're at all familiar with it, is a large scale, nationwide monitoring program of surface water for a variety of contaminants, including quite a few pesticides. But it operates on a multi year cycle.

They basically divided the various hydrologic study units that they're considering in the nation into three groups. And over -- I think it's a three year period, they go from one group of study units to the next. So annual data are simply not available for the Nocqua Program, and we're going to be reporting on a periodic, but definitely not an annual basis, with respect to this.

But it is, at least so far as we've been able to identify, the best, and for that matter the only continuing data set of actual pesticide monitoring in a reliable way in surface water consistently looked at from year to year. So we think it's the sort of thing that is

tailor made for this purpose, and we're hopeful that our colleagues at the USGS will continue to have the resources and the commitment to carry this out over the coming years so that this data source will be available.

We have certainly given them that feedback in various sessions that they've had with other agencies asking about the Nocqua Program and how it might be used, and we found them quite interested in continuing to provide data on pesticides to help us in this, as well as our assessment activities.

Beyond what we have at this point in the revised and updated EPA strategic plan, there is another project which I'll mention which is not yet completed. The Office of Prevention of Pesticides and Toxic Substances, the parent organization of which the Office of Pesticide Programs is a part, recognizing that outcome indicators and performance measures is a tough area for all of our programs, last year engaged in a cooperative agreement with Florida State University to develop essentially a compendium of ideas on performance measures for a variety of pesticide and toxic chemical areas.

Their initial report is in the process of being

finalized. But they have -- I guess because this is not data and not something that would be published, they have been maintaining a web site of their ongoing efforts. And the URL is listed there. If you want to take a look at what they have, it's available. Let me caveat that as a cooperative agreement, this is not an EPA publication. It has not been peer reviewed by EPA. In fact, it changes from day to day and week to week. I haven't looked at it in at least a few weeks, so there may be some ideas in there that I'm not even familiar with and that we may or may not agree with as useful measures.

In fact, I can tell you there are some that are there that we looked at internally when we were doing our strategic plan update and rejected as ones that we wanted to try to pursue at this point, because we either felt that the data were of less than the quality or availability that we thought would be useful for our purposes, or because we thought there were other measures that we wanted to concentrate our efforts on.

So these are some things that we will be looking at, and we're hoping that state governments and others who are interested in performance indicators for programs

will look at and will provide further comment on. But hoping that some of you may have some interest in this area, we want to draw your attention to it. And as that report is finalized, there will probably be some mechanisms by which EPA will be soliciting further input on these particular approaches.

So that's my spiel on performance measurement. Turning to --

MALE SPEAKER: Before you leave that, can we --

MR. MERENDA: Sure.

MALE SPEAKER: -- ask some questions?

MR. MERENDA: Yeah. I think that's probably a good idea rather than moving onto budget.

MALE SPEAKER: In this list of several experiments with regard to more explicit kind of metric measurables, I assume this is not the exhaustive list, or is this -- is that it?

MR. MERENDA: This is not the exhaustive list. There are a few others that you'll find in the strategic plan. There is one, for example, on frequency and extent of reported wildlife incidents, where we're trying to use some of the data are reported to us. That's one of the

ones that we recognize as being a squashy data source, because we don't have complete reporting. There is nothing that requires people to tell us, at least other than registrants under 6(A)(2). But folks in the public and states, we try to encourage that reporting, but we don't necessarily get everything.

MALE SPEAKER: Sure.

MR. MERENDA: And there are a few others.

MALE SPEAKER: I think that is a good start and it makes sense. And I think your caveat about needing to look at these more than year to year so that you can really see realistic trends -- I believe Leonard Genesse is going to release a study tomorrow that EPA has partly funded kind of looking anew at pesticide use nationwide.

And once again, I just chatted with him the other day, and he referred to the fact that, you know, some of the biggest year to year differentials are weather driven, you know, and also, you know, crop pest pressure driven that relate to weather that is out of all of our control and those kinds of things.

And so I think your point about looking at more than just one year to the next is very important,

especially in these kinds of measures. But these are really very good measures in the continuum, you know, over five and ten year windows of time to see about direction.

One suggestion would be, is there a way to incorporate a measure of unintended consequences of agency action or policy? I'm thinking -- I don't know how to sort of capture that.

MALE SPEAKER: Bankruptcy.

(Laughter)

MALE SPEAKER: But, for instance, a decision -- bankruptcy in a pesticide company. You know, a decision to grant a split registration on StarLink.

MS. MULKEY: (Inaudible)

(Laughter)

MALE SPEAKER: Just to pick one that might be current now.

MS. MULKEY: Well, if we know about a negative, we're obviously going to try to avoid it.

MALE SPEAKER: But this is retrospectively, Marcia.

MS. MULKEY: That's a fair question. In other

words, what you -- you would have to put it in the positive. Improved avoidance of something.

MALE SPEAKER: Right. Right.

MS. MULKEY: But I think that's --

MALE SPEAKER: Or just because you increase the agricultural use of reduced risk pesticides, did it result in greater soil erosion somewhere. I mean, were there some other unintended consequences beyond the limits of measures in these metrics? I just think that -- to find some way to capture that as part of this experiment, to me would give it a little more depth. But that's not an easy thing sitting here to conceptualize at this moment, but I would encourage that.

And your reference of the USGS surface water pesticide detection study reminds me that the first foray that USGS had in pesticide water detection was on the groundwater side. And I can't remember, have they continued the groundwater study?

MR. MERENDA: Yes, they have and that's an area in which we had a number of internal discussions. And there were some who were strongly encouraging us --

(END OF TAPE FIVE, SIDE A)

MR. MERENDA: -- time between what gets done in terms of application of a pesticide and when it shows up in groundwater. And we felt that we were better to -- forgive the pun -- get our feet wet with surface water first and see how that worked out.

But, yes, USGS is continuing to monitor groundwater, and those data are quite valuable to our pesticide programs as we do our technical assessments. But in terms of developing an indicator, we were a little bit shy about how to deal with timing in a meaningful way, as opposed to having people look at it and say --

MALE SPEAKER: You mean in terms of --

MR. MERENDA: -- this thing has flat lined for 20 years. What have you been doing.

MALE SPEAKER: Yeah. But in terms of sort of seeing a dose response curve here in terms of agency action and measurable metric response. But I think it would be arguable that -- you know, I don't think it's an exactly flat line. But it really actually has, I believe, gotten a lot more scientific respect in terms of the database, because there is still a lot of controversy around the USGS approach to, you know, when you monitor.

You know, what time do you interpret the surface water because of the variabilities during the course of the annual weather cycles and so on, planting and the like.

MS. MULKEY: This FSU project has been designed to really encourage participation of stakeholders. In fact, it's a little unsettling to me if none of you have heard from them, because their goal was to do a lot of outreach. And they're near to the end of this sort of phase, but I think they would still welcome any input.

MALE SPEAKER: You might want to give them the list of the PPDC.

MS. MULKEY: Yes, we probably should have, if we didn't. Maybe we did. I don't know what we did. We gave them a lot of information about our stakeholders.

A time check for a minute. We have only about nine minutes left for the whole session, which all we have to do is finish this. Joe has one more slide which is the budget outlook. If you two want to talk about this performance measurement issue, then let's take your comments, but keep them, you know, so we can finish and then have a little bit of time for discussion of everything.

I don't know who came up first, so we'll go with Bill.

BILL: As someone who has lived through more objectives, goals, strategies, measures and tactics than I would ever care to, I was a little concerned on the measures, in that these seem like things that are out of your control. And so I would encourage you to -- I like measuring widgets. You know, I mean, it's pretty easy to do, and it's pretty impactful. I think it's meaningful in a lot of ways, at least to people around here.

MS. MULKEY: We're not stopping with measuring widgets.

MR. MERENDA: Yes. Let me encourage you to take a look at the actual strategic plan. You will see that we have kept the widgets. And you're exactly right in saying that these are out of our control. That's been a source of considerable concern to various folks within our program, as well as others in other agencies who are dealing with GPRA. The concept of looking at what is happening broadly in the environment is generally out of the control, or it's certainly not directly managed by what we do.

And it is a philosophical difference that we're a little bit concerned that those who view GPRA as a way to decide where the dollars need to be spent may forget about that distinction and say, oh, well, the dollars that we've been spending in this program area isn't buying anything. Let's spend them somewhere else where we buy something real for our dollars.

But we're trying to kind of thread our way down the middle path here, and as I said, experiment with some of these measures while keeping widgets.

BILL: I think given -- yeah. I think given that some of the stuff is not in your control and having not seen the plan, I'm not sure about this. But I would just make real sure, since they're not really in your control, that they ramp up through your OGSM or whatever your term is for it, in that these measures relate to tactics that relate to strategies and objectives and goals.

MS. MULKEY: Larry?

MR. ELWORTH: Yeah. I would -- I think it's real important to distinguish between these as goals or objectives and as measurements. I mean, in a sense this

isn't so much a performance measure in terms of output, but as you were suggesting, an outcome or a result of the performance of the agency. So in that sense, you know, I would echo kind of what Bill said, but I just don't think this is a useful process. And we struggled with this at USDA. You can say we granted 10 million dollars in money, but what did that result in on the ground. So I think this is useful as long as you say that these are ways we're going to look at the effectiveness of our program and not set as goals.

The other thing in hearing what Jay was suggesting -- and there are a lot of questions that come up in this. What are you using as a benchmark. Are you looking at decreased levels or decreased numbers. This is the kind of thing that I think having either this group or some group of people to sit down and talk with you about, either in the development and/or looking at the results at the end of the year. It would be a real interesting discussion for you folks in deciding which experiments work and don't work and how do you cast them.

And I think it would be interesting for people in the affected communities to look at this and say,

okay, well, here's what we think happened from what you folks did. It would certainly identify unintended consequences and give you some sense of what context these fit into. But whether you do it through us or some separate workshop, I think it would be a real interesting thing for public involvement.

MS. MULKEY: We're supposed to be trying to enhance our public participation in strategic planning. And we are trying.

MR. MERENDA: I'm very pleased to hear that suggestion, because I for one, and I think my colleagues who worked on this, would welcome the opportunity to engage in some dialogue on these. I guess it probably comes as no surprise to those of you who have been through similar processes that often the process is a hurry up and wait one, where there is a short period of time where one has to generate something, and then there is a long period of time and then all of a sudden it springs forth into the public.

But we're viewing this as something that we're engaged in for the long term. And so while we will probably change some of these, I think it would be very

useful to have some discussion as we get through our first round of reporting against these measures with the PPDC or a subgroup of the PPDC who is interested in talking about that and get some feedback so that we can move ahead with it.

MS. MULKEY: Okay. Do you want to do the last piece?

MR. MERENDA: Yeah.

MALE SPEAKER: Can I ask -- make one point before you do that?

MS. MULKEY: Yeah. I'm sorry, Phil. Go ahead.

MR. BENEDICT: I would encourage you to go back and look at groundwater. Your agency spent millions of dollars doing state plans for groundwater issues. You built a capacity for monitoring groundwater as generally not event driven. Surface water tends to be. I think it's really a much better indicator.

In our state, we still find detections. But they tend to be very low, and I think a lot of that is based on analytical equipment -- better analytical equipment today. I really think you've got a good example to show how your program has been successful. I

think there is an awful lot of data out there collected by states and other people that could show that.

I think detection is not a very good indicator. We have groundwater standards. We have MCL health advisories. Some states have PALs. Using some of those kinds of criteria in looking at what's happened over time I think would be real important. You also need regulatory decisions that were made to impact some chemical use on groundwater. And I think you can demonstrate measurably that these impacts have been real based on the regulatory decisions. I think it's a great opportunity for you to show a success story that you're not dealing with them perfectly.

The other one I would mention is I think you've got one on the horizon that I don't think you're dealing with. That's West Nile virus. The spray programs are going to continue, I think, for a while with that. And I guess my biggest concern is I've sat in on some of the CDC calls. And we're talking about using in some cases OPs there. Now you talk about exposure to people, with OPs there is one way to really increase it is to spray populations.

So there is a big debate going on. What's going on in your agency has been kind of sitting on the back fence. You've got laid on the table everything that's registered. But just laying -- I don't think that's the way to do business today. I think you need to lay on the table everything that is registered and then help other people that don't have the expertise you have make decisions about which of those products are probably the more appropriate ones to be used today in some of these kinds of environments.

MS. MULKEY: Well, we can talk about that at some length. But the short form is, we have been very active, and our regions have been very active, in working with the people faced with the West Nile virus to focus on early prevention and larvacidal control. So I think we're not as passive as you just said.

MR. BENEDICT: Well, I hope not. I'm talking about this whole plan, though, to spray the whole northeastern corridor.

MS. MULKEY: Well, there is a --

MR. BENEDICT: And that's the part that bothers me.

MS. MULKEY: -- sort of worse case scenario plan CDC has developed. That's true. But they have worked with us on that and it's not -- it is a last resort plan. It's not a first resort plan.

Let's get the last slide in.

MR. MERENDA: Budget Outlook. I guess with most things, there is some good news and some bad news. If we had little icons here, there would be a generally smiling face for 2001 and a very quizzical face for 2002, would be my short statement of what's here. Basically we have in the 2001 budget, a modest increase in dollars that are available to us, but a small decrease in staff.

MALE SPEAKER: That means you're making more money, right? Congratulations.

MR. MERENDA: No.

MS. MULKEY: Not salary dollars.

MR. MERENDA: Not salary dollars, unfortunately.

MALE SPEAKER: Oh.

MR. MERENDA: But what it does mean is that we are under continuing pressure to find ways to do even more through extramural vehicles than we have been doing to use our staff -- the federal employees -- more and

more to manage contract activities in order to get the work done, rather than doing the work directly themselves. But that is an ongoing thing.

MS. MULKEY: At the margins. At the margins.

MR. MERENDA: At the margins.

MALE SPEAKER: What are you saying? You have more contract funds for registration and tolerance reassessment?

MS. MULKEY: Yes.

MR. MERENDA: Yes.

MALE SPEAKER: But you don't have -- what happened to -- what happened? Why did you get a staff decrease?

MR. MERENDA: The agency as a whole has been told by the Congress that the EPA will have -- and I forget the number, but it's something like 1,200 fewer employees at the end of 2001 than it had at the end of 2000. And the pesticide program -- we certainly aren't going around saying the sky is falling, because we have been spared pretty much from having to take actual reductions. But we definitely have had no growth, and we've had marginal reductions as part of the across the

board impact.

MR. ELWORTH: Okay. So that 16 million dollars you got when FQPA passed --

MS. MULKEY: Well, we're not declining from before FQPA. We're talking about -- this is from 2000 to 2001.

MR. ELWORTH: How much below the President's request is it?

MR. MERENDA: We're pretty much at the President's request for the registration, re-registration and tolerance reassessment activities. One of the odd quirks of this -- and that's what is indicated by the third bullet -- is areas that we're not protected in the budget jargon in this process end up having to absorb what is called the general reduction. And in this particular instance, EPA had an overall general reduction of some 46 million dollars plus, of which roughly 10 percent fell upon OPPTS, and about half of that on OPP, all of which had to be absorbed from areas other than registration, re-registration and tolerance reassessment.

So, for example, areas such as certification and training, or worker protection, basically we're trying to

keep them as much as possible at our FY 2000 levels. In some instances we're actually going to have to reduce them somewhat below the FY 2000 levels and absorb a general reduction.

But if you look at it overall, the big picture, we're up on dollars. We're slightly down on staff.

MS. MULKEY: Program wise.

MR. MERENDA: Program wise.

FEMALE SPEAKER: Joe, how about STAG money?

MR. MERENDA: STAG money is straight line. Thank you. That is a good point.

FEMALE SPEAKER: And STAG money is the money that goes to states and tribes to fund their partnership grants.

MR. MERENDA: Yes. State and Tribal Assistance Grants. That's what it stands for. And the salary money is really part of the whole picture, and there are, of course, yearly increases, cost of living increases and so forth which cause a regular shift of money from the contracts and grants into salaries. In this case, we have enough increase in the dollars that we actually have more dollars available for contracts and grants in 2001

than we had in 2000 for registration, re-registration and tolerance reassessment activities.

Now you mentioned, Larry, the 16 million dollars, which is a great lead in to my last bullet, and I'll just come back to the next to the last one in a moment. There was -- you're referring to the registration maintenance fees. Under FQPA they were extended at 16 million dollars for fiscal years '97 through 2000. They dropped to 14 million dollars this year and 2001. And they end abruptly to zero in 2002, which is why in part we say that for 2002 it's too early to discuss, because there is no President's budget request yet. That doesn't happen until January, and perhaps with the new administration coming in, there will be --

MALE SPEAKER: Presumably.

MR. MERENDA: Presumably. But even before the current delays, the federal government has been proceeding with what they're calling a current services budget, and then assuming that the new administration, whichever one it is, will seek to deal with their own directions and initiatives subsequent to coming on the

scene. So we don't really know, nor could we even if we did know talk about it at this point where the administration is headed on 2002.

But we do know that expiration of the registration maintenance fees is a big issue for the pesticide program. Those maintenance fees pay for the salaries of over 200 of our 835 approximately employees, so 25 percent of the folks who do pesticide work are paid for by those funds. And I can assure you that EPA's Controller's office and the Office of Management and Budget and many others are well aware of this problem and are thinking about how they're going to deal with this problem. And I don't know how it's going to get dealt with. I'm not sure anybody else knows yet how it's going to get dealt with. But we are certainly hopeful that it will be dealt with.

The next to the last bullet is, I guess, an example of how one of these things does get dealt with. In the 2001 budget the administration decided that because we were expected to issue the new tolerance fee rule after October 1st of 2000 -- because Congress had told us we would not -- we could not do it before then --

the President's budget request actually offset our appropriation request for the pesticide program by seven million dollars based on the anticipated fee collections under the new tolerance fees.

Well, as many of you probably know, when the Congress enacted EPA's appropriation bill, they said no, you will not finalize the tolerance fees and the agency will, nonetheless, fund the pesticide program at the full amount previously expected. And so part of that 46 million dollars of general reduction I mentioned a few minutes ago was seven million dollars that basically the agency had to eat from its overall appropriations to fully fund the pesticide re-registration activities to make back that seven million dollars. We're hoping that's not what happens for 14 million dollars next year, because that will hurt even more.

MS. MULKEY: One thing that might be worth mentioning -- and I don't want to be an alarmist or anything. But when you have funds that fund personnel, should those funds be eliminated, you don't and can't simply eliminate those personnel because of the way the personnel system works. There is actually an agency wide

impact about how you de-occasion personnel.

But in the short term, you scare the hell out of everybody, because it's not like you frighten the 200 people who are funded by this. You create a dynamic, which -- and that has obviously impacts on the ability to get work done and a lot of other things.

So the uncertainty associated with this has a cost. And the actual impact, of course, would be -- you would sort of be able to measure it eventually, but the impact of anticipation is a very troublesome impact.

MR. VROOM: Would it be helpful if those of us who represent the industries who are paying those fees now would try to draft a letter to you or someone at the agency, just indicating that, you know, we generally are supportive of and re-authorizing, you know, the --

MALE SPEAKER: Hasn't that already been done, though the congressional appropriations process?

MR. VROOM: This is not an appropriations question. This is an authorization question.

MALE SPEAKER: But they made that comment in the appropriations bill.

MS. MULKEY: This past bill was silent on this

issue.

MALE SPEAKER: Right.

MS. MULKEY: I don't think we would be comfortable inviting a letter like that.

(Laughter)

MR. VROOM: Okay. Clearly, certainly ACPA plans to be an advocate for extension of that authority, even though it probably means prying open FIFRA a tiny little bit this year, which we would probably rather not do otherwise.

MS. MULKEY: Well, I think that certainly the Congress always wants to know how affected entities of all sorts carry it out. But it's not our --

MALE SPEAKER: Speaking to the point you're raising -- and I've heard you and your predecessor and many others say the same thing over time, that there is a concern among EPA employees generally about this kind of a deadline coming and nervousness that it creates.

MS. MULKEY: There is a potential for it. I mean, part of my job is to try to be a responsible leader, which means on the one hand not to tell people don't worry, be happy, unless I'm confident that they

could not worry and be happy. But on the other hand, to prevent unnecessarily alarmist reactions, we do have responsibilities. And, you know, it's dicey to even say something in a form like this, because you don't want to create a monster. I will say that our work force for today is very focused on getting the work done, and there is not a lot of current undercurrent of alarmism. But it's early days yet in the fiscal year.

We've eaten up all our time. It's great that there has been as much enthusiasm around this topic as there has been. I don't want to cut off any discussion. Our time is your time. What I would like to do is see if there are any tent cards that would like to continue this dialogue. And if not, we will adjourn until tomorrow. There will be some opportunities tomorrow, so that if this is a topic where you want to continue, there will be some chances.

MR. ELWORTH: Well, Marcia, I would like to know a little bit more about this budget stuff.

MS. MULKEY: Joe is available to you at any time and he's on top on this.

(Laughter)

MR. ELWORTH: Thank you, Joe.

MS. MULKEY: We can go into this -- it's mind numbing, this general reductions, blah, blah, blah. And there is sort of the story behind the story behind the story. But the bottom line is that there is a very modest net income in our dollars after all the dust settles that is real, and we don't expect any program to suffer significantly below 2000 in the internal dominos.

In other words, we're not going to have a big wholesale cut. There may be some programs that were funded at a million last year that are going to be funded -- non-protected programs -- at what, 900 K or something. But for the most part, we are in a steady state everywhere and material growth in dollars in these big ticket items.

MR. ELWORTH: Yeah. I'm interested at some point in knowing what the general trends are. You know, was it two years ago or three years ago all the hits you took in cuts and you had to take all the --

MS. MULKEY: Right. This is definitely --

MR. ELWORTH: So I'm interested in what's going on.

MS. MULKEY: This is a far better year for us than last year. Last year it was a real cut.

MALE SPEAKER: Yeah.

MS. MULKEY: A real cut. This year it's a real increase.

MALE SPEAKER: Uh-huh.

MALE SPEAKER: This year being the current fiscal year?

MS. MULKEY: The year that started in October.

MALE SPEAKER: Right.

MALE SPEAKER: Okay.

MS. MULKEY: Okay. Well, have a nice evening. See you all bright and early, bright eyed and busy tailed. What time do we start tomorrow? Nine.

(END OF MEETING)

Transcript of

Pesticide Program Dialogue Committee Meeting

Radisson Hotel-Old Town

901 North Fairfax Street

Alexandria, Virginia

November 30, 2000

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Day Two

November 30, 2000

PROCEEDINGS

- - - - -

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CHAIRPERSON MULKEY: Good morning, all. It is 9:00. Time for your friendly PPDC meeting. Because it is the first time we sit down together, I will, notwithstanding my Martinet-type of approach to getting things going on time.

We do want to acknowledge the arrival of some folks who weren't here yesterday. That doesn't include Jim who was here yesterday, but he may have some opening thoughts. Have you?

MR. AIDALA: No, just to say I truly honestly planned to be back for a large part of yesterday, and a number of things ate my homework. I'll put it that way, so I apologize.

MS. MULKEY: We're glad to have you this morning. We note that Theresa Murtagh is here.

MS. MURTAGH: Good morning.

MS. MULKEY: From the Department of Agriculture.

MS. MURTAGH: Subbing for Al.

MS. MULKEY: A note to raise. Jenny Taylor, the Pest Management Regulatory Agency of Canada is here. She faithfully attends a lot of our stakeholder sessions. Beth Marshall, PPDC member, has been able to join us.

And we do expect some folks who were not here yesterday, other members, but I don't yet see them.

UNIDENTIFIED MALE: Ray, Bill and Jay are in the hallway.

MS. MULKEY: Yeah, they were all here. So it's time without further ado to kick off this morning session.

We have allocated almost two hours to this session as well. We hope that we can keep our presentations a little briefer than we did for residential. So we still have the full hour of discussion.

We're going to start with an overview of the Risk Assessment Process for Workers. This is something that we have presented in a number of fora, but we hope it will be useful to you.

Then we have a discussion of a portion of the public participation process, that is, the conference calls, because there's an interest in worker/community participation in that.

And I don't know whether we anticipate some attendance by some folks with a particularly keen

interest in that. But what we might do is flip that with the national assessment to maximize the availability of folks who have a particular interest in that.

And then Kevin Keaney is going to talk a little bit about the work that the Agency has going on with a number of stakeholders involving a national assessment of the Work Protection Program. And that has to do primarily with the implementation of the Work Protection rules.

So those are the various pieces of this puzzle that we plan to talk about. And then we will hopefully have a good, healthy discussion from you guys.

So, who's going to kick us off? Jim, okay, very good.

MALE SPEAKER: Good morning and thanks for the opportunity to be here. Today, I'd like to give an overview of how we do worker risk assessments. I'll touch on how the numbers are crunched, the data we use, where we get the data, and where we see ourselves going in the future.

I found this 1972 quote from President Nixon a few weeks ago and thought it was a good way to start

today's discussion. It says, "Essential to a sound national pesticide policy are measures to ensure that agricultural workers are protected from adverse exposures to toxic chemicals."

I think this is important to focus -- because it focuses us on how we got to where we are today. We've been active in the area of worker protection for many years and have continually built on our long-standing partnerships with stakeholders to improve our process.

We also recognize that under FIFRA, worker protection is a balancing act between risk and benefits. The Agency and you, the stakeholders, struggle with this on a daily basis.

In our worker risk assessments, we look at two major groups of exposed people. The first are those who are involved with applications and we generically call these people handlers. You can see in this picture a pilot making an application. And for this kind of use, we would look at the exposures to the pilot and also to the person who loaded up the aircraft.

And for handlers, we look at a variety of other industries, not only but agriculture -- not only

agriculture, but many others including the nursery and landscape industry, structural pest control people, uses on animals.

For example, a lot of USDA and veterinary uses, public health uses like mosquito control, forestry, and then of course lawn care and golf course industry. And we know that there are people in each of these industries that are exposed, so we do consider them in our risk assessments.

In the second group, we really consider in our assessments are people that are exposed because they have to work in areas that are previously treated with pesticides, and we call these generically re-entry exposures.

And you can see someone in this picture harvesting apples. And for this kind of use, we would consider the exposures to the harvester, but also many other activities that, for example, would be associated with the cultivation of apples like thinning, for example.

And again, we not only look at uses and exposures in agriculture, but a variety of other kinds of

industries. For example, people who do golf course maintenance, and particularly people in the nursery industry and floral culture, looking at doing cut flowers and those kinds of things.

So what now I would like to do is kind of focus in on -- highlight some of the details about how we do this, the data we use, how we crunch the numbers and where we see ourselves moving in the future.

This slide just shows the kinds of monitoring data that we use. When we monitor workers, one of two methods are generally used. The first measure is what can get on the skin or can be inhaled. And we measure what gets on the skin using patches or long underwear, except for the hands and the face.

In the hands and face, we measure with collecting, for example, wash water on the hands. We can also look at exposures by collecting urine and the amount of chemical residues that are in urine.

And then for the re-entry exposure, we also look in the areas that have been treated previously, what can rub off on the skin. And we measure this with what's called a dislodgeable foliar residue from the surfaces of

the plants.

Along with the exposure data, there are many other key building blocks in the process. And we have built on many longstanding partnerships to get this kind of information. We've worked very closely with many organizations to better our process and this slide just illustrates some of the types of organizations we've worked with to get this information.

For example, we've worked very closely over the last few years with USDA and the Health and Human Services to get information about actual cultural practices. And then, for example, with HHS to get information about mosquito control issues.

And we've also worked very closely with different registrant task forces, like the ARTF, which is the Agricultural Re-Entry Task Force. And we've actually provided technical oversight for them for about the last six years since the inception. And I'll talk more about what the ARTF is in a little while.

And then, of course, with the Phase VI, the six phase process we're doing that we piloted and started with the organophosphates. We've worked a lot with a

variety of different commodity organizations and other groups like Bob's group. And then, of course, with the public interest groups as well in the same Phase VI process.

Another key element to our risk assessments is getting better information on use and usage and how chemicals are involved with actual agricultural practices. And again, we rely on our partners to provide this kind of information.

And this is some of the sources of information that we've routinely used over the years, different government and industries surveys, for example the NAS information and the census of agriculture. Of course, any information we can get from Extension Services, the stakeholders through the current public participation process and other activities.

For example, this very moment, some of our colleagues are meeting the National Ag Applicators Association to talk about getting more use and usage information.

And then of course, the different literature in the trade press, for example, we might look at how

equipment types and engineering components of equipment that's available now would affect exposures and that's where we get that kind of information, and also the different product labels.

The other two key factors on this slide are we look at what's typical use and that's the -- try to get as much information as possible to try to account for most of the kinds of practices that are going on in agriculture, for example. But we also have to look at what's allowable by the label to make sure that when we let a label go, that it's protective.

UNIDENTIFIED MALE: Jim, do you know our handouts are real different from these?

UNIDENTIFIED MALE: Not real, just.

UNIDENTIFIED MALE: Well, mine is. Maybe I got the only one. No, okay. I just --

UNIDENTIFIED MALE: I didn't know that. I apologize.

UNIDENTIFIED MALE: No, don't apologize.

UNIDENTIFIED MALE: He's easily confused.

UNIDENTIFIED MALE: He's got the Palm Beach version.

UNIDENTIFIED MALE: They're fine. Actually there's more stuff.

UNIDENTIFIED MALE: Yeah.

MALE SPEAKER: Okay. The other -- more information. The other issue is the Agency has developed a science policy paper on this issue and I just put the web site on this slide. So if you want to get that and read more detail about it, you could find that at this location.

I think what I'd like to do now is to focus in on how we're actually doing these risk assessments and for the handlers, and remember that's the people involved in the application. This slide just shows how we actually calculate handler exposures. And you can see that exposures are related to how much can be treated in a day which is the acres term right there. The application rate, and again, which we get from the label or, you know, we also use typical use information when it's available and what people weigh.

And then the other factor that everyone is interested in is the exposure values. And we get these exposure values from actual measured workers and the

exposures depend on the kinds of products they used.

For example, the exposures will be different for someone using a liquid or a dust formulation. What kind of equipment they use in the application, the exposures would be, let's say different from somebody using a ground boom sprayer versus an airblast sprayer. And also whatever kinds of protective equipment they use. If someone uses, let's say, gloves or a closed cab tractor, that would lower their exposures.

And the other, I guess, the real key factor here is that we believe these factors impact exposures, let's say more than the identity of the chemical active ingredient when you're making applications.

We prefer to get our exposure estimates from data that are specific to the use pattern. And for each chemical that we're looking at in our process, we don't have this specific information many times so we rely on a system called the pesticide handler exposure database for these estimates many times.

And I'd like to focus on what PHED is now because it's used so often. PHED is actually one of the best examples of the Agency working in partnership with

various stakeholders and other organizations. It was developed by us starting in the mid 80s along with Health Canada and California Department of Pesticide Regulation and then various industry companies are involved.

We recognize, however, that there's always room for improvement and we've recently started an initiative to upgrade this system through ACBA and the working group with Health Canada and the California DPR.

Okay, PHED, it's a database that contains real data from monitored workers and it has data in there from a variety of different application methods, levels of personal protection and a variety of products. And it can be used, and this is how we use it to provide different exposures based on the protection level used, how it was applied and the type of product.

And we generically call these scenarios in our risk assessments. And currently in the system, it has information from 1,700 or so monitor workers from a hundred different studies, give or take.

The next couple of slides just illustrates some of the scenarios that we -- that are included in PHED. You can see in this slide an airblast application in

apples. We measured -- we have measured exposure data that shows if a person is using a tractor with no cab and they wear normal work clothing, when they use this kind of equipment, that they're unit exposure -- that's how we term the values that come out -- are 0.36 milligrams per pound AI applied.

Now, we also have measured exposure data with different levels of personal protection. So if they would make this kind of application, let's say, with a tractor with a cab, their exposures would be lowered and the monitor data show that and the value we get is 0.019 milligrams per pound AI applied. And keeping in mind that these values are all real measured data.

UNIDENTIFIED MALE: Are these the amount of chemical on the clothes or on the person?

MR. AIDALA: It's what would be on the skin underneath --

UNIDENTIFIED MALE: I mean goes --

MR. AIDALA: What goes through the cab.

UNIDENTIFIED MALE: What goes through the long pants and the long sleeved shirt.

MR. AIDALA: Right. Going through the long

pants and the long sleeves, on the skin or, you know, going through the cab and then going through the long pants and the long sleeves and then gets on the skin.

In this slide, this slide just shows another scenario. And this is a closed cab tractor with a ground boom sprayer. And again, we have measured data for this scenario where people with a tractor with no cab, for example, wearing normal work clothing, their exposure would be 0.014 milligrams per pound.

And if they use a tractor with a cab, again, you see from the data that the exposures are lowered and the value we have there is 0.005 milligrams per pound AI applied. And again, it's based on real monitored data.

I said earlier that we were -- had initiated a process to improve the database and upgrade the database. And some of the improvements we'd like to make are to make better use of the data. For example, you know, eventually we want to move to a probablistic type of approach for doing worker risk assessments.

We want to expand and strengthen the data. We want to look at areas where we feel we need more information such as high acreage treatments for aerial

application and try to get that kind of information. And then we want to address some of the uncertainties with the different measurement methods.

Because like I said, we have a hundred different studies with pretty much as many different investigators and labs and they all do things a little bit differently. So we want to make sure that, you know, we address some of those differences and how we use the data.

What I'd like to do now is kind of switch gears and talk about how we do post-ap risk assessments or the re-entry portion. And this slide just shows the equation that we use for these kind of calculations. And you can again see that the exposures related to how much time people work each day and what they weigh. And those are pretty standard factors.

And then the exposure values we use are from actual measured workers again. And they depend on the amount of contact that people have with the treated plant. And this is related to what they're doing, the kind of job they're doing and the kind of plants that they're working with.

And this is called the transfer coefficient.

And we have different transfer coefficients that we use for different kinds of jobs and different crops.

And the exposures are also related to how much is on the surface of the plants that they work in, how much can rub off on their skin, and we call this the dislodgeable foliar residue again.

And these calculation -- this calculation here, this is the basis for the restricted entry interval proposals that you see in the risk assessments.

These next couple of slides just illustrate some of the different transfer coefficients that we use. You can see in this slide people harvesting lettuce. And we have measured data that we use and it shows that the transfer coefficient for this scenario is 2,500 centimeters squared per hour.

And we use this information to address the same kinds of activities in similar crops, like someone harvesting collards or kale -- (inaudible). And again, keep in mind, these are real measured data.

And this slide just shows another different transfer coefficient for someone harvesting apples. It's 3,000 centimeters squared per hour. And again, we would

use this for different similar crops with similar activities like peaches and pears, for example.

And again, this is -- I actually took this at a exposure monitoring study conducted by the ARTF last year. So this is actual data point that we are using.

In this slide is just a kind of graphical representation of the kinds of calculations that we do. And you can see that as time goes by, that the FR data dissipate and then the corresponding exposures get lower and I'll walk through the slide here a second.

So on this axis, you have the DFR levels in units. And the units we used for them is micrograms per centimeter squared. And then this -- the Y -- the X axis is the days after application. And this is actually a real data set. And you can see that over time, the DFRs dissipate and then we calculate exposures for each day after application with a transfer coefficient. That's where we get the exposure values from.

And this -- the red line is just a higher application rate than the blue line. I think the red line is four pounds an acre. And then the blue line is a pound and a half per acre. So that's why there are

differences in the curves there.

UNIDENTIFIED MALE: It would be interesting if the data didn't.

MALE SPEAKER: All right. The re-entry exposure areas, an area where we're doing -- getting a lot of different kinds of information and the major source of this information is the Agricultural Re-Entry Task Force, or ARTF. And this is a large industry group that was formed about six years ago, I think. And it has 30 members and it's in the process of developing this extremely large information source.

And some of the kinds of information that they're generating is a large grower survey where I think they surveyed 96 different crops in 16 regions of the country. And this survey helps us to understand actually the kinds of activities that are being done in agriculture. You know, when they're done, the frequency, and actually what they're doing.

And they've also developed a large set of exposure data. I think it's about 70 different crop and job combinations that they're developing transfer coefficient values for. And we're using these data now

as they come in. And we've actually used these new transfer coefficients as much as possible, for example, with the current organophosphate process.

So, now I think I'd like to just talk about where we see ourselves going in the future. I think we've come a long way, but there's always a lot of -- there's always room for improvement.

In this slide -- illustrates some of the steps that we will be taking in the future. And we believe that these will make our process better and more informed. And the major efforts that we see happening in the near future are we want to make the most use possible of the ARTF data. We want to complete our initiative to upgrade the pesticide handler exposure database. And we want to collect more exposure and use information, particularly use information.

We'll also be making a major push to use data -- the kinds of data that Chris Saint talked about yesterday from ORD. For example, where we want to incorporate things like the agricultural health study which is being done at NIOSH and some of the ORDs work with farm worker children, and as far as consideration in our risk

assessment process and decision making process.

And just some final thoughts. I -- we believe that we do quality risk assessments with the information that we have, but we believe that, you know, there is room for evolution and improvement.

And we believe that some of the key challenges for us are to remain current with the trends in agriculture and also with risk assessment science because it's a rapidly evolving field. And we want to build on our long history of partnerships with the stakeholders to move forward. So if you have questions?

MS. MULKEY: Before we're taking clarifying questions, I want to greet and welcome Dr. Zuroweste. Have I pronounced it correctly?

DR. ZUROWESTE: Correct.

MS. MULKEY: Jim mentioned yesterday, Dr. Zuroweste is a new member of PPDC. He is a family physician with a focus on, among others, farm workers and their health issues from nearby, Chambersburg, Pennsylvania. So we're very glad to have you.

DR. ZUROWESTE: Thank you. Sorry I was late.

MS. MULKEY: That's all right. You weren't very

late at all. So if we have any clarifying questions? If not, we'll do the other two parts of ours and we should be well -- we should be well within our hour, more than within it for discussion. So you don't have to speak up now in order to participate in the discussion. But if you need something clarified, Jose?

DR. AMADOR: Just a quick question. On the post application assessment, your DFR, is that calculated before the re-entry period or after the re-entry periods?

MALE SPEAKER: Well, we would --

DR. AMADOR: That's the amount that we can dislodge from the residue -- the leaf, right?

MALE SPEAKER: That's what we based the re-entry period calculations on, so can we get back to that slide, Bill, with the graph?

DR. AMADOR: Post application assessment? No, back some more.

MALE SPEAKER: No, I think this -- so, what we do is start with dissipation data for the chemical and the crops that we're interested in and look at how it behaves on those particular crops. And then we use that information to calculate exposures using those transfer

coefficient values that I was talking about.

For each -- so we'd look at a crop and how the chemical behaves on the crop and then the kinds of jobs or tasks that somebody would be doing and couple that dissipation information with the jobs that we're interested in.

MS. MULKEY: What Jose is asking is, is the dislodgeable sole area residue value calculated only at one point in time?

MALE SPEAKER: Oh, no.

MS. MULKEY: Or do you calculate it at multiple points in time?

MALE SPEAKER: Right. The way that we ask people to do studies is to collect information over a period of days from the application and then we use that information to characterize the kinetics of how the thing dissipates and then use that information.

DR. AMADOR: So the exposures that go down as the date after the application.

MALE SPEAKER: Right. So the exposures would just track what the dissipation rate of the chemical.

DR. AMADOR: Thank you.

MS. MULKEY: J.J., did you have a clarifying question?

DR. STEINBERG: Two quick things. One is that if we could see that science policy web site again and maybe let it linger there for a few seconds so we could jot that down.

MS. MULKEY: That was near the beginning.

MALE SPEAKER: Yeah.

DR. STEINBERG: And the other thing is that, you know, again, this is an example where we clearly need to have, you know, we need to love our epidemiologist. And these data must be available and the epidemiologist must be able to say that it's accessible and it's convenient and it's easy to get at.

I hate to use the word, but we do have a Drug Czar in America, a general of the Army. We do, in a sense, almost need a data czar. There is so much rich data available, and to make that data accessible and easily available to the citizens, to industry, to scientists, really needs to be underscored.

And unfortunately, that will be a theme that I may mention two or three more times. I apologize for

that.

MS. MULKEY: Why don't we come back to that in discussion. Maybe we can talk a little bit about what we know about accessibility now. But we can hold that to the discussion session. Larry, did you have a clarifying question?

MR. ELWORTH: Just a quick question back on that slide you had a moment ago. Is that an actual -- is that particular slide based on actual data?

MALE SPEAKER: It is. It's an actual dissipation data for organophosphate.

MR. ELWORTH: Okay. Then I'm assuming that what strikes me about it is it's remarkably smooth and during harvest -- well, as a matter of fact, as soon as you decide to harvest, it starts raining. So it seems like an awful smooth curve. I'm assuming it's a place where it doesn't rain for 60 days.

MALE SEAKER: This particular chemical, we had several studies on it. And it pretty much in different crops, different regions of the country, you see the same thing.

UNIDENTIFIED MALE: But some -- that is true in

some -- that's why we ask for a whole bunch of studies. Some get smooth curves like this. Some have curves with breaks and stuff.

MS. MULKEY: And he said this was several different studies and you combined the curves?

MALE SPEAKER: No, this is one study.

MS. MULKEY: I see.

MALE SPEAKER: But the -- all the data for this particular chemical looked pretty similar.

MS. MULKEY: And Jay.

MR. VROOM: J.J.'s reference to epidemiology reminds me that I'm not sure I really understand the current role of epidemiology in regulatory action. I don't think there is any explicit impact. But maybe you could just speak to that a little bit, Marcia or Alex?

MS. MULKEY: You guys want to take a crack at that and then --

MR. VROOM: And then -- go ahead and then.

ALEX: Well, we used that -- we looked at the epidemiological study and we make sure that it's consistent with the, with the results of what we're getting. If we do a risk assessment and it shows that

the MOEs are all 0.05, you would expect to see something happening out in the real world.

And if we don't see something happening, we might suspect that our calculations need to be further refined. That's pretty much what we do in HED. I don't -- maybe --

MR. VROOM: And probably in worker protection, there is a more robust database of epidemiology than you would find in other exposure areas. Is that generally correct?

MALE SPEAKER: I would say it's probably true.

MR. VROOM: Does the Agency have anyone in epidemiology on staff in OPP?

ALEX: We have three people. We have Jerry Blondell is the one that does most of that.

MR. VROOM: Right. All right. I want to think some more about this. I'm still a little confused.

MS. MULKEY: Okay. I'm happy to take this remaining question, but do remember we have a full discussion opportunity here. Dan?

MR. BOTTS: This does get to clarification. Having the opportunity recently to review the data call

in that led to the creation of the Ag Re-Entry Task Force information, that was clearly geared specifically to agricultural crops, both ornamental and field crops, and some limited applications to greenhouse operations.

How is that data going to impact the other uses? Is the Outdoor Re-Entry Task Force going to parallel the same type of information and data collection to provide a database, is one question.

The second part, the directions in that was still essentially low tiered type analysis geared toward understanding to make an initial registration decision rather than doing the type of sophisticated, refined risk assessment like we typically did with the dietary exposure system in some of the other issues that are there.

Is there any follow-up toward how to build upon the Ag Re-Entry Task Force information if it's truly the low-tiered study to build some of the probablistic type analysis to determine if there are differences in regions of the country and some of the things that the growers perceive occur out in the field?

MALE SPEAKER: From -- do you want me -- from a

technical perspective, that issue is something that we've talked a lot about. For example, in the Oversight Committee discussions with them, I think everyone involved on all sides, the scientist level feels at some point, we'll move to a probablistic modeling.

For example, in the question that everyone is kind of grappling in that group is how do you do it, and some of the issues are data hogs, for example, where we need information about what -- how -- what -- where people are working, what chemicals are used, and the regional variability.

And you know, we've tried to make that best use of that information as we could as it's trickled in. And I think what you're talking about is something that once the whole thing is done and we kind of sit back and take a look at it, and then figure out how we want to use it.

And then what kinds of distributions we're willing to accept as far as putting in for those kinds of time based information and the regional variability that we really have to do to move to that. And --

ALEX: And we are getting close. We already do have software available that we're evaluating. And

actually today and yesterday, there was a group of people that were starting to learn how to use the software, and starting to evaluate it to do probablistic assessments.

And I would also like to add that we do, even now, without looking at a probablistic assessment, look at dislodgeable foliar residue, for example, from different parts of the country so that we could set different REIs for different parts of the country if it made sense based on that data.

MR. BOTTS: Yeah, but the reason that I asked the question that data call in specifically said that it had to follow the guidelines which was the highest use rate, most likely to create the greatest risk type scenarios to be looked at in the data call-in, which -- and I'm not sure having just looked at a couple of the ARTF actual studies that they commissioned to do.

I think they followed that instruction pretty much to the letter in how they designed their studies which may not represent typical worker exposures in most situations.

MALE SPEAKER: In certainly the initial batch of studies that were done and the way the process really

evolved was with the survey we've identified all different types of exposures that happen. And if you reviewed it, you understand about the clustering.

For example, you wanted them, and they are in the process of generating information that across all different types of jobs and different types crops, that we really are encouraging them to get information on the whole range of kind of occupational exposure.

So they did capture the higher exposure kinds of things first, but they -- now they're going back and following up with things like they've done some scouting studies, they've done some irrigation studies. Those kind of things which are typically considered the lower exposure activities. So when it's all said and done, we will have information that really runs the range that we'll use.

MR. BOTTS: But those use rates are still at the higher use rates in the regions of the country where the highest residues would be at.

MALE SPEAKER: Yeah, and the other component to go with it is each of the -- along with the exposure data which is the Task Force work, the companies were supposed

to develop their own chemical specific dislodgeable foliar residue database that reflects different regions and different rates and those kind of things.

So that's what we use on a chemical specific basis, coupled with the ARTF information to make those kinds of decisions.

UNIDENTIFIED MALE: Yeah, I'd like to add that even though that's the way the DCM may have gone out, the companies aren't restricted from doing their own studies at different rates.

And with recent experience has shown us that the companies don't seem to be reluctant to do those types of studies to show that the exposures are actually less with lower application rates or different methods, or whatever. We've gotten a whole lot of studies in over the last year or so that we've looked at.

MS. MULKEY: And do we -- Dan.

MALE SPEAKER: I have a quick question on the transfer coefficients. How variable are those? I mean, we've got a number for apples. And there's so many different, you know, aspects that can vary that and so how do you see that? I mean, with just the nature of the

crop, I mean, is it regular tree versus trellised or -- and then, does it vary with actual the level of dislodgeable residue?

MALE SPEAKER: Those are all very good questions, and within the Task Force, for example, we've had them more or less commission some different analysis using the data to explore those issues.

And so we get a real good definitive answer on that. And they're -- that kind of work is on-going. They are -- they do vary to some extent as you'd expect, but you know, we're trying to get a better handle on that with the analysis that they're doing now.

UNIDENTIFIED MALE: They vary -- they can be as low as what, a hundred or two hundred. And some of them are way up as high as eight or ten thousand, depending on things like how high the crop is, how big the leaves are, what the leaves are made out of, how -- you know, what the person is doing in the field if he's right in there amongst -- you know, with the foliage or whether he's just reaching down and grabbing into it or something like that.

So they are all over the place and we're trying

to right now make sense and make sure that -- make sure that all of the data makes sense in terms of what transfer coefficients we're seeing and what nature of the activity we're looking at is.

MS. MULKEY: Well, I hope this was all helpful as now we're going to ask -- I think we have folks we might have waited for. So if Lois will spend a little time with us talking about the participation and -- of the farm worker community and perspective and any others with a stake in this issue as part of our public discussion process. And Lois?

MS. ROSSI: Okay. I'm just going to -- since we haven't been to the PPDC in a long time with where we -- our process on re-registration, as many of you know, but maybe some of you don't know, we have been following a pilot process for a little over two years now.

It was discussed at the track in 1998, and we've been following it to carry out the re-registration and tolerance reassessment of the organophosphates. And we've also adopted many of the features of this public process for the non-organophosphates that we're putting through re-registration and tolerance reassessment.

The process was designed to increase transparency of the review and allow increased public participation. The process has been a challenge to the Agency as well as the Department of Agriculture and, I'm sure, to most of the stakeholders that have been involved.

But it has resulted in much new data and tremendous amount of information being generated very rapidly, extremely rapidly to assure that the best information is factored into our risk assessment and ultimately into our risk management decisions on these chemicals.

In implementing the process as often is done in a pilot, we've -- together with USDA, we've had to modify it and make changes to allow the process to allow increased involvement on the part of stakeholders.

It -- as with all public processes, when once you increase participation and transparency, there's increased work on all parts, including that of stakeholders who want to actively be involved, and a responsibility to become involved and understand the Agency's assessments.

The Agency with the Department has tried various ways to make our assessments more comprehensible and allow people to fully understand the data used and the assumptions we've used in these extremely complicated, detailed assessments. You've just got to look at one part of our assessment, but there's many, many, many more parts to it.

And they are often very, very large and voluminous. But we early on realized that if the process was going to be truly an effort to increase participation and openness, that all stakeholders had to have some basic understanding of the risk assessment in order to fully participate in the risk management decisions.

The activities that I think we have managed and again, at a cost for effort on all parts, but we have posted all the assessments on the Internet in the docket, and included them in our docket.

We've written summaries and charts and various ways to make the information more understandable and more transparent so that you can go to the area of interest that you might be able to provide information. You can go to it more easily.

We've had technical briefings. We've done over 20 of these in different parts of the country. We've had a lot of conference calls and that's particularly a topic today. And we have had meetings with just about any stakeholder that has requested one over the last two years. And included minutes of these meetings in the docket.

We've worked hard to include as many people as possible in some of our conference calls, and as I said in the CARAT presentation that we did in October on the status of our program, can we do better? Of course, we can do better. It's a learning process. It's a very big -- it was a very big change in the way we did re-registration decisions.

So, of course, we can do better, and as we sort of work through the process and make certain steps routine like closure conference calls, I mean, like technical briefings. I mean, the first technical briefing we did was a monumental effort for the Agency and now we can pretty much do them fairly effectively and certainly with a little bit less effort.

But there's always ways to make it better. And

we are constantly increasing our coordination and our contacts with various stakeholders. In the last few months, we've really focused on coordinating with our regions and states, and also with our colleagues in Canada on our decisions.

With respect to the conference calls, the conference calls provided a very easy way to get a lot of people together to discuss a certain topic. And we have worked closely and USDA has had some conference calls of their own, as well as we have had some that we've been jointly on. And we have tried to notify people who have commented on the assessments throughout the process.

The closure conference calls, I think we have done a fairly good job in notifying people who we knew were interested. And particularly if people let us know ahead of time that this is a chemical that they want to be involved in, we have made sure that they know, at least, on the closure conference call.

There are other conference calls that we have throughout to the course before we lead up to the closure call because the closure conference call is pretty much at the end when we're prior to making and issuing a risk

management decision on a chemical.

And again, I think we have been fairly diligent in making sure that people who we knew were interested in, and some groups have done a very good job in notifying the Agency that they wanted to be included. I can think of one right off the top of my head because we are dealing with them quite a lot is the American Bird Conservancy. They have let us know what chemicals they are concerned with.

So as I said in the CARAT meeting in October, with regard to the worker community, I think we are looking for ways to effectively be able to utilize the information that they may have to help in our discussions, and include them in our -- include them in more of the process rather than just the technical briefings and the closure conference calls.

So I think we'd be certainly, as we continue to roll out our pilot and continue to expand the contacts and the processes and be more inclusive, I think we're looking for ideas right now as we go through the next set of decisions and chemicals to make sure that this stakeholder group as well as any other stakeholder group

that we haven't specifically mentioned or touched on is involved.

(End of Side 1 of Tape 1.)

MS. MULKEY: -- for other discussion. The third piece we want to talk about a little bit is Kevin Keaney. Kevin, we need to limit you to about seven or eight minutes, if you can live with that.

MR. KEANEY: Sure. A few remarks on the Worker Protection Assessment, the national assessment we're doing under the Worker Protection Program. A little background for some of you who might not be aware of the nature of the regulation and the program.

In the 80s, the Pesticide Program looked at the provisions for worker protection and found them a bit too general and vague for real enforcement and implementation and proposed a new regulation specifically focusing on worker protection link to label revisions.

And the regulation became final in 1992. There was a period of relabeling of the pesticide product and then a coalition of agricultural interests brought certain provisions of the regulation to the attention of Congress and to us.

And there was a Congressional delay and some changes were made to accommodate the issues that were raised or to address the issues that were raised and to generate more training materials. And then full implementation took place in 1995.

So we're at a five year point. It's a normal point to reassessment a new program, to assess a new program. We've also come under some focus with a GAO audit, a federal advisory committee focus on the regulation. A number of concerns focusing on the silence in the regulation, relative to children, women, pregnant women and so forth.

Also a number of concerns focusing on the consistency of implementation and enforcement around the country of the program. So there's a good deal of internal impetus for assessment and external impetus for assessment of the program. So we did commit to conduct a national assessment of the enforcement and implementation.

We held a -- and we decided we would use as a focal point a number of workshops based at the heads of migrant streams. So we had our first workshop in June in

Austin, Texas. Our next workshop is in Sacramento the week after next. And a third workshop in Orlando in the spring. And the culmination in Washington about this time next year.

Now, these workshops are the emphasis is on work in the workshops. The first workshop was framing issues and themes. The continuing workshops will break out into work groups that we would hope would conduct conference calls and e-mail exchanges that we would facilitate over the interim between the meetings to grapple with the issues and bring resolution to a number of the issues proposed.

Different approaches to address problems that might have surfaced in these workshops. The themes that came out of the Austin workshop focused around training issues. They focused in four areas that we are going to be pursuing in Sacramento. And they are communication, training, and this is all outlined in the handout from our web page -- communication, training, compliance and retaliation.

An overarching would be children and special populations and needs for concerns relative to them.

Those would be spread over all the other -- the four other workshops. The end result would be a strategy to reinforce the regulation to create a national consistency as far as implementation and enforcement.

Our office of compliance is conducting an activity that will feed into our national assessment and that's -- they're calling it a program element review in which they're auditing our regional offices for the effectiveness and consistency in the guidance that has been given to the regional offices. And then the further guidance that the regional offices give to the states.

Because the states -- these are delegated programs as you probably know. And the first line of implementation and enforcement is at the state level. So our enforcement office will be conducting this audit. They're beginning their audits next -- or their program element review. They're not calling them audits.

They're beginning them next week in the region -- in the Denver office and the Kansas City office, and will conduct a series of audits of the regions. The regions will then look at states and the guidance and reporting structures that they have in place.

So by this time next year, we would have a better picture of how to restructure the program, strengthen the program, change the program, change the regulation, if necessary, institute a number of more aggressive marketing of good models that we have around the country that are working in the states or propose before then a number of activities that we can actively begin before the end of the assessment if we think that's appropriate.

And coming out of the Austin meeting, we do have some indications of some things that we can begin now. And we'll pursue them and frame out the mechanisms for that at Sacramento and Orlando.

And on a side point, we're also involved in a very aggressive activity with the health care community and we intend to try to bring them more actively into the networks that we deal with in the worker protection program.

MS. MULKEY: All right. Any clarifying questions for Kevin? Larry?

MR. ELWORTH: After you have all these meetings, what procedure are you going to use to report the results

of the deliberations or any conclusions or any summaries?

MR. KEANEY: The results of the meetings will all appear in an executive summary in full text in our web site for one. And we are establishing a list or mechanism for all the attendees of the workshops to exchange information and so forth. The ultimate capturing in all this would be in a strategy package we'd present at, as I said, the culmination.

MR. ELWORTH: Are you going to do a summary of those especially if, let's say there's some, as you said common themes or consistent recommendations that come out of this that the Agency uses?

MR. KEANEY: Yes.

MR. ELWORTH: Okay.

MS. MULKEY: Okay. And is there a summary of the first workshop somewhere?

MR. KEANEY: Yes, the executive summary is in the package, the web site.

MS. MULKEY: All right. That's a good place for it.

ANNE LINDSAY: And it's on the web and the full text is available, too.

MS. MULKEY: Full text is available just for asking for, is that what you mean?

MR. KEANEY: Yes, and we'll eventually put the full text up in the PDF on the web.

ANNE LINDSAY: On the web and we're open to other suggestions for ways to make this available because that's one of our goals.

MS. MULKEY: Okay. Bill.

MR. TRACY: Kevin, you mentioned enforcement. We've had the program in place for five years, for five years now. What have you seen on enforcement uniformity? Have you had a program review prior to this one?

MR. KEANEY: No, no. We haven't had the program review prior to this one. There's anecdotal evidence that it's widely varied across the country. And that was supported by the audit done by GAO. And there's inconsistency.

Some of it is rooted in definition, the guidance given to the regions and to the states as to what constitutes a worker protection inspection, how should it be reported and aggregated. A real problem that GAO pointed out and we agree with is that there isn't a

consistent reporting structure across the region so that we can get a national picture easily.

MR. TRACY: Do you see a variability in, just in enforcement infrastructure from state to state?

MR. KEANEY: Yes.

MS. MULKEY: And perhaps quite a variability as it relates to this kind of enforcement than other. In other words, there's variability from state to state in enforcement in general. But there may be even greater variability with respect to enforcement of the worker protection.

MR. KEANEY: It's delegated -- as I said, it's a delegated program, usually delegated to Departments of Agriculture and their enforcement inspection structure is usually key to dealing with growers. And in many instances, they are unfamiliar or incapable in dealing with this particular labor segment because of language issues or other issues. And that has to be addressed in some fashion.

ANNE LINDSAY: One other thing I might mention. We've actually been working on this sort of uniformity of reporting issue which the GAO report underscored. And

that we're going to have a SFIREG meeting next week. This is the -- SFIREG is the mechanism we use to meet with our state partners.

And there will be a discussion on the agenda about a proposal to develop that uniform reporting mechanism so that in the future what we would actually hope is that we'll -- we will at least be able to actually look across the country, either at a national level or on a regional level or a state level and say, here's what's going on, which at this point in time, we're really not able to do in an easy fashion.

MS. MULKEY: It's for reporting, it's not just for work protection.

ANNE LINDSAY: No, but worker protection might be a pilot area that we would start out in given the level of interest in this.

MS. MULKEY: Well, let's -- we have now about an hour. And let's open this up for discussion of this topic area, the three things we presented or other things that may be on your mind that were not included in our presentation. Okay, Bob.

MR. McNALLY: Well, I would just offer a comment

on Lois' presentation. I think my organization feels very comfortable with the fact that you all have done an outstanding job of reaching out to us at the appropriate times and places. And I think we feel, you know, empowered by the efforts that you've made.

One thing that I think that maybe could be done a little better has been, I think, on the non-ag side, especially, there hasn't -- there maybe could be a better effort to identify who the other stakeholders are and to reach out to them.

I think PCOs have been reached out to enough. But I don't know that tree care guys or lawn care guys or golf course guys or vegetation management guys and women have been reached out to as much. And I think it would be a worthwhile endeavor to try to identify who some of those stakeholders are where they're not that well known to the Agency.

MS. MULKEY: Do you know is there a worker community in that area that is different from the vendor community, and if so, do you have any thoughts about how one might engage them?

MR. McNALLY: When you say a worker community --

MS. MULKEY: People who work for PCOs, lawn care guys and gals, et cetera. The employee, the exposed persons --

MR. McNALLY: You mean kind of like a farm workers, kind of analogous to farm workers.

MS. MULKEY: Yeah, the sort of functional equivalent, yeah.

MR. McNALLY: We don't allow that, our industry.

MS. MULKEY: You don't employ people?

MR. McNALLY: I don't think they're particularly well organized. And I wasn't thinking of them, although I think they're entitled to know these things as much as the folks that I represent who are the owners of these companies. I'm thinking more in terms of other types of non-ag users who are less involved with this process.

MS. MULKEY: No, I knew that. I was asking you --

MR. McNALLY: Yeah, but I don't think there are organized worker communities.

MR. AIDALA: Well, I think that's your guys aren't organized in your segment and other folks are even less organized, is my observation.

MR. McNALLY: That's right. I mean, as disorganized as it must appear that we are, there's others worse than us.

MR. AIDALA: Well, I meant to say more vis-a-vis the workers organized, Bob. Not the management of your segment of the industry.

MR. McNALLY: But I think what we can help you with and, you know, I think we can help very easily provide, you know, names and information about who all those other people are, at least to the extent that we know who they are.

MS. MULKEY: Um-hum. We'll make a note of that. Kim, did you need to make a point?

MR. McNALLY: It is increasingly becoming an hispanic work force, though. So it would have some of the same types of problems, as far as communication and training.

MS. MULKEY: Larry?

MR. ELWORTH: I've only been tangentially involved in some of the conference calls. I still think that's a good idea. And Jeff mentioned a couple of times the six phase process that has been established for re-

assessment. I was involved in all of these advisory groups, the names of which -- the acronyms of which I can't remember anymore.

But I think of all of the things that happened in those advisory groups, the most salutary outcome was the process that the Agency went through to make really clear the process by which it does dietary risk assessments. I think that was -- I think it was good for the stakeholders and the affected community. And I think as a public policy outcome, it was really good for the Agency as well.

It gave your people both the pressure and the opportunity to articulate to people outside the Agency what they do as far as risk assessments. And I could really -- I have dozens of questions based on Jeff's presentation. It's not because it wasn't a good presentation, but there are a lot of things that I think if they were put out on the table as transparently as the dietary risk assessment, it would be extremely helpful.

And I would really like to encourage the Agency and Bob was kind of going there yesterday with the residential exposures. I think it would really helpful

for the Agency to have -- to go through a process with PPDC if that's the appropriate venue of really systematically talking about the assumptions, the SOPs, the kind of training that takes place for people to do diet -- do worker risk assessments.

I think having a process like this with PPDC, again if that's the right organization, right committee, would be extremely useful. I think it would useful for the Agency in terms of -- to having the practice of articulating of what it does in terms of risk assessments.

I think as Bob mentioned yesterday, that process really builds confidence in the Agency's processes. And I think it also would help people like Jeff and Mike in doing their risk assessments if they have an opportunity to say here's how we go about this and to find out that there's data, that there's assumptions that could be revised, that there are ways of designing your procedures to get information in a more timely fashion.

I think that would be really helpful. And I think it would be especially helpful in this issue since you have both the connection with the dietary assessment

and also you have all the re-registration issues. You've got questions of how benefits are used in this process since it's primarily a FIFRA process.

I mean, there are all sorts of questions that we really haven't addressed that would really helpful. I mean, to the extent that I want to raise an issue for consideration of the Committee and for you folks, see if there's not a way that we can do a substantive process like we did on dietary, both for this and maybe also for residential because I think that's where Bob was going yesterday.

MS. MULKEY: Well, there's been a lot of discussion about an interest in that in the CARAT as well.

UNIDENTIFIED MALE: Um-hum. Um-hum.

MS. MULKEY: On this particular topic, even though it is not strictly speaking, a tolerance reassessment topic per se. Because as you said correctly, it's a FIFRA topic. But you may not have picked it up in my remarks yesterday morning, they were hurried. But we are planning a workshop on worker risk assessment methods.

The current thinking is early March, based upon the interaction with all of the worker activities that Kevin talked about. I think our anticipation had been that for that workshop, like the one day we did in cumulative last summer, that we would take special efforts to include the CARAT members. We did that last summer. We brought them in.

We gave them their own special seat. We -- to the extent that travel is funded for CARAT. We handled that workshop the same way. We arranged for conference calls. I will tell you that I frankly was a little disappointed in the relatively low level of attendance by actual CARAT members.

A lot of the stakeholders who are represented on CARAT had other representatives at the workshop. And maybe that's just as effective. But I think we would be receptive to making this workshop sort of a combined PPDC and CARAT event. So that those of you who are on PPDC, but not on CARAT would get the same kind of enhanced opportunity to be actively engaged.

And we could think further about whether there's other -- but the whole point of that is to take enough

time and to make it possible to get more in depth than we had the opportunity to today. And the hope is that things like today, start people at a little higher level when they do get involved in it. But we do have that plan.

MR. ELWORTH: Well, I think the workshop is a good kind of foundation for that kind of work. And I think it's important to go through the process once. I think of a lot of what happened in the CARAT work groups was real important where people could sit down and talk with, you know, whoever -- with the HED folks, for example, and say, here's what I understood from your presentation of the work group, but here are the eight or ten questions that really come up out of that. And that kind of interchange was really helpful. So I think the work group is a really good idea.

You raise the issue of where this fits in. Is it a PPDC issue? Is it a CARAT issue? And it's partly the time and energy the Committee members, so of whom are the same. But maybe we'll talk about that a little bit later. But I think that kind of interchange that took place within the work group was real important, too.

MR. AIDALA: All's I know is Keith has talked about this in the past, what we need to have the Department sort of more involved, which is not just as a component of expertise contributing to what we're doing, but also as a way to communicate back to, you know, that set of stakeholders, too, which obviously is especially -- (inaudible) -- with the Department. And Theresa and I have had the sight bars on that all morning already.

And basically, in order to further, again, your basic premise of the more you understand it, a, you might have advice, but also I think it sort of demystifies a lot of what's going on. And that, yeah, we may, you know, for example -- one of my favorites is why did you assume 100 percent dermal absorption? Well, no one gave us a study to tell us a new number.

Well, they gave us a study about the new number and guess what? The number is changed. And that's not unlike that whole business about how that risk assessment at one time was totally a black box. But if you don't have PDP data, what are you supposed to use? Okay, you get PDP data or other market basket surveys, boom, you've got different numbers.

And again, okay, I understand that. So the Agency is willing to accept it. You know, how do we accept it? How do you get it, et cetera. And that's part of I think what agreeing with you about the whole, you know, the good ends that came out of that whole discussion in other arenas.

MR. ELWORTH: Yeah, yeah. And especially with pea head, some of the revisiting of pea head that you folks were doing. Doing that in the context of articulating what it is you're doing in the first place, I think it would be real helpful.

MS. MULKEY: Are you finished, Larry? I'm sorry. We'll go with Dan, Jay, Phil, and Bob again.

MR. BOTTS: Once in my life, I totally agree with Larry.

MR. ELWORTH: Can I revise my remarks?

MR. BOTTS: I totally agree with Larry. Having gone through this process at the request of the grower community in Florida and with the leadership of some of the people sitting around the table today, we specifically asked for this on a compound that had gone through a red and was an OP.

And I think it was enlightening to everybody sitting around the table as we worked through that case study and saw where the actual numbers came from, what assumptions went into the process, how the calculations were done.

And granted, Jim, a lot of it was new data on the dietary, but there were also process changes in how the calculations were done as well. And a lot of times, the conversations that have led to the decision process on worker protection issues have been done between the registrant and the Agency based on purely the hazard side of the equation.

And the growers have a lot to bring to the table in that discussion, as well as the farm workers and other groups that are out there involved in it everyday. So I would second that.

And in light of Marcia's comment about the relative low attendance at the cumulative exposure workshop, there were a lot of us that would have loved to have been there. But because of other jobs that pay our salary, ended up having to be other places.

And I can't tell my executive committee I'm not

coming to their summary board meeting to go to those. I would just suggest that if you want to do this, let's go ahead and set a date as soon as possible so everybody can get it on their calendars, especially if you're talking a late March time line. It's not too late to try to set that meeting date as soon as possible.

MS. MULKEY: That's very helpful. And then Jay.

MR. VROOM: Could you tell us what percent, I think, Joe read us -- said yesterday, 850 employees in OPP work on worker protection and what percent of the budget, whatever that number is? I forgot to ask him that last night.

MS. MULKEY: It's -- let me, there's direct and indirect, and I mean, it's very hard to do these kinds of things. But work directly on worker protection in HED would be approximately --

UNIDENTIFIED FEMALE: Are we talking about worker protections?

MS. MULKEY: No, worker risk assessment for now. And we'll get to worker protection. That's --

UNIDENTIFIED MALE: If you -- worker combined with residentials, maybe, 20 to 25.

MS. MULKEY: That's NHED Science direct, and for exposure, and then the hazard work, remember, is done for worker and for everything else. So all the people working on hazard, you have to tribute a portion of that to worker. Then the Worker Protection Program at headquarters involves approximately --

UNIDENTIFIED MALE: Four or five.

MS. MULKEY: And then in the regions, there's some fractional addition. And the Office of Compliance, so that's a very hard number to generate. It would be even harder to tribute dollars exclusively. Do we have any direct expenditure for worker risk assessment dollar figure?

UNIDENTIFIED FEMALE: We do have contracts and that's probably -- it's less than a half a million a year.

MS. MULKEY: But that's direct expenditure exclusively for this purpose. And it would be all of our work to maintain our data system. Some of that should be attributed.

UNIDENTIFIED MALE: It sounds like it's less than 15 percent of all the resources.

MS. MULKEY: Fifteen, yes, I think that would be fair.

UNIDENTIFIED MALE: Is that bigger or smaller than it might have been five or ten years ago?

MS. MULKEY: Percentage terms, I would guess that it's slightly -- well, it might not be bigger because the denominator grew. In absolute terms, it's certainly bigger.

MR. AIDALA: You know, observationally, if nothing else, obviously, one thing about ten years ago, is you were in the middle of writing the rules. So there was that kind of big, you know, sort hype on for writing the rule.

I think since then, it's been implementing the rule as well as we go through FQPA, and frankly forget FQPA. I mean, this is basically what was going to happen as part of the re-registration because re-registration was always going to have to have this big component of these issues.

And finally, as we got back on however we got there after the '88 amendments, you started to see in the '90s more of this focus. And especially given

insecticide use with OPs or whatever, but not just OPs. You started to see more of a focus, I think.

That's just with observationally looking at the program over 20 years.

MS. MULKEY: I intuitively feel that it is an increase. But whether it -- how much it's a percentage increase.

MS. STASIKOWSKI: Yeah, there is an increase, definitely.

MS. MULKEY: Yeah, but it may just be an absolute increase, not an percentage increase.

UNIDENTIFIED MALE: It wasn't a trick question. I was just trying to get some sense of, you know --

UNIDENTIFIED MALE: You can tell we do budgeting at EPA, too.

UNIDENTIFIED MALE: Right. Yeah.

MS. MULKEY: Well, it is very hard to attribute -- you can sort out the amount that's exclusively worker protection.

UNIDENTIFIED MALE: Right.

MS. MULKEY: But there's an awfully lot that's --

UNIDENTIFIED MALE: Well, the reason I asked the question was more fundamentally, where are we headed. And I was just curious to know whether you could answer the question of what are the three most important things to be achieved in the next year for OPP on worker protection.

MS. MULKEY: Well, the worker protection reassessment is certainly one. And that's not just for OPP, that's for the whole Agency. Appropriate chemical specific risk assessment and risk management, I certainly think you have to -- and that of course includes improving the science as well as making -- and then I think the third is this area, this sort of untended to area of young workers, special categories of workers.

Those are the three I would pick completely off the top of my head. If I omitted something conspicuous?

MR. AIDALA: No, I'll just give you again, just impressionistic wise, I mean, what is, again, the worker program review? Just as Kevin said, just it's time to do that. And that may be big or small in terms of the kinds of implications of it. Is it simply especially, as Bill raised the issue about in sort of enforcement consistency

across states and regions, or is it also -- will it belie that some more significant things need to be done? That's number one.

Number two, the general emphases as we work through, again, not just insecticides. That's not to say that, you know, herbicide applicators are never at jeopardy and all that. But obviously, the whole general, you know, as we complete, again, call it re-registration, call it FQPA assessments. Again, the worker issues just are, you know, just are important. That's part of our job to continue on.

And who knows predictably whether there will be a particular chemical that has a big, quite a big problem or potentially, apparent big problem or not.

And then thirdly, and I'll put one a little more outside the box that we've been kicking around internally. There's a number of things from the '92-'94 era when the regs came out of that we basically have not -- and I think -- you can call this as part of the retrospective five years after or even just looking at that list.

There's hazard communication, right to know

kinds of issues for workers that were left behind then. And that's something that we'll be seriously considering whether or not -- how to do that. Some states do it. Other states don't. Do we need a federal, you know, the federal role in that? We had -- that was part of the proposed rule back in the earl 90's but then it's frankly not been dealt with since.

And that's sort of the only addition, I think, the substantive addition to Marcia's list. And since Kevin runs the program, he gets to have to fix it, too.

MR. KEANEY: Well, when we're talking about workers, we shouldn't overlook the applicator community which is part of the worker community we're dealing with. And there was an assessment of the certification and training program that came out with some sweeping concerns and not the least of them would be better integration with the worker protection regulations, so that you have some sort of integrated worker safety program.

MR. ELWORTH: But imbedded in both your question and the answer is the fact that if, I think, when you look at when OPs are finally dealt with, worker risk

assessments will have been the reason for as much or more regulatory action than dietary.

MS. MULKEY: At the individual chemical level.

MR. ELWORTH: Right. Right. And depending on the crops, say, for example, Bill's crop, cotton. That's going to be the primary reason that any regulatory action would at least be proposed. So I mean, I think that's kind of where you were going with this. That this is just as key an issue on the OPs and polycarbamates as the dietary is.

MS. MULKEY: That's what Jim and I were both trying to say.

MR. ELWORTH: And my point is simply --

MR. AIDALA: Right. Right. Right.

MR. ELWORTH: And frankly outside of FQPA, not just because formally under the law it is per se. But as you continue -- unless you assume the re-registration was never going to happen, which was I guess at some point. But anyway -- but obviously as you finally implement the '72 and '88 amendments, you have to address those issues, so.

MR. AIDALA: Right.

MS. MULKEY: Right. And Jim mentioned the insecticides, acute toxins.

MR. AIDALA: Um-hum.

MR. ELWORTH: But there are also reasons to worry about the percentages.

MR. AIDALA: The other thing, Jay, would be sort of asking your industry at the same time. I mean, for example, is there some new technology. Over time, there's always been this business about ways to reduce drift. If you reduce drift, you're going to have other impact -- I mean, what you need to do in a whole number of reasons would also probably have a worker or occupational impact.

New technology about whether the truly double closed cabs reduce those numbers further. I mean, if my back calculations right here, where you have a 20 fold reduction from going to airblast to closed cab. Well, does that still say that we can do better on closed cab. I'm making that up.

But I mean, that's partly -- and that's not just your industry, but the other input supplier industry as to changes here in this whole arena for a whole number of

reasons, both whether it be the insecticides, whether it be carcinogens, or just less is more as you go over time, that if you reduce exposure, whether it be dietary or occupational, you've got a better risk profile over time.

UNIDENTIFIED MALE: Well, I -- and not only are there new application technologies and/or new chemistries, but can agriculture afford them. And when will they be able to be implemented which I would argue or suggest that USDA, you know, needs to be part of kind of a larger strategic thinking here because we can have a lot of great stuff, but you know, if farm economy doesn't allow farmers or dealers to afford, you know, to buy, you know, the newer, better stuff, then it really doesn't affect anything in the way of risk mitigation.

Kevin, you started up the sort of production chain, but you didn't talk about plant manufacturing plant, formulation plant workers that -- is that dealt with entirely separately in this process?

MR. KEANEY: Yes, it would be. I mean the regulations we're dealing with are ag and employer driven, employer/employee.

UNIDENTIFIED MALE: So you don't deal with

manufacturing people?

MR. KEANEY: No, no.

MS. MULKEY: That is OSHA jurisdiction. It is the case that sometimes there are epidemiological studies that come out of that population that are useful to us. So there is some science connection. And then there is a few pesticidal uses that occur as pesticides in manufacturing plants that on occasion might be an issue. That's sort of a residential.

And finally, there's a question of whether things like seed treatment which occur in a factory-like setting, but are an application that basically we regulate. So there are a handful of those things that might merit. That's sort of one of those special population questions.

But for the most part, the people who work for your member companies to make the stuff are under the jurisdiction of OSHA.

UNIDENTIFIED MALE: OSHA, right. Okay. Well, I -- it sounds to me like the only thing that might be in the next 12 months a significant departure from the more or less business, incremental as usual effort in this

area might be youth in agricultural settings. I don't know how you describe that, but a special subpopulation group of children in harvesting conditions and that kind of thing might be a big incremental extraordinary effort if you got to that.

MS. MULKEY: Well, I suppose -- it's only if you have the word might. I'm not sure how big or extraordinary it would be, but -- and the other thing Jim mentioned which is -- I don't know if you'd regard that as big or extraordinary, but some movement in areas like risk communication to workers, maybe greater stakeholder involvement of workers, those kinds of issues.

MR. AIDALA: Yeah, my take on it is these audits is sort of routine, but as Bill raised the issue, gee, if some states are doing a different job than in other, there's everything from a level playing field for the producers to just sort of doing their job. I think that's the most significant thing over the next year as we go through these reviews, frankly.

In addition to hazcom or, you know, risk communication, and I think with -- it's been this steady issue of this special subpopulations. And it gets raised

in a number of different ways. It's basically, I'd like to think of it frankly as more of a general issue of bystanders, drift and bystander issues.

Whether it's a person who you want to claim as a farm worker family living near a field or just a suburban family living near a field as suburbanization and agricultural ends meet. Either way it's something we've all had to wrestle with.

We, as regulators, you as the, you know, the producers of the chemicals, users, as the people that apply the product, of what you're doing to your neighbors. I mean, that's -- I'm not sure that's a big, new thing this coming year or any other year. But it's an on-going issue and at some point, it may become a pivotal issue in a decision or not.

UNIDENTIFIED MALE: I think all of this to me supports Larry's suggestion that we ought to think about some way of getting, you know, a group to think more strategically about big picture issues here because there's so much effort going into a lot of the incremental work.

But are we focused on an achievable strategic,

you know, long-term or intermediate goal, and are we getting there or not. You know, I think that all of that's useful and --

MS. MULKEY: Well, if you all are not --

UNIDENTIFIED MALE: -- I didn't say that we're a work group yet, but I think that's what Larry is thinking about.

MS. MULKEY: Well, if you all are not actively involved in this series of workshops which has work groups relating to the worker protection rule, you definitely ought to be. I mean, that is clearly a very significant effort and it is pretty large in scale, scope, jurisdiction.

It doesn't go to the risk assessment piece, but virtually everything else we've talked about is at least tangentially connected to that effort. And that is stakeholder based, stakeholder designed at a pretty high level of effort. I believe that -- oh, boy, Phil was next, yes.

MR. BENEDICT: Marcia, I was wondering if you'd consider doing one of these workshops by satellite. It would allow people to participate from the Himalayas. It

would allow a lot more staff scientists from state organizations, universities.

MS. MULKEY: We talked about that for the cumulative one last summer and for a host of reasons, of logistics, we did do a telephone hook-up. So yes, we would and you know, have a down link at a local hotel or something.

MR. BENEDICT: The USDA used to do a lot of down links. You know, you've done down links, too, on C Band.

MS. MULKEY: We have. Now, that's a very viable --

MR. BENEDICT: But I really think it would allow for an awful lot of participation at the staff science level.

MS. MULKEY: That's a very good suggestion. I think the other stakeholders would find that helpful, too.

MR. BENEDICT: It would train a lot of people.

MS. MULKEY: I don't know enough about the technology to know just how easy it is, what kind of costs we're looking at. We -- but I think we certainly are prepared to explore that.

MR. BENEDICT: I think if you put the word out on your web page and put out a lot of mailings where people could go -- there's an awful lot of old C Band satellites. I've got one. In fact, we sat at my house last time you did it.

And with a couple of telephones, people can call in their questions, and I think you can do a lot of training that way and get to a lot of staff people which aren't going to get to meetings.

MS. MULKEY: I think that's a very helpful suggestion. I appreciate it.

DR. AMADOR: The reason is that is what we did one time at Texas A and M.

UNIDENTIFIED MALE: We did it in the early days of work objection.

MS. MULKEY: We did.

DR. AMADOR: We did and it worked out real well.

MS. MULKEY: Thank you.

UNIDENTIFIED FEMALE: Texas A and M facilitated all of it.

UNIDENTIFIED MALE: Well, that's a good idea.

MS. MULKEY: I think that's -- yeah, excellent.

UNIDENTIFIED FEMALE: Also, Farm Bureau has facilities, there are many organizations with facilities.

MS. MULKEY: Right.

UNIDENTIFIED MALE: And if they keep the deadlock, C-Span is going to be looking for material so --

MS. MULKEY: You can only watch the county and vote so long. Okay, well I think we go to Bob and then Beth, and then Bill.

MR. McNALLY: Well, it won't surprise you that I wanted to say that I appreciated Larry's remarks. Larry was saying something that caused me to want to respond to something you'd asked me yesterday, Marcia, which I answered really badly.

You asked whether a workshop or a work group would be a better or different way of approaching these issues, and I didn't know what the right answer is. And I still don't know what the right answer is.

There's something about workshops that gives me the feeling of this discussion times five. There will be more discussion of the same things, more in depth and maybe even a little bit of an exchange of ideas and

that's good. But work groups give me the feeling that they produce an end product, recommendations or do things that actually produce real changes.

And I just, maybe it's just semantics, but the idea of a work group seems to me to be a much more -- well, a much more worth while endeavor for my organization. And I know it's a huge drain of resources on the Agency. You've got two CARAT work groups. There's still an INERTS work group here. I guess, rodenticides is done. And this would add another work group. But if there was some way to do that, I think that would be really useful.

And just one other thing, I think somebody's suggested yesterday that the notion of forming a work group was designed to impede or delay regulatory decision making. Believe me when I say that's not our intention on something like this.

MS. MULKEY: Now that you've raised the R word, and Dan actually was really interesting after hearing all this lobbying for extensive work groups to hear Dan's very real expression of the tension between demands on his time and the ability to attend even a single day

session, especially if it wasn't scheduled particularly artfully.

The tension here, let's be very frank. We -- believe me when I say we have no hesitancy to be as transparent as possible and to engage with all of you and others and to get as much of your point of view as possible.

Both of those things are those things that we are eager to do. But frankly, not to the exclusion of keeping the trains running. And for us, it is very much a tension between those two things. And so yes, we seek things that are intermediate, not because we are reluctant to have things that go the whole nine yards.

But I've got to tell you, I feel very good about the work we're doing on INERTS. We've had two full day meetings and seven long conference calls, and we are still understanding each other. And there are -- that is just a very high price. It is worth paying, but we cannot, we simply cannot afford to pay it on every topic.

We have to find some ways on some of these topics to find some intermediate ground. That's also why I made the remark I did yesterday which was a little

snippy on my part about there's only so much hand-holding and you guys have to invest, too.

And part of what I hear you saying, quite frankly, is this is hard for me to understand and I need you to spend a lot more time with me helping me understand it. Frankly, I'm not a scientist either, and I understand that dynamic. But the reality is there's only so much of our resources that can be legitimately be spent working people through very multiple tiers of understanding.

We did invest that on dietary. It clearly paid off. We are trying to find smart ways, efficient ways, ways we can live with and resource drain terms to accomplish some of that and to get -- and we're also asking you, not only make yourselves available for work groups, but find some ways for you to carry a little more of the burden. Whether it means how you staff involvement and these kind of things, or whatever.

In other words, you pay for some of the cost of translating this material. You know, either through your resources or whatever. That is why you don't see us saying, great idea. We'll start that one. Another great

idea, we'll start that one. Oh, now, let's -- you know, because there is a real and pretty dramatic cost.

UNIDENTIFIED MALE: And let me just comment. I understand that and am sensitive to that. Yesterday, and -- well, yesterday particularly, the president -- the presentation on residential exposure reminded me a lot of the discussion that we had in the pre-briefing for the first track meeting.

Which is to say we were all surprised that there was that much information out there and we were all a little startled that you had done as much work as you had done. And we were all a little bit mystified about what it all means. And I think that's kind of where we are on worker exposure to some extent and residential to some extent.

The process that did give rise to so much confidence building in the measurement of dietary exposure could occur here as well, I think. And I think it's an investment worth making.

MR. AIDALA: Now, my version of this is sort of all points are correct.

In other words, meaning you've acknowledged that

there's the tension. We've acknowledged that there is the tension between the payoff and you know, sort of the demands. I think it's sort of -- to me it's also a menu of different things. For example, whether you call it a work group or not per se, A, there's continual meetings of this group itself.

Secondly, there is the workshops that we've already articulated, long scheduled about, oh, across the country workshops on the Work Protection Program which obviously can be not just a one-way thing.

I think the comment about workshops is that workshops by definition are sort of initially at least, one-way-ish. It's that we're telling you how we do it and obviously taking questions. That's a little more one-way than oh, I've got an idea. What about this or that?

It's sort of a series of workshops though. What's the difference between a series of workshops? I don't mean every month, but I mean, you know, more than one and a work group. I'm not sure there is big one per se. Because at a workshop, you can certainly make suggestions, it's just at the first one you're learning.

You know, you're around the T.V., Phil, learning what the heck is going on. By the second or third one or something, you might then say, well, hold it. At the first one, we learned this. We asked for a little more follow up on that. Here's some new technology come from the industry. Have you figured that in? You know, et cetera, et cetera, et cetera. It becomes more interactive after the first one when it is just the data dumper, like the first meeting before the first track. I mean, I think it's all those things taken together. Whether you call it work group or not, I think that again, everything has been stated in truth. This is a useful exercise, not just for dietary, not just for work --

(End of Side 2 of Tape 1.)

MR. AIDALA: -- you could spend a whole lot of time with all of you about all number of issues, but again, you have to pick among what your priorities are because of time constraints both of you and also our guys. So, sort of all taken together.

I mean, it's not just the one workshop. And that's not the only time you get to talk about worker

issues. It's the workshop that's at CARAT. It's at this next meeting and the meeting and the meeting after that about this group. It's the national workshops and any other ideas.

Again, that's not to say that we're saying that's enough, and that's all we're going to do. It's just any other ideas. And so it's sort of everything taken together in my book.

MS. MULKEY: Lois is going to FYI a little bit.

MS. ROSSI: I just want to say a couple of things on this because having probably taken the brunt of many of the frustrations and comments on the worker assessments in the last year and a half or so, I think it would be very helpful.

And I guess there's, you know, the dietary was easy to kind of figure out what it took to make it clear. I mean, to present in a table we accomplished that essentially. By, you know, telling everybody what percent crop treated, telling everybody the source of the residues, telling everybody if you used juice or what you did.

And in a table, I think that, not that I'm sure

anybody here would know the inner workings of the Monte Carlo, but at least you got, you know, the assumptions that were going in and you could comment. You could say we don't treat that percent.

Now in the worker, it's a little bit difficult although some of the variables, there's probably maybe less than ten things that go into a worker assessment. And some of them are standard, how much the guy weighs, how long he works, that kind of thing. I mean, some of them are standard.

But I think what my frustration has been and I think in order for and probably your frustration is what is it exactly that needs to be really articulated. And I think that's -- and I think, Dan, the meeting that we had that you referenced was really a very intensive four hour, roll up your sleeves, where did this number come from.

That's hard to do with a large group of people. But if that's what's necessary, that's a different thing than getting up and doing slides and showing it. And I think at this point, I really think, you know, there's a lot of frustration I think, certainly on my part and

probably on your part, to what is it more that we can do and how can we do it to put this to bed to make it be something like the dietary. Enough said.

MS. MULKEY: Okay, well let's --

UNIDENTIFIED MALE: I wish I had said it that way.

MS. MULKEY: Let's go to bed and then I'll try to figure out where I think the cards came up. But we'll get to all of you.

UNIDENTIFIED FEMALE: Two things. One, I think the teleconference idea, I really like. As much as I would love to get to Orlando in the spring, I probably won't. And my best way of sitting in on one of these national workshops is -- would be the teleconference. And I think I agree that a lot more people get involved that way.

You mentioned a couple of studies that I was curious about. One is a NIOSH study, ag-health study. What is -- and the second one study is of farm worker children. When are these studies going to be completed? How do you see incorporating them?

MR. AIDALA: I was going to mention that.

Whether that's the next year or the next two years, those studies that have been under way for a while won't hear the time lines. Those could make a difference as to obviously depending on what the results are.

UNIDENTIFIED MALE: The ag-health study is -- I guess it was really initiated about seven to ten years ago. It's a large epi-study. I think they have 70 thousand participants in the epi- part. And it's being done in Iowa and North Carolina. And it's NIEHS-NCI and then we're doing an exposure component. And the exposure component I think it is in the pilot stage at this point.

To kind of verify what they're seeing in the epi-study, it's a multi-year thing. I think 30 years, whatever their budget is. So, you know, we'll get that information as it comes in and use it to get --

UNIDENTIFIED MALE: That's focusing on farmers, applicators and their families.

UNIDENTIFIED FEMALE: Okay, when -- how far along are they?

UNIDENTIFIED MALE: I think they're reporting out this year.

UNIDENTIFIED MALE: I think they are reporting

out some of the initial health effects information from the epi component this year. And then I believe that the R-field component is piloting this year. It may -- the first phase may be done already. I'd have to go back and really check the details. It's been a while.

And then the farm worker -- the children studies are what was discussed yesterday and that's basically worked through an axis and some of the environmental centers that are set up through one office of research and development. And much of that work is on-going.

Some of the preliminary information is just coming on line within the next year, for example. So we'll be using that to just help us, you know, characterize the overall risk and get as much kind of the factors data that we can from risk assessments from it.

UNIDENTIFIED FEMALE: Is the new program -- are there any plans to include protection for farm worker children if this study shows the need for it? I mean --

MS. MULKEY: Well, obviously, if any information indicates a need for something that we have jurisdiction over, we look into whether we can do something about it.

UNIDENTIFIED FEMALE: Dumb question.

MS. MULKEY: There was a person from our Office of Research and Development here yesterday. And his materials are not in the packet, but we're going to supply them. And they list a lot of studies. And he mentioned that a lot of that material is on the web. And I believe his presentation had some web sites in it.

And so that may be a way for you -- and also, you could just call him. His name is Chris James.

UNIDENTIFIED MALE: Chris Saint.

MS. MULKEY: Saint, excuse me. Who is Chris James? Somebody I'm sure that I know.

UNIDENTIFIED MALE: They're a rock band.

MS. MULKEY: Is that it? But -- and we can get you that. So that may be helpful to you. All right. Well, Jim suggested that I just go down the line. And I'm pretty sure Dan's card was up first, so I'll do that and then go down.

MR. BOTTS: Actually, I think Mr. Tracy's was, but I'll take the opportunity anyway.

MS. MULKEY: Okay. Then I'll go down the line the other direction.

MR. BOTTS: Specialty crops are more important

than cotton anyway. From a worker protection standpoint I think we could make it --

MS. MULKEY: Do you mean that they have more problems with worker protection?

MR. BOTTS: -- a case for that. Maybe not the handlers side, but the worker's side, we probably could. Just to reinforce one issue. And this is something that I take a lot of personal interest in.

And we have supported both Kevin's program through our labor division at FFVA by doing -- providing worker protection training for our membership and their workers and also through support for the workshops. We will have somebody in Sacramento.

We had somebody in Austin. We'll have somebody in Orlando. We'll have somebody in Washington. Whether it's me or our labor division or somebody, we've actually engaged in this issue at least since 1982 at the level of intensity that we are right now. It's not an issue that we take lightly. It's not something that we don't support moving forward.

One of the things that frustrates me is we're still talking about the same issues and it's more

rhetoric than it is actual rolling up your sleeves and getting to the point of determining where the real risk points are so you know what to deal with. And we've got to get to that point. And until you understand how the assessments are made or how the work takes place in the field, you can't do that.

And that's part of what this workshop that Larry is talking about will be critically important in doing because it will show how the risk assessment is defined, give the people who are going to have to deal with it a true understanding of how they can actually provide real mitigation for real risk.

Because right now when we go into a meeting and hear somebody say it's a fourth of a drop of a product that has been used for the last 40 years with no history of incidence out there. You've got a hard time selling a grower that he's got a problem that he needs to deal with.

And until they understand where those numbers come from, what's driving the policy decision to drive the decision that that's the endpoint they want to regulate on, you're going to face this same frustration

that you hear that ends up in the polarized positions that we've faced on some of the other issues the other day.

Until you get a common understanding of what drives that process, you're still going to have these same conversations from now on. So it's critically important that we get to the level of understanding where we can actually define the goals of the workshop.

And this is one place, our work group, this is one place where I'd differ with Bob, maybe not differ with Bob, but right now, if we sat down to form a goals and objectives statement for a work group, I don't think we could do it. Because everybody's understanding of what the issues really are different.

And until we get to that level of understanding which I think goes to the point and I will agree with Lois. The meeting that we had back in July or whenever it was, on the product that had already gone through the -- essentially had reached closure on where it was going to end up and probably not continue to be labeled on the crop that the people that were at the table who still would like to see it registered on that crop were raising

hell about it.

We left that meeting with a much better understanding of where the number came from. We might not still disagree that you're being protective or actually dealing with an issue that needs really to be dealt with, but until you get that level of understanding across the board, you can't move forward in coming to a real definition of how you want to address this problem.

MR. AIDALA: And then given that, I'll call that the case example, or whatever you want to call it, that you and your folks got really involved in. What was the real -- was it that you better understand it and therefore, might accept the fact that, yeah, something's got to change, or that hold it, there's something we can do. Just kind of was there a particular --

MR. BOTTS: It's a combination of both because what it was -- probably the single biggest thing, and Jeff, you weren't at the meeting and I'm going to take on the model just a little bit. The thing that drove us absolutely batty, it was an air-blast application sprayer. They looked at the dermal exposure issue.

You've got a 50 percent reduction in the dermal

exposure number based on science who came in, but it made less than a five percent difference in the risk number at the end of the day when you took that into consideration with the assumptions that went into the model that led to that number coming out.

Now how do you deal with that? You either provide information to change the model, you question the model, you go in and look at some of the issues surrounding that. And probably the thing that brought it home to me, it goes back to the presentation yesterday on the residential stuff, we've had hammered in our head it's exposure plus hazard.

We've got hazard issues out there that you can exchange an exposure route in the model and you don't get the corresponding change in the risk that you do in the dietary exposure assessment and other things. And that leads me to believe that there's some things that need to be done within the modeling process, either in pea head or in how they do the calculations around the residential -- or the dislodgeable foliar residue issues.

And some of the other things that need to be plugged into the equation until we can -- until that can

be explained on why those changes don't happen when you make those major differences in what should create differences in the risk number coming out at the end of the pipeline.

You're going to have a hard time explaining it in a manner that anybody out there is going to buy into that these are real numbers that need to be dealt with. I don't want to minimize the issue because I designed a program in 1983 to protect five thousand farm workers that is probably more stringent than anything the Worker Protection Program ever put on paper.

We are concerned about it. We want to deal with it, but we want to deal with real risks, rather than something that comes out of perceived risks.

MS. MULKEY: I think I'm hearing two things. One is that case studies are real helpful.

MR. BOTTS: Yes.

MS. MULKEY: Whatever we do. Whether we do a workshop, whatever. And that I think -- the other thing out of -- this is the second time I've picked it up from Dan in this meeting is that the hazard side is also very important in these worker protection.

Quite frankly, that is harder to engage with and it harder to make any one case study useful for others and so forth. And I think it is a very different science, group of scientists and everything else. And it's not that different from diet. Sometimes it will be different and point to a different study. But often, it's the same basic set of questions that drive dietary.

So eliminating hazard in this area would be eliminating it again in a lot of ways. But I think that the role of a case study, the benefits of a case study, I think that's certainly feedback that we know we can make some use of.

UNIDENTIFIED FEMALE: Yes, I've got to agree with that.

MS. MULKEY: Yeah.

UNIDENTIFIED FEMALE: And I also wanted to mention that this is an issue that's really important to the Department and to land grant universitates. We have expertise in this area. We also have access to exposure information.

Our NASS people, the National Agricultural Statistics Service, has a lot of the data that can help

with developing your models. They are already working with the Agency to try to develop additional data or to figure out how they can use existing data without violating their confidentiality issues.

So we are working very closely with the Agency and with grower groups and with land grants. This is an issue that is very important to us. So Marcia, you can count us in when you talk about, you know, needing the resources to help move this along. The Department will be there.

MS. MULKEY: Well, let's go down this way. Bill, apparently, has been patiently waiting.

BILL: Just a perspective from the field, the regulated community out there and to emphasize what Dan has said, the mindset of the people that are drawn to agriculture is show me, don't tell me. And I think that's where we can get everybody on board.

And I wanted to emphasize and compliment the Agency on the uniformity issue and encourage you to continue with the Train the Trainer Program. We have found that to be a tremendous asset. You know, even the boss has one of your applicator cards there that one of

our employees trained me. And made me legal with the training program.

Secondly, I wanted to compliment the Agency on assisting my industry on putting out worker protection bulletins that goes across all 17 of the cotton producing states. We found that to be beneficial and I realize that takes time from your other duties and all. But it's a tremendous asset to have that available to us, that expertise.

MS. MULKEY: Thank you. Larry.

MR. ELWORTH: We should have called on you earlier.

MS. MULKEY: We saved him for the last.

MR. ELWORTH: Marcia, you raised an issue that having been on the staff side of these federal advisory committees, I remember being mortified at what had to be what Lois' and her staff's workload, going into both the Food Safety Advisory Committee and especially Track. And so I have some personal appreciation of being up until 11:00 or 12:00 at night for weeks at a time dealing with that and I don't want to minimize that.

But I think there's an issue here. It's not

just that people don't understand what's going on, although that's a huge issue. I think what Dan's saying and what I've heard from other grower groups is that to the extent that they do understand, they're unnerved by it. And they're on a case by case basis on each of these assessments.

You will hear from the grower community that there are either mistaken assumptions or data that simply wasn't included that would have been really beneficial to the assessment. So in that sense from a public policy point of view, if on a case by case, you have chronic concerns about the risk assessment, it would useful to step back and look at the process and see if there are ways that the process could move more efficiently and more effectively that would at least minimize the kind of case by case problems you keep running into.

So I think, again, and I'm not so focused on what the mechanism is as long as there's that kind of interchange, both to look at the policy and to deal with the fact that it's not just that we don't understand it, it's that at times we understand it and we really think there are problems with it.

I also have an additional concern having worked on pesticide issues for a long time and that is if you don't get the risk issues right, not only do you mess up the risk assessment on this side, but you end up focusing on risks that aren't the important ones.

So I think there's -- in terms of focusing on the right risks, whether it's farm worker, rather than applicator/handler or the other way around, I think it's important to get the risk assessment right so that you focus on the right risk and mitigate the right risk.

Again, whoever the risk is assumed by. So I mean, I guess, what I would recommend in this case is some substantive process that both has a benefit to the grower community, but I think a benefit to the Agency as well. I mean, I would not suggest that the -- what came out of the dietary risk assessment was solely useful to the affected community.

I thought it was really useful to your folks. I mean, you know, you learn something best when you have to teach it to somebody. And I thought that was real helpful to people at the staff level.

MS. MULKEY: Yeah, we don't disagree with that.

Jim?

MR. VROOM: Yeah, I just wanted to weigh in on a, just a generic sense about this work group kind of issue. And I think Dan and Lois have -- are onto something about having a clear sense of purpose at the outset of what's trying to be accomplished. It helps drive the success of the work group.

And so in consideration of whether we're going to go forward with some of these things, I think if we have clear definition at the outset, that's going to help everybody in terms of the efficiency of the resources used in those work groups.

I also think that you need strong leadership and good facilitation in those groups to make them happen. Because you can -- people can come to the table and it can be a complete wash or you can really help drive them.

So if we have clear purpose, maybe time frames in which things can be accomplished, a willingness to participate and good facilitation, then I think they can be successful. Otherwise, we shouldn't do them.

MS. MULKEY: Jay.

MR. VROOM: Just to come back to the Ag Health Study for a minute. I'm fairly confident the Agency staff is aware that the industry is doing some of its own independent research with regard to those populations in North Carolina and Iowa workers and farmers and their families -- applicator workers and farmers.

And we do take that issue very seriously and you know, because there are so many government agencies involved in the Ag Health Study and it's been going on for so incredibly long, there are some concerns about, you know, remembering where the protocol started in the study and how it's evolved and so we have decided to make that investment, a substantial investment of an independent look at some of that epidemiology and are prepared to share that once we have it pulled together.

I think that's a very important point and I'm glad Jim raised that because it could be, you know, both substantively and probably more likely politically a driving factor whenever more information starts to emerge out of the Ag Health Study.

MS. MULKEY: Jay.

UNIDENTIFIED MALE: Did you set the timing on

that? Or did you? Timing?

MR. VROOM: Of the industry data? I'm sorry, I can't remember at this moment. But I think it's catching up to the same time lines that the reports.

MS. MULKEY: This is new to me. That doesn't mean that the Agency didn't know plenty about it.

MR. VROOM: I think you guys knew about it.

MS. MULKEY: Yeah, are you actually dealing with the same people and gathering data separately?

MR. VROOM: No, I don't think it's --

MS. MULKEY: Or are you reviewing our work?

MR. VROOM: No, I don't think it's the same people, but we are --

MS. MULKEY: Getting data in the same places?

MR. VROOM: Yeah.

MS. MULKEY: Oh, okay. Well, we have -- we've finished our timetable. We've had a full hour of discussion. Actually, a little more, I think. It was very rich. It is time for our break. We are scheduled to reconvene right at 11:00 and let's try to do that.

(Whereupon, a brief recess was taken.)

MS. MULKEY: -- be able to finish on time or a little early in spite of my executive decision to run a little longer than it was scheduled. However we have a goof-up, our goof-up, which is that one of our members -- you'll remember that we mentioned yesterday that Nelson Carasquillo would not be here.

Remember, because he was out becoming a grandfather, and Theresa Niada is here for him and she has been here all day, sitting dutifully in the audience, unaware that she was a part of the Advisory Committee. And I think she would probably like to participate in our discussion on worker protection.

And given our failure to make that practical and possible during the way that we are doing it, if it won't trouble her, we would love to hear your prospective now. And we'll take some time to do that before we go back to our program.

MS. NIADA: Good morning, everyone. And I'm very happy to be here on behalf of Nelson Carasquillo. There were just a couple of comments. First, I found it very interesting and the presentations provided a lot of useful information.

One comment, though, I think Jeff, who I don't see, had mentioned something with the pesticide handler data base and I had a question if this just includes registered and licensed handlers because I was concerned that there's a lot of farm workers in our constituency who are not licensed and registered and may not be a part of this. So some valuable data is being missed.

We know of a lot of the farm workers who handle, mix, apply pesticides who are not registered, who are not trained, and who are not given the protective safety equipment. And we had a meeting, actually, with a group of farm workers last night and one gentleman had mentioned that he mixes pesticides with water and he has received no training or equipment.

And this is something that is very common, both in the area where Cotto (phonetic) works in New Jersey and Pennsylvania, but also, too, in our other member groups in Florida and along the U.S./Mexico border. So I was concerned that workers aren't being included in this.

This worker was also a field worker and is going into an area that after has been treated with some pesticides, begins to vomit and gets dizzy and nothing --

and no reporting is happening of this. So I just wanted to bring some different scenarios that it's real important to try to include the farm workers, especially with the pesticide handler database.

And also with our field workers, I was a little concerned, I know, with the NIHS study, too. I think it was Kevin, if I heard correctly, it's with farmers, applicators and their families. And a lot of our constituency is very concerned about the long-term exposure of pesticides on their health and that of their family. The low-grade, you know, daily exposure.

So, too, I know EPA has some initiatives and it's doing some pilot work to get some of this data, but would stress the importance of getting more long-term data and especially working with community groups who basically have daily contact with farm workers and can act as -- you know, to see what sentinel cases there are and to provide some very useful information. So, just very briefly, those comments.

MS. MULKEY: Thank you. Thank you. Bill, did you want to add something?

BILL: Just one comment on regarding unlicensed

and untrained mixers, loaders, handlers and flaggers. That is definitely illegal use of pesticides. I talked earlier, it's against the label. I talked earlier about uniformity of enforcement. And this is where the regulated community's concern lies in the fact that the example just given is extremely, highly illegal.

MS. MULKEY: Thank you. Thank you, both. All right. The next item is an update that several of you requested about tolerance reassessment and re-registration. And Lois, are you doing this, or is Bob doing this?

MS. ROSSI: Bob is doing this.

MS. MULKEY: Bob McNally, who is part of our Special Review and Re-Registration Division. And there is a paper on this, two papers, actually, I think.

MR. McNALLY: Yeah, Marcia, there's two things that were just handed out. Let me show you what they look like. There's a set of slides that entitled status of re-registration and tolerance reassessment that Margie put on people's chairs and made available for the public.

And then a thicker document that has the six phase OP process on the front and sort of the status of

each of the OPs are in that. So if you have those, those are sort of the basic materials.

What we wanted to do this morning was give you a brief update of where we stand on tolerance reassessment and on re-registration. To do this, let me just give you a brief summary of what we did this past fiscal year, Fiscal Year 2000, that ended September 30.

We had a good year. We completed 19 individual assessments in Fiscal Year 2000. And in the material that Margie handed out, that thicker package, later you can look at, there's a summary of each of those decisions we made on the 19 to give you a little bit of flavor of the kind of actions we took.

As you can see here from the slide, there's sort of three broad categories of actions that we took. But first, there were six chemicals where we had re-registration decisions made. That's what a RED stands for. These are chemicals that were registered prior to 1984.

And essentially what we've done with these is that we've completed the re-registration activity on them. Now, there is one in here that's an OP, you'll

notice, ethylparathion. That one was voluntarily canceled so we're able to count that as a RED completion.

The next set are what we call IRED. Some of you are familiar with those. Seven of those were completed last year. Six of them were OPs. One was a carbamate. And what an IRED is an interim re-registration decision. These are those chemicals that are part of a chemical family that has to go through a cumulative assessment at a subsequent point.

And lastly, there are six, what we call TREDs, which stands for tolerance reassessments. These sort of fall into three categories. These are post 84s which under our program are not subject to re-registration. Secondly, they might be import tolerances only, such as something like Mevinphos that you see on the list there.

And lastly, they might be follow-up activities to REDS we did before FQPA was passed, that we have to come back to under FQPA and look at it again. And an example of that would be Coumaphos.

Now, the next slide, we wanted to give you some sense of where we stand overall with our re-registration program. With the effort that we conducted this year,

we're now over 200 REDs completed, which we feel pretty proud of. There were an additional 231 cases that were canceled.

So when you look at the numbers in total, thus far, we've completed about 70 percent of our work on re-registration either through the voluntary cancellations or through the 204 REDs that have been completed.

The next slide gives you sort of a quick summary of those OPs that we did this past year. Again, these are interim decisions that are pending the cumulative assessment that needs to be done subsequently. There was some discussion earlier with Jeff Dawson about the worker activities.

What you'll see in the summary in that larger material that Margie handed out is we have taken risk mitigation steps, for example, for workers or ecological areas in these. What these don't include is the cumulative dietary assessment, although they each talk about the individual dietary assessment.

So that's where we stand on the OPs in terms of what's been completed through Fiscal Year 2000. Now, I wanted to give you a flavor for sort of what's coming up

in our next set of chemicals.

The next slide that does that is you'll see on this slide essentially the ones that we'll be doing next are going to be the OPs that remain and also the last one there which is not an OP which is propargite. So the next set you'll see coming out of the Agency will come from this list.

And then lastly, we wanted to give you a sense of where we stand on tolerance reassessment. As you know under FQPA, we were required to reassess all of the tolerances that were in existence when FQPA was passed. And that number is 9,721.

The law required us to reassess a third of those by the end of first three years, which was August 19, 1999, another third by August by 2002 and the remaining approximately third by August 2006. Last year, we completed a 121 decisions that we can count. And that's a key point here as you see a lot of the work we're doing now is on the organophosphates. And as I mentioned, we can't count those until we do the cumulative assessment.

The next bullet gives you some sense of where we stand in total. The key point here is that by August

2002, the law calls for us to complete 64 hundred assessments by that point. I would add that 3,551 is an accurate number. We counted two -- we had two manual recounts this week to verify that number as correct.

And several of those tolerances came in from Florida, late in the day. The last point I would make is that there are approximately 11 hundred tolerances that are associated with the OPs. That once that cumulative assessment is done, then we would be able to count those as reassessed.

So that's a quick summary of where we stand on re-registration and tolerance reassessment as of today. Let me turn it back over.

MR. AIDALA: If -- Bob, maybe get at the number of -- if and when that time comes that OPs are because of cumulative, et cetera, et cetera. The number of OPs that would make that 35 hundred number be --

MR. McNALLY: It would be about 11 hundred.

MR. AIDALA: Eleven hundred.

MR. McNALLY: So that would get to about 46 hundred. There are about 20 OPs we could count as REDs. So the 204 number would go up to 224, for example.

UNIDENTIFIED MALE: Right.

MR. ELWORTH: Could I ask a dumb question?

MR. AIDALA: No, only smart ones.

MR. ELWORTH: With the cumulative -- when you do -- do you issue a RED before the cumulative is completed?

MS. ROSSI: We've been issuing individual -- we call them IREDs, interim RED decisions. So we've been issuing -- that's what we issued at the end of the fiscal year on the 14 that we did.

MR. AIDALA: That's the interim part of it.

MS. ROSSI: That's the interim RED, and that includes the worker and the eco and the entire picture.

UNIDENTIFIED FEMALE: On those, the -- where you've identified ecological and worker risks, what steps have you taken beyond that? Has PR notices been issued for worker risk? What, if anything, is issued for eco risk?

MS. ROSSI: Each of those REDs contains a mitigation section. And unless those mitigation measures are implemented, including reduction of rates, increasing REIs, increasing PHIs, and including discontinuing of certain application methods, each one of those REDs gives

a regulatory risk management decision, which includes mitigation measures for eco and worker.

UNIDENTIFIED FEMALE: Right. But having -- I'm sorry. Go ahead.

MS. ROSSI: And those are -- the labels, the revised labels need to be submitted on a deadline through the processing of the product re-registration.

UNIDENTIFIED FEMALE: Okay, I just -- from reading those --

MS. ROSSI: From reading the individual IREDs?

UNIDENTIFIED FEMALE: -- IREDs and going through the different mitigation measures that are identified and some are very specific, what, in addition to that document, would identify the deadlines by which these measures need to be taken?

MS. ROSSI: That is the document.

UNIDENTIFIED FEMALE: That's it. So, if it's not in the document, then there is no deadline, or?

MS. ROSSI: If there's a measure that's not in the document, then it's not implemented.

UNIDENTIFIED FEMALE: Well, because the only thing that you can really see is, for example, it says

cancel -- voluntary cancellation of lawn uses and --

MS. ROSSI: Right.

UNIDENTIFIED FEMALE: -- and whether or not the Agency has already worked that out with the registrant. But for example where there are -- there's a mandate to implement different re-entry intervals --

MS. ROSSI: Right.

UNIDENTIFIED FEMALE: -- it doesn't -- I mean, the labels aren't a part of the document and there's nothing beyond that. Is this an honor system?

MS. ROSSI: The labels have to be submitted, though. Now, granted the label --

UNIDENTIFIED MALE: As far as --

MS. MULKEY: She wants you to explain the deadlines and REDs, the label submission deadlines.

UNIDENTIFIED FEMALE: Yeah.

MS. ROSSI: There are different deadlines because for some of these OPs, we have shortened the deadline for label submission. Traditionally, the label submissions on a lot of our previous REDs have been very long. I mean, they've been like 24 months and then another 24 months to clear through channels of trade and

this kind of stuff. But on many of these individual ones, they have specific deadlines that -- where the labels have to be submitted.

MR. AIDALA: If there's no deadline in the document, does that mean that it has already have to have been submitted? I believe that's part of the question.

UNIDENTIFIED FEMALE: Thank you, yes. That's exactly what I was asking, Jim.

UNIDENTIFIED FEMALE: If there's no deadline in the document.

MR. AIDALA: No other says -- it says that the label must be changed to delete the lawn use or the blueberry use. Does that have to have been submitted before it's written down unless it has a date in the document? I think that's your question.

MS. ROSSI: In cases where we've asked for deletion of uses, we generally have those in hand before we write the document because we don't eliminate a use that -- we don't eliminate a use from a risk assessment unless we have a commitment that that use --

MR. AIDALA: Right. Well, unless the document -- I say the blueberry use is phased out in the year

2001. It would say that.

MS. MULKEY: I think there's a minor little administrative point. You guys are talking across each other. The two year you talking about, the sort of generic timing for REDs.

MS. ROSSI: When the entire labels need to be submitted.

MS. MULKEY: Right. If there's not a specific date for a change, then that change is picked up on this two year window.

MS. ROSSI: The product re-registration process.

MS. MULKEY: Okay.

UNIDENTIFIED FEMALE: That's exactly what I was asking.

MS. MULKEY: Right.

UNIDENTIFIED FEMALE: Thank you. Thanks.

MS. MULKEY: Okay. Was Bob in the middle or are you finished?

MR. McNALLY: Done.

MS. MULKEY: So any other questions, comments, discussion? People are ready to move on, huh? I think for those of you who are deadline followers and who worry

about our ability to get our work done, and I certainly count myself among that, I think Bob did some of it. It might be worth pointing out.

For example, the remaining work on REDs, 177 REDs to complete. Bob said that's, I don't know, 20 -- 30 percent of our remaining work. We hope and believe it's not 30 percent of the total work the re-registration program had to do. For example, included in the 177 are all of these IREDs that are not yet REDs.

So there's all the OPs that are in the two complete, but for which almost all of the classic RED work is done or nearing done. So that's it.

And also, these are organized around, to some extent, priorities. So while we still are working on the worst first, tolerance reassessments, we are, as you saw, increasingly doing that work and there will remain a lot of the easy stuff at the end of the day.

And I couldn't tell you how many out of the 177 are going to be easy scientifically and managerially, but there is a subset of them that are the ones that you save to the last because they are the least important under tolerance reassessment.

MS. ROSSI: Yeah, I think in the whole universe of REDs, if for those of you who remember the original list A, B, C and D, with A and B having sort of the ones that were -- or had the perceived worst -- or potentially worst, I think we have something like 12 remaining on list D that need to be done. And 20 odd on list C. So -- and if you take away the OPs, actually, A gets into almost like 50 or 60 left that we would have.

MS. MULKEY: So of the 177, there's a meaningful percentage that are hard and big work, but it's not a 177.

UNIDENTIFIED FEMALE: No.

MR. AIDALA: For example, if that's about 40 or so OPs or 35 or so, 40 plus are anthomicrobials (phonetic), 30 are list C and D. Certainly, that's to be subtracted, if you will, under that kind of accounting from the 177.

UNIDENTIFIED FEMALE: Right.

UNIDENTIFIED FEMALE: So, I guess, just to clarify, when you say that we had a very good year with 19 per year, this isn't to say that these 177 will take, and I have not done the math, but 19 per year of these --

MS. MULKEY: Eight or nine years, no.

UNIDENTIFIED FEMALE: Yeah.

MS. MULKEY: That's not to say that. That's part of the message I was trying to send.

UNIDENTIFIED FEMALE: Okay, that's what I thought.

MS. MULKEY: We are, as Joe said yesterday in his presentation, we are planning on a -- on the FQPA statutory time line basically. And we are planning to integrate RED completion with tolerance reassessment completion on that time line.

MR. ELWORTH: But we're not on that 4,030 schedule we were a few -- what was the number --

MR. AIDALA: Yeah, 22 hundred or something like that. The number I estimated before I had this job.

MS. MULKEY: And of course, you're the reason why it's so different story today?

MR. AIDALA: Why not. I'll let you think that.

UNIDENTIFIED MALE: A lot of memories.

MS. MULKEY: Okay. Very good. But anyway, I just -- Jim was telling me we needed to be able to send that -- we need to be transparent on this, including the

fact there is still quite a lot of work to do. Don't misunderstand me. It's not all just moving boxes. Adriana, did you have more or are you --

ADRIANA: Oh, no. I'm sorry.

MS. MULKEY: Any other? Well, that's fine. I think we can move directly into our discussion of future PPDC issues. Now, we've heard a lot about work group/workshop, deeper, more comprehensive.

I'm choosing to hear all of that as not a single message, but as a mix of messages about interaction and -- because we are going to be selecting members as well as planning agendas and timetables, and because our timetable is obviously appropriately integrated with the CARAT timetable, I told you what I know about it yesterday.

We would welcome your feedback about topics and issues, about scope, about membership and about timetables for this advisory committee, including the whole question of should we continue to pursue this advisory committee.

Obviously we've decided we should, or we wouldn't have done a call for membership, but any subject

is open for this session. So, have at it. Wow, you guys are really in a hurry to leave.

UNIDENTIFIED MALE: So when is -- what's the deadline for submission of interest to --

MS. MULKEY: I believe it's December -- December 27 sticks in my mind, but it's in the FR notice. It's about a month from when it's issued.

I have -- I think I said yesterday, in addition to indicating whether you personally wish to continue, you might want to indicate others that you think would be appropriate and interests or points of view, bearing in mind that you all tell us and we concur that the scale of this advisory committee is very -- it works. But you pay a price for this scale.

And the price is that we don't have a lot of -- I mean, agriculture is incredibly diverse. You cannot represent the range of agriculture in this room. The non-agricultural pesticide using sector is incredibly diverse. You can't probably represent it in this room.

The public interest community is -- is itself no one speaks for all. They bring different interests to the table and they feel -- we all feel resource

constraints. They seem to have fewer numbers and it's sort of obviously apparent that they have fewer numbers and that creates some special strains.

So if they're to be -- if their voices are not to be crowded out, and if they're to have sort of an -- that's sort of a critical mass of points of view, then that limits it. So there are a lot of factors. I'm filling time, hoping somebody will put up a --

(Laughter.)

MS. MULKEY: Warren.

WARREN: Well, in the spirit of looking at tolerance reassessments, as we look down the road to 2003, 4, 5 and 6, there are roughly 771 food use inerts that are going to have to get reassessed from a tolerance point of view.

That affects every single food use product that's out there. And the registrants and the inert suppliers, I think, really need some lead time and some guidance from the Agency as to what we might anticipate in the area of tolerance reassessment for inerts.

There is going to need to be business decisions made. You're going to have to cost out the data or the

information. You're going to have to have some kind of a time line to complete studies and work on that. No one's figured out a way to do a year's study in six months.

So the bottom line is we need as much lead time as we can. But we have a very complex set of issues. And we certainly don't want to have 771 task forces out there, each generating their own data. So we need to think of ways of cost-sharing and grouping and putting families together.

I think we need to try to set some priorities in those 771. Which one do you want the first year, the second year, the third year and the fourth year? I think it's also important to look at that timetable.

But I also think we need to try to coordinate with other data generating issues that the Agency is involved with, such as HPV and other programs so that there's a coordination of tests and protocols so that we're not wasting time, effort, research --

(End of Side 1 of Tape 2.)

WARREN: -- inerts. And raises ultimately the question dealing with transition to other products and substitutes for those that you are, in fact, losing.

So there's a long series of, I think, complex and complicated issues. And yes, 2003 sounds like a long way off, but we're already working on the 2002 budget and that time is really very short.

So we're really looking for some guidance from the Agency as to how we might proceed in trying to address some of the issues or concerns that are going to be raised and would certainly recommend that perhaps we put a topic like that on our next PPDC meeting and have a briefing on that as to where we're going.

MS. MULKEY: Well, as you know, we have inert that's been an issue that this committee has at least spent some time with. Not just inerts disclosure issue, which is an important one and has a work group, but you remember we did discuss all the inerts issues.

There's some data compensation issues and others. If this committee is interested in sort of un-owning the inerts issue in a robust way, I think we have thought in the past that it was an appropriate forum and we continue to think that. So any other reactions to that would be welcomed to hear.

I think Bob had his tent card up next, but Bill

seems to want to speak something that's more immediately relevant.

MR. McNALLY: Yeah, Bill can go. I was just trying to help you out. Yeah.

MS. MULKEY: Yeah.

BILL: I wanted to talk a little bit in general about the value of PPDC. And specifically to Warren's point which is one the things I'm concerned about is this impending data call-in on inerts and the data requirements in that.

And what that looks like is something that seems to be bubbling up and we weren't really hear -- we were here bearing different venues, very scary, very, you know, demanding on these chemical producers in terms of generating data.

And that seems to lack transparency to me in its evolution. And I would have -- I mean, if it's coming out next month having it be a PPDC issue at this point seems kind of late. But to Warren's point, I think it's a huge issue that needs to be addressed.

If this is the right forum for that, great. But it needs to be addressed in some manner. I think you do

need to hear from stakeholders on it.

Okay, having said that, I have found my experience on PPDC has been incredibly enriching. You know, personally coming from the non-ag side, being able to hear the breadth or the scope of what you guys have to deal with in an agricultural sense. And on a lot of different things, I've learned a tremendous amount.

I think my frustration has been of what value do we provide to the Agency, or what do you ask of us. I mean, we come, we spend a couple of days. I learn a lot. I communicate a lot back to folks, but I kind of at the end of the day wonder is this -- what is the value to the Agency. Do you want more out of us?

I think the work groups look like a very good mechanism of getting product, where the committee seems advisory. You get maybe richer work out of these work groups. And if that's a mechanism -- if the committee is a mechanism to have the work groups, then I encourage us to keep that going.

But I am wondering, you know, what value do you guys get out of hearing from us?

MS. MULKEY: Do you have any thoughts? We've

talked once or twice about our giving you feedback about what we heard and how we reacted to it. I actually made some little feeble attempts to do a little bit of that just in the course of this meeting.

Mindful that that was -- but if you have any thoughts either here or later about -- we actually do benefit enormously from hearing your perspectives. And some of it influences the way we write our documents or the way we choose how to spend our time and I'm not sure we even have a conscious, full awareness of the link between the kind of feedback we get here.

You know, we go away, say we're hearing these things. And we may not remember whether we heard them here or somewhere else and they influence them. So I'm not sure we can have a perfect feedback loop, even if we tried.

We would probably understate the extent to which we are relying on you. But if you have any thoughts about how -- I mean, what I think I hear you saying is you're afraid that your input to us just goes into a black hole and you have no clue about whether it's valuable.

UNIDENTIFIED MALE: I don't fear that. I wonder -- and I'd actually like to hear from others on this who have been on the committee for a while. Do they -- is it a reciprocal kind of relationship. I mean, it's certainly -- I learn a lot. There's a lot of education, there's a lot of information download that happens here.

You know, we tend to then throw out some thoughts back to you guys. So is that good enough?

MS. MULKEY: We experimented a little bit in CARAT with having members prepare and present things like we did. But you know, obviously on somewhat different topics. So, in effect, you began to educate us and each other.

And it was a little bit more sharing of and maybe -- and part of what I think I hear you saying is you feel that a certain amount of what you do is seat of the pants. It's less prepared. It's more reactive, and that given a different subject area, you might --

UNIDENTIFIED MALE: This is a -- you know, I don't know if Bob shares it. I mean, this kind of easy deal for me, anyway. I fly in. I sit around. I go home.

MS. MULKEY: You didn't have any homework.

UNIDENTIFIED MALE: No, there's no homework. You know, and you guys are working and putting together and to your point earlier, sharing a tremendous amount of the burden in this thing. And that works for me if it works for you. But if you want something else, I wouldn't be afraid to ask for it.

MS. MULKEY: Okay, that's helpful. Bob.

MR. McNALLY: Well, you know what, that's the California way of saying the same things I was going to say.

MS. MULKEY: You would say them with a lot more intensity then, right?

MR. McNALLY: I would have more of a New York approach. But it was very thoughtful and caring.

(Laughter.)

MR. McNALLY: I want to hug you.

UNIDENTIFIED MALE: Kumbaya.

MR. McNALLY: I just want to offer an opinion. And the opinion is that I guess, I see the Committee as serving two roles. One of which is for us to come to you once in a while and say, gosh, you know what, there's

this issue out there. You people aren't paying enough attention to and this is like a great opportunity for you to create some process for that.

And residential exposure, I think, was an excellent example of that being done. I thought, though, from the beginning the more important role for this Committee was to be something like a SAP-II. It's like a stakeholder advisory panel. It's in the nature of what you do that you have to confront contentious issues.

And I guess the normal course of dealing with those issues in the absence of fora like these is that you just sort of do things in back rooms and people suspect that you did them for all the wrong reasons. This creates and opportunity for you to get some honest feedback and some public process and open discussion of difficult issues.

So I kind of see this as a place where you come to us with your concerns and we create some opportunity for you to discuss them in a public way. And I think it's been successful in that regard.

MS. MULKEY: Okay, Adriana.

ADRIANA: I was actually going to second the

suggestion on looking at inerts, not only for inerts, but I mean in continuing along the lines of the whole tolerance reassessment process.

I think it would be a good idea to have the PPDC take part in the planning so that this work does get done in time to facilitate things for EPA and for those who are going to have to be submitting the data. So I would just second that. I think that was a good suggestion.

MS. MULKEY: I should react to what Bill said. Whatever initial data call-in might be issued whenever it's issued, that's certainly not going to be the end of or necessarily the biggest chunk of the issues that will come up with inerts. So I don't think that should that occur between now and the next meeting that would mean that this issue would be moot or sort of too late.

BILL: Well, just specifically to that point, if I may. There was a meeting with the biocides panel with Rob Forrest and the folks who were working on this DCI a couple of days ago, and their feedback to him was have you coordinated these data requirements that you're thinking of for these inerts with the HPV program and they're barely aware of the HPV program, so --

MS. MULKEY: I think that was misleading. Susie's been working on this. She might tell you a little more on that.

MS. HAZEN: I'm surprised that that was the response --

BILL: That's what I heard. I was not there for those here.

MS. HAZEN: Oh, we have been working very, very closely with OPPT on the HPV program and in fact, are this close to being able to issue publicly a matrix of the testing requirements for the various HPV programs all along the lines to the kids testing program, the overlap with DCIs and what that might be. So it's very active and very coordinated for about the past six to nine months.

BILL: Yeah, the word that -- that's great. I mean, the word I heard was that the data requirements were going to be different and that they weren't coordinated. So I just --

MS. MULKEY: Go ahead.

MS. HAZEN: There certainly may be differences in the data requirements between a voluntary program like

HPV and data call-in requirements.

What I am saying is that our efforts here have been to lay out very clearly for the participants in the HPV program as well as those who may be subject to DCIs and those who want to participate in any of the other HPV kind of voluntary programs, to lay out -- if you think you're going to be covered by the DCI and you want to participate in the HPV, here are the data requirements for both of those.

Here's the overlap. If you want to be covered under both programs, do this. If you're only interested in HPV, do that.

BILL: So I can talk to you more about that.

MS. HAZEN: Absolutely. Please feel free.

BILL: Okay. Great.

MS. MULKEY: But one of the -- it is evident that we have a transparency need if nothing else.

BILL: Right.

MR. ELWORTH: What is HPV mean?

MS. MULKEY: High Production Volume. It's a program for non-pesticidal chemicals as well as pesticidal, I guess. But --

UNIDENTIFIED FEMALE: It's the 12 hundred -- not 12 hundred. The high production volume chemicals off TRI for which the basic data set has not been developed over time.

MS. MULKEY: Because you know pesticides are the most tested chemicals of all, with the possible exception of drugs. And this is an idea of beginning information on other kinds of chemicals. But it is a voluntary program except that I think it's going to be -- become a regulatory program, right?

BILL: There's a component of it, a kid testing rule, which will become --

MS. MULKEY: Will become regulatory.

UNIDENTIFIED FEMALE: Probably.

UNIDENTIFIED MALE: And does it include a lot of inerts, or not?

MS. MULKEY: There is some overlap with inerts. I guess there's no overlap with actives because they're all tested. Yeah.

ADRIANA: I just wanted to conclude my statement real briefly.

MS. MULKEY: Sure. Absolutely.

ADRIANA: I think that the importance of keeping our eye on that part of the inerts, I think it does relate directly to the work group on inerts. Because the work group and the people who I've talked to on the work group are concerned with also how the data call-ins are going to be done and whether or not that's going to end up being part of the disclosure or dictate what's part of the disclosure or dictate if it even is going to be a part of the disclosure.

So I mean, I don't think we can really separate them. So it would be important to have -- rather than have -- send off a work group and then come back with a lot of criticism really integrate that portion into it.

MS. MULKEY: Interesting. Jay.

MR. VROOM: I'd strongly advocate that the PPDC not just for the next meeting, but at every meeting have on the agenda some time associated with the big picture. We talked about, you know, earlier, what percent of OPP is dedicated resource for worker protection and how does that look over time.

I think if PPDC regularly looked at that sort of big picture, resource allocation in a little more detail

on a regular basis on achievement of goals that Joe Merenda talked with us about yesterday afternoon. If you made that a regular feature to allow us and I would imagine it would be helpful also for you, on the Agency's side, to continually get in the habit of looking at that big picture.

Because there is so much detail that you can in any one program area, you can fall into that and never come out of it. And I think it would be very helpful to always keep as a regular feature of every PPDC agenda that big picture scope look updated.

Keep it into the continuum perspective because you know, a number like 850 people on the OPP payroll doesn't mean much unless you know how many that is compared to a year ago and what you're anticipating, and that 200 of them, you know, are, quote, at risk, because of the uncertainty of the re-registration program reauthorization and so on.

I think all of that is very important, but it needs to be put into that larger picture in continuum.

MS. MULKEY: The kind of thing that Joe Merenda presented yesterday, is that the kind of thing you mean?

MR. VROOM: Well, except for the fact that I even forgot to ask him what your budget this year. You know, what's the total dollars. Yeah, that's subject, but with more complete detail and perspective, I think.

MS. MULKEY: Okay.

MR. VROOM: And I've got a couple of other issues, but not really at sort of the level of agenda for the next PPDC meeting.

MS. MULKEY: Well, do you want to go ahead and mention them?

MR. VROOM: Sure. We have a growing concern and this doesn't relate to OPP, it's OECA. The reduction I think, now, to the number of staff dedicated to GLP enforcement inspections has been cut by 30 percent. And you'll probably tell me that's in part because Carol Browner had to find money to make for the seven million dollars.

MS. MULKEY: There probably is some relationship between those two facts.

MR. VROOM: So I'll save you from having to make that statement. But it's creating now a significant problem for companies trying to market pesticides in

other countries that traditionally have deferred to and accepted U.S. GLP laboratory test data.

More than one -- we've had one problem with one South American country in particular over the years with regard to acceptability of U.S. and European laboratory data. But it's really spreading now because of this reduction in the amount of staff that are doing GLP inspections and just raising questions in the international community about the credibility of U.S. based test data.

And I think that's a problem that needs to be addressed. And I'm sure that OPP has an interest in that, even though this is not your direct line authority. So that's one issue. I don't know if we can talk about that now.

MS. MULKEY: Let me answer that very brief. We've shown an interest in that in some very particular ways. I'm very careful not to air internal agency deliberations publicly. But we've shown an interest in that. Have you attempted to engage OECA senior leadership on this topic?

MR. VROOM: I think we have, but probably not

effectively and probably not on this most recent level of concerns.

MS. MULKEY: Well, one of the things we can do is offer our offices as -- so we could meet jointly with you if there was that. (Inaudible).

MS. LINDSAY: Well, I was going to say, not the senior most level, but at least at my level, there actually have been meetings and discussions between OEKA, OPP and ACPA. It's not that we've solved the problems yet.

MR. VROOM: Right.

MS. MULKEY: But you've met with ACPA on this topic?

MS. LINDSAY: On this very, very topic. And we've talked about some possibilities of what can be done on the credibility front, not so much on the OECA resource problem.

MR. VROOM: Right.

MS. LINDSAY: Which doesn't mean that it can't usefully be raised to higher levels, but I thought it would be helpful for people to note that there's already a discussion ongoing.

MS. MULKEY: I did not know that. I was -- I mean, I've offered some memorandum and so forth. But that's helpful to know that that's and important -- I think we have a meeting on that tomorrow, too, with another interest group.

MR. VROOM: What are there, like 1,500 laboratories in the United States that are GLP. I mean, it's a big job.

MS. LINDSAY: Yeah, I mean, this is actually, I think, in a way a chronic problem in that for countries who want like regular annual GLP certification of laboratories, there's never been the resources I think since we've had a GLP program to do that level of inspection.

We've piggy-backed on some FDA resources, but you're still not going to get to every lab every year, or every lab every other year, or every third year.

MR. VROOM: We think with six employees in OEKA doing this, that you know, they can do maybe 25 or 30 a year.

MS.LINDSAY: Yeah.

MR. VROOM: And there's 1,500 or so.

MS. LINDSAY: There's a disparity --

MS. MULKEY: And always has been, is what you're saying.

MS. LINDSAY: Yeah, and Jay is right, though, that there is some of the recent reorganizational efforts have diminished still further the level of resources there.

MS. MULKEY: And you had another item?

MR. VROOM: The 2001 company/agency priority list, we are confused by which is which and how the list got created, quarter by quarter, that Jim Jones has shared with us recently and would like to have a little more conversation on that.

MS. MULKEY: Yeah, absolutely, you're always welcome. J.J.

DR. STEINBERG: Kind of hitting the agenda items for 2001 and beyond. To me there were three high points and a number of other smaller areas which I think will evolve, but all very important. As I promised the data center, and you need some central repository that will supply the -- you need the perfect data page, the perfect inventory. I think you should continue to strive to do

that to make that available to everyone. I think it would be helpful to the public, helpful to academia, unquestionably helpful to industry. If they had the basic data, then everyone can contest whatever models they want, but the data has to be easy, accessible, user-friendly and of course, as we said, the perfect data center.

UNIDENTIFIED MALE: Free, right?

DR. STEINBERG: Right.

UNIDENTIFIED MALE: Free?

DR. STEINBERG: But of course. Free, means that they're coming out of the pockets of 275 million Americans, all of us included. Labeling is coming back. And labeling is -- we spoke a little bit about it. I suspect that as time goes on, labeling will be as important to everyone as it was to the industry, to the American public, and to the EPA as it was when FDA went through this.

So I think everyone needs to understand that this is going to happen one way or another and I think that's going to move along. I would not be surprised if in two or three years, you have 50 people working on

this.

MS. MULKEY: Are you talking about ingredient labeling?

DR. STEINBERG: I think ingredient labeling for consumers, to make this available just like the FDA made this available. As you well know, and I hate to mention it, this was a multi-billion dollar cost to everyone involved. It is going to happen. I think it's a good time to start thinking about this across the board.

To me, one of the more exciting things that was revealed was this EUP process because I think it's one the future thinking processes that you know have with industry and with the EPA. It's a wonderful opportunity to get novel products and new ways of using products into the pipeline. Any way that you could expedite that would be terrific.

It's a way of catalyzing the next generation of products that people will use which will be better and safer and anything that you do that, I think is future-forward thinking stuff. And I view that as very exciting.

Smaller things, I would have liked a report,

even 15 minutes, on kids. That should be, Jay mentioned, kind of reports as it relates to big picture stuff. That was on my list. I'd like to see things related to kids. I loved having ORD here. Again, a 15 to 30 report is a minimum from ORD.

Obviously, the worker related issues, if we have big issues related to that, we need to discuss it. If it doesn't make a PPDC agenda, it should still be put on -- de riguer -- so that we can at least know what's going on.

As Phil mentioned, we also need a technology wizard somewhere in here to make sure that we can get this information out. Maybe actually do this in real time. Maybe make this available to many constituencies across the country. And I think that technology is available and I think that would be a great thing to do.

And, you know, I think the PPDC with the work groups and with other potential workshops, I think it delivers a very good product. I like the products. I like the stuff that the rodenticide group did. I think the committees are doing a good job in delivering on what the PPDC should do.

And therefore, I think, it should be encouraged. And obviously the staff did a great job in putting it together.

MS. MULKEY: Hearing you -- we haven't -- EPA has a new Office of Environmental Information. One of the primary purposes of which, as I understand it, is to provide a central focus to the development of data, the making publicly available of data accessibility of data, so among of the things we might facilitate your ability to engage with that office, as with ORD. Hear straight from them. Dan, I believe you were next.

MR. BOTTS: Looking around the table and recognizing only probably four people who sat down at the very first PPDC meeting back in 1995, right after the shut down of the government, infamous shut-down of the government, consider this gray beard concerns and whether or not I volunteered to up for another term or not is going to be totally contingent on whether my boss feels he can justify the 200 segments a year on Delta flying back and forth to Washington at our expense, by the way.

Just to bring some of the issues here today, one of the frustrations that I've had over the history of the

organization is I don't think we've ever been utilized to the degree that we could have been utilized to help the Agency work through some of the more controversial issues that have come before.

Not just tolerance reassessment and FQPA issues, but other issues that are out there. And somehow the work group mechanism, some of those kind of things need to be fuller -- more fully developed, but it needs to be developed with the help of the PPDC members. We need to help you drive that process forward rather than relying on staff resources at the Agency to do that.

And toward that end since we hammered the worker part of it almost ad infinitum earlier, I'd like to suggest that there be a -- essentially a three or four member group put together of PPDC membership to help frame how we would like to see this whole worker issue brought forward. And maybe have that as a work assignment between now and the next meeting.

And at the potential expense of the wrath of my boss, I would like to volunteer to participate on such a work group because it has been something that has in a tremendous -- or focus group or whatever you want to call

it -- to bring that issue back to this group to see, explore how to move forward.

Some of the other issues that I think we need to be advised of, and I really appreciate the presentation by ORD and the Research Triangle Park Scientists on the risk assessment information and that health based information that was provided yesterday, but there's also other research efforts at the Agency, the Environmental Fate Lab out of Athens and the Cincinnati lab that looks at anti-microbials and efficacy testing, some of those issues.

I think some of those things would be as interesting as the human health effects information if we could just get brought up to date on what those labs are doing in support of the programs and the decision process at the Agency.

And just to hit on one particular point, the presentation yesterday was amazing. I really enjoyed that. But I think it would almost worth a field trip down to their facility where you could get the individual scientists that are directly involved as well as the person overseeing it.

So -- and have more of a real informational distribution so we really see what information is being generated, and beyond just the summary scope of the information. That would -- I think that's almost worth maybe on an invitation basis, if you want to come, come.

And we'll set it up, or facilitate setting it up and then have that kind of discussion. I think you'll get almost as large of an attendance at that kind of meeting as you would at a formal PPDC meeting.

Recent PR notice on what was advisory language versus enforceable language on labels. The Consumer Labeling Initiative dealt with one segment. I share a tremendous level of frustration with my membership on ag labels and in being able to read and understand what they actually mean, both from a use instruction standpoint, as well as the environmental fate, restrictions and those kind of things.

I would like to see a discussion of that whole issue and the process because some of the labels that are out there now, if you read every word on there like you're supposed to do, they become contradictory to a large degree.

And I'm not real sure that in some cases that it's -- based on the label language that accompanies the product, that you could actually apply the product in some locations, in particularly Florida.

Harmonization issues, we had a meeting with some -- with an ACPA Committee on Tuesday afternoon discussing harmonization with Canada or the NAFTA process. And there's some labeling issues there, some worker issues, some other things. It would be real interesting in the long term focus of where impacts on OPP programs.

That whole harmonization issue, not only with the NAFTA process, but OECD and EU issues and those kind of things, there's a whole universe of emerging things that come out of those type discussions that I think this group needs to at least be briefed on so that they understand that those are potential impacts as well.

What else? I think that pretty well covers my list of agenda items and issues. But I just -- I would really like to see this group become much more active because of the discussion potential that you get in a smaller group.

There's a lot more in-depth, relevant discussion

than you get at larger group, larger advisory group type efforts. And I don't think we've fully reached the potential of this group because of how we function and the structure and the process. And I'm going to put some of this in writing and get it to Margie, even though she's tired of getting e-mails from me.

MS. MULKEY: Well, that's good. That's helpful. We're trying to take good notes, but let me come back to the first item you mentioned which is the worker issue. And what I understood to be some interest in PPDC, my word, owning the worker issue to some extent and from the standpoint of Agency advisors. As you know, since you're a member of CARAT, there has been a lot of vocal interest in having that advisory committee embrace the worker issue. We've not instantly accepted that, in part because it is not within the subject matter of tolerance reassessment or transition, at least not directly.

Do you think, through your good offices or others, the ownership of that issue in organization as it relates to advisory and stakeholder pieces, would substitute. Because otherwise, I mean, we're going to be looking at, you know, all the things you suggested and in

effect, to repeat them or double work them or something in that forum as well.

MR. BOTTS: Personal opinion. There's so much cross over representation between the two groups. You've got a core group of people that are on both groups. And it almost depends on how it's structured and how it goes forward. I don't see that there is absolute ownership in either place. I think that the actual work group aspect and getting the understanding and getting it through the process probably does more appropriately reside with PPDC than it does with CARAT or any of the other FQPA advisory groups just because of how those were structured and what they were directed to. But that's not to say that it wouldn't become an agenda update item for CARAT to say this is what PPDC is doing. We'd like your advice on whether we're addressing the issues that you want to go forward with. It's not an either/or type situation in my mind just because of cross over --

MS. MULKEY: Do you think there's a workable way to keep --

MR. BOTTS: I think so. But I think you've got to get more ownership at the committee level of the issue

in framing the process rather than coming in the way we have.

And that's why I think it's going to take a little bit of work and a little bit of effort to get down a straw document that says this is what a subset of this group thinks needs to be done to really get it to the point where we're not doing a presentation that we're going to end up having more questions on afterwards and more focus to make it more meaningful, to get it directed into a direction that can really be meaningful to the largest audience possible.

MS. MULKEY: And let me ask you one more question on that topic. If we were to start that exercise by asking a group from this membership, mindful as well that this membership as PPDC membership is going to come to a close and we'll have a new membership, which may have the same bodies, but legally is a new thing. But if we were to start by asking that group to engage in the exercise of planning the workshop that we've already announced, would that be a productive first step?

MR. BOTTS: It depends on how far the planning process has already gone on for the workshop, itself.

MS. MULKEY: Not very far. I can tell you that.

MR. BOTTS: Then it probably would be extremely valuable, no matter whether the people that were involved in the planning process of the existing PPDC now are still on the PPDC down the road. I don't think that makes any difference.

MS. MULKEY: That's helpful. Thank you. I think Beth and then Larry, and then Jay, I think.

MS. MARSHALL: I heard Dan say that it's been five years since we started this committee.

MR. BOTTS: I think it's six. I'm not sure. It might be --

UNIDENTIFIED FEMALE: It was formed in '95, but there was a --

MR. BOTTS: A gap before it started.

UNIDENTIFIED FEMALE: -- because the government went down for a while.

MS. MULKEY: Two or three weeks.

MS. MARSHALL: You know, time flies when you're having fun, I guess.

UNIDENTIFIED FEMALE: I know, but the funding to do --

MS. MULKEY: I see.

MR. BOTTS: We got delayed by six months from the first meeting because of a three month delay in dollars coming out of budget.

MS. MULKEY: I see.

MS. MARSHALL: So I also want to echo some of the things that Bill said. This has been a tremendous learning experience for me. I have found myself over the years always fascinated by what we talk about. Frequently, very impressed with the quality of work that OPP has done and continues to do. And sometimes, infuriated and appalled at some of the things I hear. I think you should demand more of the members of this committee. I was active on two work groups very early in the process. One designed a the infamous brochure that went to --

UNIDENTIFIED MALE: Never to be seen, I'm sure.

MS. MARSHALL: Well, yes, I haven't seen any, yes.

MS. LINDSAY: It's right outside, excuse me. It's right outside.

UNIDENTIFIED MALE: The store.

MS. MULKEY: The store, he said.

MS. LINDSAY: No, it's been sighted in the store.

MS. MARSHALL: A remarkably liberal store owner is all I can say.

UNIDENTIFIED MALE: It never made it to the west coast.

MR. BOTTS: It did make it to Florida. It's in supermarkets in Florida.

MS. MARSHALL: But that thing is -- one of the things that came up during that process was that this was to be the beginning of an outreach, OPP outreach to the general public. You have tremendous communication with the direct stakeholders, the users and workers. But the general public, I think, is still pretty oblivious to what you do, and that's unfortunate for you and the general public, too.

So I would like to see a topic, you know, where have we gone since the brochure. What's happened since the infamous brochure and should there be more infamous brochures out there.

The other work group I was on was the ecological

standards work group. Now, the ecological standards work group had a lot of homework. They actually, probably had about six inches more paperwork then the rodenticide work group had to read. And I think we all felt good about what happened at that committee. So demand more. Don't be afraid to ask us to do homework.

I guess that's --

MS. MULKEY: Okay. Thank you. Larry?

MR. ELWORTH: A couple of things. One is -- well, several things actually.

MS. MULKEY: What I want to know is can we meet in Boone?

MR. ELWORTH: Sure, sure. Come into Asheville.

MS. MULKEY: I love Asheville.

MR. ELWORTH: One is I would echo what Dan said. I like -- well, a couple of people have noticed who aren't members of the committee, but noticed the difference between this committee and CARAT and the ability for people to be able to talk across the table to each other rather than just to the Chair. And also to the extent to which people do not have prepared statements coming into the meeting as often happens in

CARAT.

MS. MULKEY: Do you think it's a function of scale or a lot of other things?

MR. ELWORTH: I think it's a function of scale. I think this committee predated some of the political attention to the issues that subsequently happened from Food Safety Advisory Committee on.

But I also think it's the issues, too. They tend to be more technical in nature. And I actually wish we had a better fight on the inerts thing. I think that was shaping up. I think we could have had a better argument going on. I'd like to see more of that.

MS. MULKEY: You like the little flavor that you got.

MR. ELWORTH: Right. And as probably the most significant source of Beth's frustration and irritation, I'd like to see more of that, too, so --

MS. MULKEY: Why not.

MR. ELWORTH: One thing on work groups and it goes back to, I think, all the work groups, I really support and maybe expand on what Dan said as far as when we set up work groups.

I think it's real important, a real useful step in this would be to have a relatively, a committee of only PPDC members to sit down and really talk about outlining the scope of work or charge for the committee before you bring in lots of other people.

I think that would make it clear what it was that people wanted to accomplish from it, and also give some structure to the committee. So it's a more direct process. You can get from one place to the other. I think that would be real helpful.

I do appreciate your raising the issue of the intersection between CARAT and FIFRA and I think there may be other issues and maybe residential is one of them in which the focus from PPDC -- focus at least on the issue in PPDC is a more natural fit over a longer period of time than with CARAT.

And I do think it's possible to focus on an issue here and then brief CARAT on the deliberations and maybe engage that committee as well. So I don't think that's especially difficult conceptually for people.

On issues, I would like to see PPDC focus in whatever way is appropriate on worker and residential in

a substantive way, you know, on the risk assessments in particular. One thing that came to mind as we've been talking about worker is -- and I think there was some international programs on worker.

And there was some junk that I couldn't go to when I was in the government to Costa Rica which really disappointed me. But there is some international stuff the Agency is doing on worker protection, if I'm not mistaken.

UNIDENTIFIED FEMALE: That's right.

MR. ELWORTH: And I think that's pretty interesting work.

UNIDENTIFIED FEMALE: Yeah.

MR. ELWORTH: That's in the larger context of the international program.

MS. LINDSAY: We're doing some specific stuff actually through NAFTA. The literal worker protection stuff is primarily focused on U.S./Mexico.

MR. ELWORTH: Right.

MS. LINDSAY: The applicator/handler stuff at this point is primarily focused U.S./Canada. But in both cases, we've also talked about, at least over time,

making it sort of a full tri-national continental approach to an integrated worker safety program.

MR. ELWORTH: I mean, that's not a pressing issue, but it's one of some interest. And by the same token, we haven't talked about harmonization efforts on the registration side with Canada in quite a while.

MS. MULKEY: We can mention that --

MR. ELWORTH: Yeah, and I think that's worth doing. And the other thing that I -- we haven't talked about in a while is the extent to which on some of these FIFRA issues the Agency is looking at, in quotation marks, benefits assessments, and how that's -- I mean it's -- I mean you've got plenty to do, but I'd be interested.

And I think it also has some bearing on the way the department's really reordered its data collection process to make it more accessible and relevant to the agencies' uses. So I think it would be a useful conversation between USDA and EPA.

And actually, one of the things I was going to ask you if you would do, just briefly, you went through a schedule yesterday of kind of the up-coming events with

CARAT on the work groups.

MS. MULKEY: On a couple of topics.

MR. ELWORTH: Could you go through them.

MS. MULKEY: I guess I could that right now because it's not that long.

MR. ELWORTH: Please.

MS. MULKEY: On CARAT, the things I mentioned were a two workshops and two work groups. A work group on public participation and transition. Sort of the public participation process issue and transition. Apparently we are looking to solicit participation on that very quickly. And the idea is that it might meet is in late February and that's because it would be in conjunction with when we think we would have the first CARAT meeting.

MR. ELWORTH: You're thinking the next CARAT meeting would be late February?

MS. MULKEY: February, and that's what Mike McCabe said. And again, that's obviously a little tricky date to commit to for obvious reasons.

MR. ELWORTH: Right.

MS. MULKEY: Assuming that CARAT continues as

everybody anticipates it will, to involve the senior political leadership. But it's obviously possible to have a meeting in which people acting in those positions are included.

MR. ELWORTH: Um-hum.

MS. MULKEY: The work group on cumulative -- that was cumulative. I said transition, but I meant cumulative. Oh, I'm really messing up. I'm tired. I'm looking at the work group on cumulative would be to meet in January to get started. And that's the one in which we have early solicitation and to get started. The work group on transition would have the meeting in February, consonant (phonetic). In fact it's somewhat of a cost saving, too, of everybody. Not just of our travel costs, but everybody's costs and time, to have it with a meeting. So cumulative gets started early because of the public participation process needs to be ready for the risk assessment. And so the idea is to get that started so that we can combine those in time. And I think the USDA has been particularly active in urging that. So the cumulative work group gets an early start. Transition work group, a little bit later start. The two workshops,

the worker one, as I said, we were planning on holding off until March because we have these other workshops on the worker protection program. And that's also consistent with the idea of having some planning time. And the other workshop is on --

UNIDENTIFIED MALE: Drinking water.

MS. MULKEY: Drinking water. And I believe that's for early January. We were actually prepared to do it in December. And I think we were lobbied by some of you --

UNIDENTIFIED FEMALE: By the CARAT members.

MS. MULKEY: Oh, the CARAT members, by some of the CARAT members that that was just -- wait until January. So that's January. That workshop we're going to -- you know, take some of the lessons we heard from you guys about making it as meaningful. One of the things I'm curious to know was whether some kind of break out groups as part of a workshop get you a little more of this flavor of a work group meeting and so that's one of the ideas I took away from this is I don't know how many of you attended the cumulative. It was not really a whole day. It ran until about 2:00 or 3:00. If we

really did a whole day, we could have had sort of a morning deep downloading, a two hour work group and then some. So, you know, if you're really make these a whole day, you can do some things to try to make it more meaningful. So that's one of the things we'll try to factor into that.

MR. ELWORTH: I would to the extent that it's possible would urge to do the worker as soon as possible since those assessments are ongoing.

MS. MULKEY: We understand. We talked about that in that trade-off and the importance of that. That's why I also heard you -- I think the case study which is the -- appears to me to be the single best thing to do around transparency.

I think we're going to look for an opportunity, whether it's a technical briefing that we just say we're going to do an extra, you know, period on worker, case study, or whether, you know, time it so it's the same people and the same case, or something else. And I'm just doing this off the top of my head.

UNIDENTIFIED FEMALE: I think their input is needed to help us --

MS. MULKEY: Oh, I know so --

UNIDENTIFIED FEMALE: -- to figure out what it is we're not --

MS. MULKEY: -- a case study. Right. But I think we're going look for some opportunities to get some things going on transparency, at least.

MR. ELWORTH: Yeah, and I would at least to the extent my sanity is possible --

MS. MULKEY: You're going to volunteer, too?

MR. ELWORTH: Yeah, I mean I took seriously what you said. If you all want to get this work done, could you all pitch in a little bit?

MS. MULKEY: Yeah.

MR. ELWORTH: And the other thing is I appreciate having USDA here. I know that when we set up PPDC, it wasn't -- this is different from CARAT in the sense that it's not the two senior leaderships.

MS. MULKEY: Right.

MR. ELWORTH: But I think it's real helpful to have USDA here, both its representatives and I really appreciate that.

MS. MULKEY: I do, too. And FDA and you know,

perhaps, sometime CDC. And I think we offer to you guidance of whether we ought to do more to share the leadership of some sessions with other federal agencies. So if you have input or thoughts about that, I think we're open on that. Jay?

MR. C: I liked Larry's idea about focusing on benefits. And I would suggest that maybe that be a regular agenda item. Some segment at every PPDC meeting to talk about the benefits because almost everything we talk about relates to risk assessment, risk management, risk mitigation.

And I'm trying to get out of that discipline, just internally. So I think that would be a healthy thing to strive to try to do. Not to manufacture something, but just to make sure we're thinking about that side of the equation all the time.

MS. MULKEY: The very brief presentation we had yesterday on use and usage --

(End of Side 2 of Tape 2.)

MS. MULKEY: -- effect of that makes sense routinely.

UNIDENTIFIED MALE: The other topic I don't

think I've heard mentioned which is reemerging and the representative from the City of Seattle mentioned salmon yesterday. But the convergence of pesticide regulation and the Endangered Species Act is coming back around.

MS. MULKEY: We've noticed.

UNIDENTIFIED FEMALE: It's converged.

MS. MULKEY: We have several. I think the right number is several filed lawsuits that we're defending. Two at least.

MS. LINDSAY: Well, we have several notices that have been filed, one of which has moved from the notice stage to a lawsuit stage, and the others have not.

MS. MULKEY: All right. There's still notices of intent.

MS. LINDSEY: The two big ones involve salmon.

MS. MULKEY: All right. Theresa.

MS. MURTAGH: I just wanted to comment. I could see with the worker topic this morning, with the mechanisms that are in place to protect workers, the risk assessment for measurement and also the WPS for medicating health effects. But we find that this is really based on compliance where there are a number of

growers who are complying, but we're finding in our experience the overwhelming percentage are not complying. Which -- although these mechanisms are in place, because of lack of compliance, the reality is that workers are being exposed to pesticides that are giving them both acute and chronic health effects. So I'd like to see more -- one of the priorities for here, too, is to use this as a venue, not only the national assessment that's been going on and especially for next month, but also use the PPDC to address issues such as reporting, enforcement and also more health data regarding farm workers, especially the chronic effects.

I mean, I could see from the list here, this is a very diverse group with very different interests. But I think a common interest we all share is health and safety of workers and growers and the families. So to try to use this as a mechanism to address when compliance is not happening.

MS. MULKEY: This is the, at least, the second and maybe the third or fourth time that I've heard enforcement, compliance and that part of our mission, EPA's mission.

So I've heard information, research, enforcement/compliance. We pretty much, the communication activities internal to OPP, there is a press office. And they have some involvement with these matters, but -- so I think I'm hearing a theme here that integrating the rest of our agency with the work of this organization in some more robust way would be welcomed.

And that of course, includes our regional offices. And we hear you. It's not easy. But it certainly makes sense. Well, I think, Phil, you might wind up having the last word which seems sort of suitable.

MR. BENEDICT: Probably that's wrong. I want to thank you. This has been very rewarding for me. I've really enjoyed it. I always get a lot out of coming to these meetings. I do think, though, that you could challenge us a little more. I think you could give us briefing. I think we do have the best discussions when we have the briefing papers ahead of time. And spend more time talking about those issues. And I really think that we need the dialogue here. So I think you could get in -- Margie's good about sending the stuff. I didn't

read the rodenticide thing that was this thick, but I read everything else that came to me.

MS. MULKEY: They insisted that you get this, you understand. They were hoping somebody would, I think.

MR. BENEDICT: So I guess I would challenge you to challenge us more and spend more time dialoging. The other thing that I personally think has been missing here and I understand why it's going on. When you have brand new laws that are very complicated to implement, and there's a lot of science behind it, you need to bring people up to speed on all of those issues.

But at some point, I really think some group needs to talk about more -- and Jay said it, more long term planning, long term direction. For example, we had a subcommittee, a work group at one time on environmental measures. They never did very much.

I really still think that it's extremely important for all of our programs, either there's a federal law that says now you're supposed to be doing things to show these kinds of measures. Having a dialogue around what we can use in the states and the

federal agencies.

And to me, the pesticide program is more than OPP. It's OPP, it's -- and it's also your sister agency there that does enforcement. Having those people to the table is very important. To have in the USDA is important. Having all the players are -- well -- so, from your leadership, if you could drag some of those people to the table, I think it would help.

And also, if we could begin to spend a little bit of time and have somebody or this body spend a little bit of time on kind of being a little bit visionary on where the program is going, and how we can do a better job of measuring what we've done, I think everybody would benefit.

MS. MULKEY: All right. Well, we have some public commentors and we have plenty of time and we'll still be through early. So we'll go to them now. By my count, three, because I'm assuming, Theresa, you no longer since we had made that mistake. The first name I have, the handwriting is just vague enough that it looks for all the world like the name is Dan Glickman (phonetic). Now my guess is that we do not have Dan

Glickman with us today. Dan, is it Gluxman? From an organization called ISEA, I S E A. Interested in talking about occupational exposure. Well, maybe Dan came and left.

UNIDENTIFIED MALE: Maybe he was the Secretary.

MS. MULKEY: Yeah, maybe it was. Lori Berger, California Minor Crops Council.

MS. BERGER: Yes, my name is Lori Berger. And I'm with an organization, the California Minor Crops Council, which is a coalition of growers from stone fruits, citrus, strawberries, kiwi fruit. We've got about 15 commodities that are members of this organization. And I also sit on CARAT.

And I'd like to comment that I really enjoyed observing your meeting. I've really appreciated the dialogue that you all do have across your table. And I hope that CARAT will evolve. I don't know if it's a matter of size or history, but I think it's really good how much conversation does go on across the table.

I just wanted to make a couple of comments. One relative to a topic covered yesterday, and that has to do with EUPs. These are very, very important as we move

into reduced risk scenarios and so forth. The acreage considerations, I would really appreciate the opportunity to have input on how many acres these commodities get to test out new products.

If there's a formula that can be devised, rather than just a 100 acres per minor crop, we really need to look at that more closely for the benefit of these growers as they move into new types of pest management, especially orchard crops. Just -- we need to look at that more closely.

Also, the watershed considerations, Rick Kegwin (phonetic) did comment that there was going to be room for adjusting the comments or the requirements for the watershed. But I think we really need to be careful when we determine the EUP requirements with regards to watershed because that could be extremely limiting to our ability to test these new materials or old materials across the wide variety of circumstances and situations that we have in many of these states.

And I also just wanted to say that we really appreciate the agency moving towards putting the EUPs outside of the priority ranking for the registrant. We

really do see, though, we need to be able to have these on new chemistries as well. So anything we can do along those lines to have new chemicals evaluated with this new set of circumstances would be very helpful.

Then the second area that I wanted to comment on has to do with the workshops on worker protection. I did participate in the cumulative risk workshop and I was also disappointed that not more of my CARAT colleagues were there. I think part of that might have been there wasn't a whole lot of lead time and I think people are really interested in that.

And for those of us wanting to have more dialogue, those opportunities for education are extremely important. So I really appreciate that, both the opportunity just for those workshops and the fact that you literally do provide resource for us to travel to those meetings. That makes a real big difference for those of us representing grower groups. So thanks for that.

And let's see, just if you can try to schedule those meetings in conjunction with PPDC or CARAT, I think that you will have greater participation. And anything

that we can do from the field level to support your efforts and get more people involved, whether it's getting people back here to Washington, or setting up some of these teleconferencing seminars, just please let us know. So those are my comments. Thank you.

MS. MULKEY: Thank you. Well, as we solicit written public comment on the EUP proposal, we hope your organization will be able to weigh in and give us -- not that we didn't listen today, but give us maybe some specific suggestions or options around these issues that you raised.

And Julie Spagnola, who works with Beyer, Buyer --

MS. SPAGNOLA: Beyer, Buyer, U.S.. This will be pretty quick. So I won't keep you much longer and I'm glad Lois is still here because I really wanted to talk about the value of the conference calls and the process and especially involving the state -- the user/stakeholders.

The input that they've been able to provide in this process is getting the agency and the registrants a lot of information about actual use practices and the

situations that they encounter, you know, that the users encounter in applying products.

And I think we've seen the range of this input, you know, the involvement going from the conference calls to presentations, all the way to OPP staff going to Florida and going up in helicopters to see how mosquito control applications were made.

And I think this has just been absolutely invaluable to the agency and to the registrants as we go through this process in coming up with the most -- you know, the most informed and, I think, ultimately, most effective risk mitigation measures. Because I think by knowing exactly how products are being used and the situations encountered, we can, you know, make the best decisions.

And I guess I would also, you know, encourage the agency even to consider maybe soliciting some of this input from the user community early in the process, even into the risk assessment process, so that maybe some of those inputs can be put into the assessments and not, you know, and help come up with a more refined assessment that then, you know, prior to going to the mitigation.

So, again, I just think that that input from the user community has just been really valuable and our experience. And I think we've probably been -- Beyer's probably been in more conference calls with the Agency than probably anyone. So it's really been -- I think that's been something that we have learned through the process. Thank you.

MS. MULKEY: Thank you. Well, by my understanding, we have come to the conclusion of this last meeting of this Chartered Pesticide Program Dialogue Committee. Thank you for your service. Thank you for these two days.

Jim asked that I particularly thank you on his behalf. He, you know, the hot issues -- he's around, so you may get a chance to greet him as you go out. But he wanted to be sure that you understood his desire to share the salute to your service and to thank you.

And we, of course, look forward to seeing all of you because all of you matter to us in our program whatever your next incarnation is in dealing with us. Whether it's as a part of this committee as we reconstitute it or whether it's a part of some other

means, by other committees or otherwise.

We are really glad that our colleagues from the USDA and FDA and Canada were here. We're going to try to do more and better with that regard. My brother is a senior ORD official, so I entertained a group of them last night.

But one of the things I instilled in them was how valuable their presence was at this meeting. And it was that they are trying to sort of think more in terms of outreach and customer service.

And so I think this is a sort of a fertile time, not to mention that I know somebody there for us to get them involved. He's at the Cincinnati lab, Associate Director for ECO. So good-bye, good days, see you soon.

UNIDENTIFIED MALE: Happy new year.

(Whereupon, the meeting was concluded.)

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