Transcript of Meeting of

Pesticide Program Dialogue Committee

Conference Center - Lobby Level

2777 Crystal Drive (One Potomac Yard South)

Arlington, Virginia

November 8 & 9, 2006

COMMITTEE MEMBER ATTENDANCE LIST

Jim Jones	Director, Office of Pesticide Programs, OPPTS, Chairperson
Margie Fehrenbach	Designated Federal Officer, OPP
Adam Sharp	Congressional Relations, American Farm Bureau Federation
Dr. Jose Amador	Director, Agricultural Research & Extension Center, Texas A&M
Cindy Baker	President, Exigent Company
Lori A. Berger	Ph.D., Director of Technical Affairs, California Minor Crops Council
Carolyn Brickey	Executive Director, Protected Harvest
Amy Brown	Coordinator, Pesticide Safety Education Program, Univ. of MD.
N. Beth Carroll, Ph.D.	Senior Stewardship Manager, Syngenta Crop Protection
Richard Colbert	Director, Agriculture Division, Office of Enforcement and Compliance Assistance, EPA

ATTENDANCE LIST (cont'd)

Caroline Cox	Staff Scientist, Northwest Coalition for Alternatives to Pesticides
Shelley Davis (11/8 only)	Deputy and Co-Executive Director, Farmworker Justice Fund, Inc.
Dr. Michael Fry	Director of Pesticides and Birds Program, American Bird Conservancy
Greg Masson	U.S. Fish & Wildlife Service
Frank Gasparini	Responsible Industry for a Sound Environment
Dr. Melody Kawamoto	National Institute for Occupational Safety and Health, Centers for Disease Control & Prevention
Caroline A. Kennedy	Director of Special Projects,

ATTENDANCE LIST (cont'd)

Phil Klein	Senior Vice President,

(11/8 only)	Legislative and Public Affairs, Consumer Specialty Products Association
Susan Little (11/9 only)	Consumer Specialty Products Association
Gary Libman	Vice President, Regulatory Affairs and Quality Assurance, Emerald BioAgriculture Corporation
Amy Liebman	Environmental Health Consultant, Migrant Clinician Network
Angus Kelly	California Cotton Growers Association
Patrick Quinn	Principal, The Accord Group
Dr. James Roberts	Associated Director of Pediatrics, Medical University of South Carolina
Robert Rosenberg	Director, Government Affairs, National Pest Management Association, Inc.

ATTENDANCE LIST (cont'd)

Jennifer Sass	Senior Scientist, Natural

	Resources Defense Council
John Schell, Ph.D.	Vice President, Toxicologist
	BBL Sciences
Mary Ellen Setting	Assistant Secretary, Office of
	Plant Industries & Pest
	Management, Maryland Department
	of Agriculture
Dr. Hasmukh Shah	Managing Director, American
	Chemistry Council
Julie Spagnoli	Executive Director, Regulatory
	Affairs, Clorox Services Company
Dr. Warren Stickle	President, Chemical Producers &
	Distributors Association
Ray McAllister	President & CEO, CropLife
	America
James Wallace, Jr.	Manager, North American
	Registration Section
Joseph Conlon	Technical Advisor, American
	Mosquito Control Association

ATTENDANCE LIST (cont'd)

Kristie Stoick	Research Analyst, Physicians

	Committee for Responsible Medicine
Matthew Keifer	Associate Professor, School of Public Health and Community Medicine
Dennis Howard	Chief, Bureau of Pesticides, Florida Dept. of Agriculture & Consumer Services
Rodney Guske	Salt River Pima-Maricopa Indian Community
Dr. Robert Holm	Executive Director, IR-4 Project
Carol Ramsay	Extension Pesticide Education Specialist, Washington State University
Michael Kashtock	Office of Plant and Dairy Foods, CFSAN, FDA
Rebecca Derr	Lead Region Coordinator, Office of Compliance and Enforcement, EPA

P R O C E E D I N G S

\- - - - -

DAY ONE - NOVEMBER 8, 2006

MR. JONES: Good afternoon. Welcome, all of you, to Potomac Yard. This, I think, is our second PPDC meeting in our new facility. Margie points out to me this is actually the 21st meeting of the Pesticide Program Dialogue Committee. We're about ten years old as a FACA and this is our 21st meeting.

We actually have a couple of enhancements to the facilities that hopefully we'll get to experience today that the last meeting -- as most of our meetings, it's very difficult to have visuals so that no one's got to be craning their neck or turning around or just sitting on the side. We have now some screens over here that hopefully will allow us to be on all four sides of the table and no one have to turn their neck too far to be able to see the presentations. So, I'm very pleased with that.

And we actually have a system set up now such that we don't have in the middle of the circle or the square big funky AV equipment. It's now up there somewhere. So, I'm very pleased with the way this facility's turning out.

I'm pleased that this afternoon, a little later on, Jim Gulliford, who is the Assistant Administrator for the Office of Prevention, Pesticides and Toxic Substances, the parent office of OPP and my boss, will be joining us. I expect many of you have not had an opportunity to interact or meet with Mr. Gulliford and this will be a nice opportunity for all of you as well as it will be for Jim, who will be sitting next to Anne (inaudible). He'll actually sit through the spray drift discussion later on this afternoon.

I want to remind folks that this is a Federal Advisory Committee, and as such, is governed by the Central Advisory Committee Act, which is a law in the United States that provides guidance requirements for how the Federal Government gets advice, designed pretty much to ensure that in getting advice from stakeholders, there is equitable opportunity for stakeholders, that the Government doesn't just listen to one set of stakeholders at the exclusion of others. So, the requirements include things such as just there needs to be broad participation across the stakeholders, which this committee achieves; that there be open meetings, which this committee has

both for its full committee meetings and its work group meetings; and that we post agendas in the Federal Register, which we do as well. So, I think it's just useful to remind folks that there are -- there's a law that governs how the agency gets advice and we are a FACA, Federal Advisory Committee Act, work group.

We do also tape the meetings, so it is important to use the microphones, as we will ultimately transcribe it to create the record for this meeting, which we find to be very helpful. I mean, this really is an opportunity for EPA to get advice and we take that very seriously, and it isn't unusual for us to go back to the tapes just to make sure we were hearing things accurately. So, I want to make sure that you're using your microphone. You pretty much just push that button and the mic will activate. And always introduce yourself before you start speaking, so that when we're transcribing it, we know who said what.

A little later in the agenda, actually, the next agenda item up, you're going to get a summary of our -- from Debbie Edwards, the Director of the Special Review and Reregistration Division, about our Old Chemicals

Program, and not to take any of her thunder away, I don't want to miss an opportunity to brag a little bit about our organization. It's been -- since the last time we met, August 3rd came and went, and this program, I think, achieved a pretty monumental accomplishment in basically meeting the FQPA requirements around tolerance reassessments. I think most of you are probably familiar with how that has played out.

There was one chemical, aldicarb, which did not get completed due to some restrictions on the agency imposed by Congress last year, but we're well on the way to finishing that last one up. But I'm not -- and Debbie will get into greater detail. I'm not familiar with another EPA organization or, frankly, another Federal agency, although I assume there's one out there, that has had such an all-encompassing requirement to review, it's a large number of chemicals for safety or, frankly, any other sort of comprehensive programmatic review in a short period of time if Congress gives EPA and the Pesticides Program under FQPA, who was able to do it and do it on time.

And I'm incredibly proud of what this

organization was able to do over the past 10 years. The people who have -- are here right now, as well as the many who worked here during that entire 10-year period, it couldn't have been achieved without the combined efforts of all the people in this program over that period of time. It's really quite noteworthy. And Debbie's going to get into specific detail, giving you somewhat of an accounting around that, and we have taken some of your advice to heart around how we talk about our accomplishments and that we get -- we talk not just about the numbers, but about the results associated with it, and I think you'll see that pretty clearly in Debbie's presentation.

If you know, as Chair of the PPDC, I have tried to do -- have more of the work done of the Committee through work groups. One of the things that I've observed over the years is that the issues that we deal with in the Pesticides Program are quite complex and it's very hard to get advice on complex issues when a group gets together a couple of times a year and spend an hour or maybe an hour and a half on any given issue. And so, we began to try out, instead of doing that, having work

groups set up amongst this Committee, which is something we have done in the past. We're relying more often on work groups. When the work group gets together for a day or a day and a half, sometimes once or maybe more than once, in between the PPDC meeting, and so, when the full Committee reconvenes, there is a meaningful subset of this Committee who have really invested the kind of time, energy and thought that is necessary really to, I think, proffer well-informed advice.

And I think that that's served us well and we're going to continue to use that model. So, you know, if you're looking to really make a difference in terms of making sure your advice is being offered, I really would strongly encourage you to take advantage of this Committee structure. If you're participating in the Committee, you're going to have an opportunity, first, to learn more, and by learning more, I think be able to offer more informed advice, which is pretty important for us to be getting informed advice.

We'll probably initiate a new committee during this meeting around registration review, which is sort of different from the one that many of you participated on

that helped to create that program. Now we're going to have one that's going to help us on implementation. We'll talk about that later, probably tomorrow, when we're talking about registration review.

And we may be ready to de-commission one because I think that the group that was working on performance measures has given us -- and we'll see this later in the meeting, probably actually tomorrow, they've given us very thoughtful advice. And I think it's important that once you accomplish your task, you move on to another one. But we'll cross that bridge tomorrow after we've heard from that work group.

So, we're going to continue to rely, in this meeting, on the committee structure, and we have two of our committees who will be reporting out today.

And with that, why don't we spend a minute going over the agenda. We start, as we usually do, with just some programmatic updates around our registration program, our reregistration and old chemicals programs. And then, a follow-up to a discussion we had at our last meeting around a pilot exercise we had with the Office of Water around OPP using data coming from the states

associated with impaired water bodies. We're going to have a summary of that -- a continuation of that work as well.

We're going to hear from the Performance Measures Work Group, which has drafted a report for our consideration. One of the other rules around the FACA is that advice to the agency needs to come from the full Committee, so when you have a work group, the work group brings its product to the full Committee and then the full Committee meets to decide whether or not to adopt the report or recommendations of the subcommittee, and so, the Performance Measures Work Group, which has done a very nice job of giving insight into our performance measures in the Pesticides Program, will be -- actually, you all have it because it was sent to you about two weeks ago. This Committee will then be asked whether or not to endorse those recommendations, and that's what we'll be doing right after the updates.

The work group on worker risk met this morning and they will be providing an update for us next and then the work group on spray drift, which met all day yesterday and this morning, will be giving us their

report out. We'll have public comment and then break for the day.

Tomorrow, as much as I tried to avoid this, I think that we're at somewhat of a critical crossroads in OPP. What I've tried to avoid is too much of us talking, which I'm obviously off to a bad start on that. But where we're just talking to you and telling you about ourselves and what we're doing, and I've tried to have these meetings be much more about you reporting your observations based on largely work group experiences. But we're about to embark on a new -- our new Old Chemicals Program registration review and there are -- there are a couple of elements of that that are also -- have new characteristics associated with them. They're not new -- for example, the Species Acts are not new.

And so, we're going to be spending time tomorrow talking about, first, the registration review program and what our plans are around that, and that's where we'll have this discussion about the work group. We're going to give you an update on the Endangered Species Act, which is going to be our work to get into compliance with Endangered Species is a very critical element of our

registration review program, which is why that follows it directly.

We want to give you a sense as to how we're beginning to think about nanotechnology, which is emerging technology, another new thing, and then an update on Endocrine Disruptors Screening Program, which is a program mandated by FQPA that heretofore has been largely focused on developing test methods. In the not too distant future, it's going to go from methods development to program implementation. Program implementation will happen here.

And so, there's somewhat of a method to our madness here of why these things are all following registration review. So, there will be a little bit more of the classic talking heads that we've tried to avoid, but this is a time in our program where we need to begin to give you a sense as to how we're going to be going forward in these areas and we'll be looking for some ideas back from you as to how you'd like to participate. We have some ideas around that.

And then the last topic tomorrow morning will be an update on something this Committee has spent some time

on several years ago and we periodically get an update, and that's around alternative testing. So, that's pretty much the agenda over the course of the next two half days or of someone who one full day.

With that, I would like to go around the room and have people introduce themselves. If you are here on behalf couldn't make it and come to the meeting, if you can just make reference to that, that you're -- who you are, who you're with and who you're here representing.

MS. LINDSAY: I'm Anne Lindsay, Deputy Office Director for Programs in the Pesticide Program.

MR. STUBBS: I'm Don Stubbs, I'm the Associate Director for the Registration Division.

MR. McALLISTER: Ray McAllister with CropLife America. I'm here on behalf of Jay Vroom.

MS. SPAGNOLI: Julie Spagnoli, Clorox.

MR. ROSENBERG: Bob Rosenberg, National Pest Management Association.

MS. SETTING: Mary Ellen Setting, Maryland Department of Agriculture.

MR. CONLON: Joe Conlon, American Mosquito Control Association.

DR. ROBERTS: James Roberts, Medical University of South Carolina.

MR. WALLACE: Jim Wallace, S.C. Johnson.

MS. COX: Caroline Cox, Center for Environmental Health.

DR. HOLM: Bob Holm, IR-4 Program.

MS. RAMSAY: Carol Ramsay, Washington State University.

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

MS. SASS: Jennifer Sass with NRDC here in Washington.

MS. DAVIS: Shelley Davis, Farmworker Justice.

MS. DERR: Rebecca Derr, EPA, on behalf of Mike Bussell.

MR. HOWARD: Dennis Howard, Florida Department of Agriculture.

MR. SHARP: Adam Sharp, Ohio Farm Bureau, representing Rebeckah Freeman with American Farm Bureau.

MS. BAKER: Cindy Baker with the Galiant Group Company.

DR. STICKLE: Warren Stickle with the Chemical Producers and Distributors Association.

DR. SCHELL: John Schell with BBL Sciences.

MS. KENNEDY: Caroline Kennedy, Defenders of Wildlife.

MR. KEIFER: Matthew Keifer, University of Washington.

DR. CARROLL: Beth Carroll, Syngenta Crop Protection.

MR. QUINN: I'm Pat Quinn with the Accord Group.

MR. KELLY: I'm Angus Kelly with the National Cotton Council filling in for Cannon Michael who is a California cotton farmer.

DR. BERGER: Lori Berger, California Specialty Crops Council.

MR. LIBMAN: I am Gary Libman representing the biopesticide industry with GNL Consultation Services.

DR. FRY: I'm Michael Fry with the American Bird Conservancy.

MR. KLEIN: I'm Phil Klein with the Consumer Specialty Products Association.

MS. LIEBMAN: I'm Amy Liebman with the Migrant Clinicians Network.

MR. GUSKE: Rodney Guske for the Tribal

Pesticide Program Council for Jeremy Phillips.

MR. GASPARINI: Frank Gasparini with RISE sitting in for Allen James.

DR. KAWAMOTO: Melody Kawamoto, DCD, National Institute for Occupational Safety and Health.

MR. COLBERT: Rick Colbert, EPA's Office of Compliance.

MR. KASHTOCK: Mike Kashtock, Food and Drug Administration representing Nega Beru.

MS. BROWN: I'm Amy Brown, University of Maryland, representing the American Association of Pesticide Safety Educators.

MR. JENNINGS: Al Jennings, USDA.

MS. MONELL: Marty Monell, Deputy Director, Office of Pesticide Programs for Management.

MR. JONES: Okay. One last thing before we get started on our first agenda item. We talked at our last meeting -- I made a commitment to all of you that I would explore some opportunities outside of the PPDC to have some dialogue around pesticides and the safety educator program funding, which is something that I believe is not just EPA responsibility but something that's shared

responsibility amongst probably most of the groups represented in this room, maybe some who aren't.

And we have begun to have those discussions internally and we've had some preliminary ones with USDA, but at this meeting, I'm not prepared to say, and here's what we have to suggest as an alternative forum to discuss that. But we're going to continue those discussions inside of the government, and hopefully, by the time we get together the next time, we'll be able to say here's our idea.

Okay, with that, I am going to turn it over to Don Stubbs, who is the Associate Director of the Registration Division in OPP.

MR. STUBBS: Thank you, Jim. I want to quickly go through an update on the registration activities for OPP.

First, our new active ingredients, we registered 32 new active ingredients this year. Eleven of them were conventional pesticides. Of those, eight were import tolerances only and not registrations. They're listed above there. We have Nicarbazin -- if I can pronounce these things -- Metofluthrin and Furfural, which were all

registrations. Then Fenpropimorph, Benthiavalicarb, Epoxiconazole, Dithianon, Metrafenone, Ethaboxam, Metconazole, etc. They were all import tolerances.

(Laughter).

MR. STUBBS: And they get worse as we go along. We also had 15 biopesticides that we registered, and some of these I can pronounce and some I can't and I'm not even going to try. But there they are.

A couple interesting ones, coyote urine, good for the coyote, Methyl Eugenol, Potassium Silicate, Ammonium Nonanoate and some others.

In addition, we had six antimicrobial new chemicals registered. These were Benzoic acid, Bis(3-aminopropyl) dodecylamine and some others.

I'd also like to point out so far in FY '07, we've registered two new active ingredients. One is Polymeric Betaine, which is an antimicrobial. The other one is BT corn, MIR Cry3A. I was told to make sure I said that. That's in a biopesticide.

New uses, we approved 186 new uses associated with 723 different crops. That's because some of these we've categorized in crop group. Of these 186 new uses,

we covered 44 conventional chemicals. Within that 186 new uses, we did 40 reduced risk new uses and four OP alternative new uses.

In addition, we approved 10 new uses of previously registered antimicrobial ingredients.

Under the Section 18 activity, we received 419 emergency exemptions. We approved 278 of those. We did not deny any. We did have 22 withdrawn and we had 36 crises declarations taken. The turnaround time on the emergency exemptions was 48 days if you exclude the soybean rust 18s. To include those, it was around 68 days now. The reason for the time increase is a handful of those were new chemicals being looked at under the Section 18 program and they take a little bit more time to look at all that data.

Registration activity for fast track and non-fast track items. For fast track amendments, which do not fall under the PRIA categories (inaudible), we processed 3,332 actions. Most of that's where we get a lot of our workload. The breakdowns by division are underneath if you want to look at those.

For non-fast track amendments, what we call R34,

for those that use (inaudible), 332 were processed.

For fast track new products, these are R codes 30 through 37, 308 were processed; and for non-fast track new products, R31 through 33, 492.

Inert ingredients, for new inert ingredients, we processed 13 in FY '06. We had 26 petitions received. Of those, we scheduled 11 for FY '07. Fifteen have yet to be scheduled because they're missing some information. We haven't scheduled out FY '07 entirely yet. But we have scheduled 26 because there were another 15 that were in house prior to FY '06 that we had gone ahead and scheduled. So, everything prior to FY '06 has been scheduled and most of FY '06 has been scheduled. We anticipate scheduling the rest -- honestly, we had our focus on tolerance inert reassessments for the most part this year through August 3rd.

PRIA performance, since the start of PRIA, we've processed 4,193 submissions. We've completed -- or we've received, excuse me. We've completed about 2,950. Ninety nine percent have been completed by their PRIA goal or before. That means 1 percent weren't.

Twenty-five not grants have been issued. That's

less than 1 percent. And 396 of the actions we've had to renegotiate a due date on, about 9 percent.

Breaking that down, AD had one not grant of a total of 705 actions; BPPD had 15 not grants of a total of 378; and RD only had nine out of 3,110 actions.

Actions with negotiated due dates, AD had to renegotiate 140 out of 705; BPPD, 107 out of 378; and RD, 149 out of 3,110 actions.

And, finally, new active ingredients currently pending with the agency. We have 22 conventional new active ingredients pending; of those, 20 are tied with a registration action, and two of them are strictly the tolerance import petition. We have 24 biopesticide new active ingredients pending. We have 11 antimicrobial new active ingredients pending.

Currently, these are all -- we plan to make the PRIA date, of course, and they're all scheduled actually to be completed prior to the PRIA date. That's my update on registration activities. Any questions?

Ms. Sass: This is just a clarification because I don't understand this. Earlier -- let's see, on page four, anyway, is the fast track --

what are the fast tracks? Is that the reduced risk and minimum risk ones?

MR. STUBBS: No, fast tracks are -- actually fit -- are substantially similar -- there are two types, one is substantially similar to another pesticide registration; the other is a fast track amendment that (inaudible) to an amended registration. And they're called fast tracks because they're required to be done within 90 days. They're actually some of our more simpler actions.

Ms. Sass: Thank you.

Mr. McAllister: Is there anything in particular to account for the high number of import tolerances during the past year?

MR. STUBBS: Yeah, actually, there is. Prior to PRIA when we were doing actions based on a priority type system, we didn't give a lot of priority to import tolerances. And so, the petitions that were in-house kind of stacked up. With PRIA and the payment of fees, everything in-house was scheduled to be done, and so, we picked up a lot of those tolerances that we had not done in the past which happened to be import tolerances.

Mr. McAllister: So, these are actually holdovers from PRIA days.

MR. STUBBS: These are holdover from PRIA days, correct.

MR. JONES: Gary?

MR. LIBMAN: Very interesting presentation, appreciate it. I'm kind of curious about these negotiated due dates. It seems like my beloved division, the biological one, has almost like 30 percent on negotiated due dates. Is there any sense of what those negotiations are all about or is that something (inaudible)?

Ms. Monell: Yeah, we've done an analysis of it and predominantly, there are issues around product chemistry and -- and those issues also primarily arise with smaller companies and I think the Biopesticide Division tends to see a larger proportion of smaller countries -- companies, less sophisticated, may not be part of associations and so forth.

So, it -- but the actual reason in-house is because of failure of -- around product chemistry issues.

MR. LIBMAN: Thank you.

MR. JONES: Okay, Debbie Edwards, who's the Director of the Special Review and Reregistration Division.

(Brief pause in the proceedings.)

MR. SHARP: While you guys are getting that ready, I actually have one --

MR. JONES: Adam Sharp.

MR. SHARP: One quick question while you guys are getting your next slide ready. Just on the Section 18 activities, just throwing together some of the math on that, there's like 120 some that are still sitting, I assume, that there's been no action on, and then I noticed that the average turnaround time is about 48 days and that seems higher than maybe it had been in the past.

Can you explain to me a little bit about what the function is around -- or what's happening in the 18 Program?

MR. STUBBS: The number of 18s we get, obviously, depends on what's submitted, and we get them at given sets of times. They fluctuate, of course, depending on the pest season and where you are. Right now, you would see 18s coming in for (inaudible) the

herbicide season, which probably starts in April. What we try to do is because about 60 percent of these are repeats, we ask the states to get them in early so we can process them early.

Also, you've got to get your -- the companies have to have their pesticide product lined up and ready to go. They start selling and moving that stuff around right about now or actually more like September/October. So, you'll see a lot of them coming in now. You'll see the next peak generally around January for the insecticides coming in for us in -- later in the season in July and August. So, that's why we've got quite a few still left in-house.

As far as the 48-day turnaround time, you know, that's gone up a little bit in the past, but I think a lot of that has to do with we spent a heck of a lot of time on soybean rust and a whole slew of chemicals and products not only for soybeans but for the legume vegetables. I think that's driving part of it.

MR. JONES: Michael?

MICHAEL: Yes, continuing on the Section 18 stuff, there were 36 crises declared. I think there was

a change in law that made it a requirement that EPA approve crises declared by the states before they were done, and you had a 36-hour turnaround time on that. I think a very, very short turnaround time.

Were there any of these crises that were denied or -- I know there were a couple of them where greater restrictions were put on, but were any of these crises denied?

MR. STUBBS: You know, I'm not sure if they were or not. What we -- on the crises, what we've told them is that that come in beforehand to make sure if they're going to go crises that we can set a tolerance to cover the resulting food residues and (inaudible), and they do do that, they do come in advance. And I don't think we probably would deny one per se. It would be like, well, we can't set the tolerance based on what we have at this time for this use, and so, they wouldn't take the crisis. So, I don't -- you know, if you want to call that a denial -- I don't think it's a denial, I think, you know, they come in with an idea that they've got an emergency and this will do it, and they find out that we can't set the tolerance and then they'll go look for something

else.

MICHAEL: The idea that you have a request to -- for them to send their information in ahead of time, isn't that kind of, by definition, not a crisis?

MR. STUBBS: Again, what we're looking at there is can we support the residue tolerance picture on that use, okay? So, we can do that fairly quick unless you come in with a brand new active ingredient, which I don't think we allow under crises anyway.

We're not looking at the nature of the emergency at this point in time. So, all we're doing is trying to take a quick look and see that we can support tolerances if they use it. If we can, we let them know. The state goes crisis and uses the pesticide, follows it up with a specific, and at that time, we'll start looking at whether or not an emergency existed in doing the paperwork to set the tolerance to the Federal Register.

MR. JONES: (Inaudible) the way you were the 24, 36 hours. They give us notice that they're going to issue a crisis and that gives us the time to determine whether or not we're going to be able to set a tolerance or we have -- maybe any other issue that we would want to

discourage them from issuing that (inaudible).

Okay, Debbie?

MS. EDWARDS: Yes, okay, I'm on. All right. What I want to talk to you today mostly is about what we've achieved in the last 10 years and what our path forward is for '07, '08 and so forth.

Jim mentioned we feel we've had quite an accomplishment record over the last 10 years. Within that decade since FQPA was passed in 1996, we completed over 99 percent of the required tolerance reassessment decisions and over 99 percent of the reregistration eligibility decisions that needed to be done by August 3rd, which are the food use chemicals. And through this, we believe we've enhanced human health and environmental protection.

You know back in 1996, FQPA set the new safety standard, which was the reasonable certainty of no harm. We were to reassess nearly 10,000 tolerances within 10 years and look at the greater susceptibility for infants and children, aggregate exposure, cumulative, as well as the possible endocrine or estrogenic effects. And we were to complete one-third of those tolerances within

three years, 66 percent within six years and 100 percent within 10 years and that's where we are, at 99 percent right now.

Through this process, we have recommended the revocation of over 3,000 tolerances and we are well on our way to achieving that through our tolerance rule. We've also recommended modification, that could be raising or lowering tolerances, or changing the tolerance definition of over 1,300 tolerances, and then we've reconfirmed the safety of around 5,000.

Every time we come we show you this chart. It's looking pretty well filled in now. You'll see there we've got percentage reassessed 100 percent down the entire right-hand side except for the carbamates, and those are the 1 percent that we're talking about. There's a few carbamate tolerances that haven't been completely reassessed yet.

These are the remaining 84 tolerances for five pesticides that need to be reassessed to meet that final 1 percent. You can see again they're all N-methyl carbamate pesticides. Once we complete aldicarb, which as Jim mentioned earlier, and the N-methyl carbamate

cumulative assessment, we will be able to say that we have reassessed 100 percent of the tolerances.

In addition, we were to reevaluate pesticides first registered before November 1984 not just for their food use situations of, you know, the tolerance reassessment, but as well the worker risks, ecological risks and so forth. PRIA told us we needed to complete all the food use REDs by August 3rd of 2006. At the same time, we reassessed the tolerances. Again, we've done 99 percent of those REDs and the REDs that aren't done are the ones pretty much on the previous slide, and some -- a couple others I'll mention in a minute.

The non-food use REDs are to all be completed by October 3rd of 2008. We have a schedule in place to do that and we're on track to complete that on time.

We started out with 613 chemical cases. We've done 330 REDs. 229 were actually voluntarily canceled. There are 58 REDs yet to complete. That's 9 percent of them. But 47 of those are non-food REDs that don't need to be done anyway until October of 2008 as a final deadline, and those remaining seven with food uses.

This is just reiterating some of the things I

mentioned before. We've completed decisions for 91 percent of the reregistration cases, 99 percent on time that were food uses. This has actually resulted in over 4,000 end-use product registrations being canceled, and for the rest, we believe that we've ensured that the products can be used safely with the label amendments that we've required through the REDs.

For the cumulative assessments, there were four to do. We've completed three of those. The organophosphates were completed this past July; triazines in April; and chloroacetanilides in March. We have been or will be looking at all the public comments we've received on these and determine if any changes are needed in those cumulative assessments.

Again, the final one is to be completed this year. That's the N-methyl carbamate cumulative assessment.

I'll talk a little bit about some of the results, focusing principally on organophosphates. I know last time people said they'd like to see results. Obviously, we need to get more of this information out possibly through web venues and other meeting venues, but

I want to give you a little summary of some of our key accomplishments we think we've seen for OPs here today.

We've reassessed 1,700 tolerances for the organophosphate pesticides and assured they meet the safety standard for the ones that are able to remain. There's been a voluntary cancellation or phase-out of 18 of the 49 original organophosphate insecticides on the market -- that were originally on the market. We believe we've made food safer through this process, eliminating a lot of the pesticide uses that drive the risks or reducing the use rates and increasing the PHIs and so forth so that the allowable residues are safe.

To get specific about OP, there's been a cancellation or phase-out -- this number's actually wrong. It's over 60 pesticide uses on kids' foods.

In terms of residential risk, we believe we've made risks in homes and schools safer. Often, the risk management, risk mitigation you'll see through our REDs has to do with residential uses. It's rarely that a RED has residential uses that we haven't gotten some reduction in risk through our decisions. We have an actual voluntary cancellation for OPs of several

pesticides entirely in home environments. Two key ones that I know you're all aware of are chlorpyrifos and diazinon, but there are several others.

In terms of worker risk, again, we believe we've significantly improved the risk to workers through this process and, in particular, for OPs, a number of OPs have been voluntarily canceled or phased out in part due to worker risks, and for many of the others, or actually most, if not all of the others, there have been reduced application rates and longer reentry intervals, increased personal protective equipment and engineering controls and so forth.

In terms of ecological risks, again, we think we've accomplished quite a bit there. We've put into place in many cases buffer zones to protect water bodies and wildlife habitat. We've put in spray drift reduction measures, including setbacks, outer row spray limitations, and as well as, in some cases, actual restrictions on the timing of applications so they don't coincide with breeding seasons and things like that.

As a result of all this, OP use is declining pretty significantly. In the 10-year period between 1994

and 2004, OP use on kids' foods decreased nearly 60 percent, going from 28 to 12 million pounds per year, and the use of alternatives to these chemicals has been going up. OP alternative pesticide usage increased, you can see there, 2,900 percent over a five-year period, and reduced risk pesticide usage increased 1,700 percent over a 10-year period. That's in part -- in fact, in large part due to the registration program and the emphasis that's been put on registering reduced risk and OP alternative chemicals.

In terms of actual outcomes, we've seen that, too. A lot of what we've talked about are outputs. We actually have seen, particularly in the acute risk situation, outcomes that are -- we think are very meaningful. In the area of incidence, overall -- I'm talking about all pesticide exposures in this first bullet here, unintentional pesticide exposures have declined 26 percent and pesticide poisonings declined 37 percent, whereas with OPs, it's even more significant. Those numbers are 72 percent and poisonings by 70 percent, the declines we're seeing.

What's next for Old Chemicals? Well, first, we

have to obviously complete that last 1 percent of tolerance reassessment. We're on track to do that this year. We need to complete the remaining REDs, again there are seven food uses REDs to complete and 47 non-food use REDs to complete. We need to implement our decisions, and I'll talk about that a little more in a minute, but it's very important to get those decisions implemented and to the streets and to the users. We intend to close out the remaining special reviews that are still open and start up our special registration review program.

Okay, here are the food use REDs left to complete. I mentioned some of them already. The first five are N-methyl carbamates. You can see that we actually have interim REDs completed for four of those. It's just Aldicarb we haven't actually completed the IRED for yet. You will see Aldicarb come out next week for public comment of risk assessment. We can be looking for that.

Ethylene oxide, we actually reassessed all of the tolerances for that chemical, but our Scientific Advisory Board through the Office of Research and

Development is going to be looking at the cancer situation for that chemical and there are some risks for workers. It also recognizes it's a very high-benefit chemical, it's a hospital disinfectant. So, we wanted to make sure we had the science right on that one and that's why we delayed the worker assessment for ethylene oxide.

And then, finally, methyl bromide, we actually, as most of you know, completed the tolerance reassessments for that chemical and the RED for the commodity uses this summer, but we have maintained the fumigant uses, along with the other soil fumigants that we're going to be reassessing this year. That includes those soil fumigants.

I'm not going to embarrass myself by reading these, but these are the non-food REDs that we have on our schedule to complete in FY '07 and you'll see there, just to mention a couple of them, we do have the soil fumigants in there. There are going to be pretty challenging decisions to make for (inaudible) the metam sodium and then along with the methyl bromide there. And you'll see also there at the bottom, Tricolosan, that's obviously a very important chemical for the antimicrobial

world.

I'm not going to read any of these, but this is -- these are -- obviously, like I said before, we have these chemicals all scheduled out. It's all on the web. You can look there. We have people assigned to them and they're working on them. Those are the last remaining REDs on that slide.

This is something that I always try to talk about here and I can't under-discuss how important we think it is, is to get these decisions to the street and implemented. I'll just give you some highlights here. Obviously, very soon, we'll be making decisions -- final decisions on azinphos methyl and phosmet, what the state of those chemicals will be.

This past year, we determined that many, if not all, uses of carbofuran, organic arsenical herbicides and PCNB were ineligible for reregistration, but we put those decisions out for public comment and we have, actually, I believe for all three of those, extended the comment period. So, once those comment periods close and we reevaluate the situation based on the comments, we will determine the appropriate path forward for those

chemicals.

The rodenticides, as you know, we're looking at a large group of rodenticides as a group. We're going to come out with a proposed decision on how those chemicals should be regulated both for human and ecological risks this fall, probably in the next month or so.

We have petitions in to do product revocations for carbaryl and DDVP from public interest groups. Both have been out for public comment and, again, once those comment periods close, we'll evaluate the comments and respond to those petitions, the people that submitted them.

For many, if not all, of the decisions, for probably the majority of them, we did put the decisions from '06 out for public comment. A lot of those are still out or we haven't responded to the comments yet. We have that on our plate to complete. And any necessary addenda to the REDs that would be required as a result of looking at those comments.

We need to get our data call-ins issued, both the generic and product specific. We're working on that. I think we're about to get them over to OMB. Then we

need to review the acute tox and product chemistry data, do the label reviews and product reregistration. We also need to implement all of our tolerance decisions to proposed and final rules in the Federal Register. There's a lot of implementation work to be done.

This slide shows some -- it's not every one, but I think it's essentially every one -- special review close-outs that we intend to do as we close out the decisions on these chemicals. This will be done publicly through FR notices where we solicit comment and then file final notices. So, I think each of these you'll be seeing the notices as we close out the decisions and then we intend to take steps to close out the special reviews as well.

And then next steps, there's actually going to be -- I just saw in the agenda there's a one-hour session on registration review tomorrow where we'll be seeking your input on where we are with that and in a more detailed way, but just to mention here, it is the next step for us. The final rule was effective on October 10th. We have actually very recently posted our four-year schedule for docket openings on the Internet. You

can see that there. And we intend to open our first docket, possibly one or two this quarter, certainly if not several next quarter.

In that docket, what we're going to be putting in, in a nutshell, is what our view is of the situation for the chemical; in other words, what we think the work plan or path forward would be on registration review for the chemical, based in the documents that will be placed into the docket. Then we'll seek public comment on that, so you'll have an opportunity to show us additional data, dispute our -- or agree with our conclusions about what the appropriate path forward is, and then at the close of that -- we'll probably have 90 days public comment periods on these since we're starting up this process. And then probably a couple of months after the comment period closes, we would set up our final work plan and post that for you to see.

Again, just to point out here, there's a number of comment periods that are actually required by the regulation. One is when we have the docket opening, which that's mostly what we'll be doing this year, and then we'll be posting any significant risk assessments

for public comment, and in this case, a little bit different than the requirements of reregistration, we will be proposing all decisions for public comment.

Again, this year, we're going to be opening dockets for 25 cases. It's 15 conventional chemicals, four antimicrobials and six biopesticides. I'll have -- those numbers are in your packet in the presentation for tomorrow, the names of those chemicals. But they're also posted on the web page. And I think I just talked through what the next steps were once we open those dockets and get the comments.

And then, finally, we always show this slide, but I did want to point out this time that I think for all of these websites, there's quite a bit of new information that's been very recently posted or updated for these. So, you may want to check out our websites and see what's new. Thank you.

MR. JONES: (Inaudible).

UNIDENTIFIED MALE: I guess I just want to say I know you haven't finished every last little action quite yet, and everybody's always not happy with every action, but I want to say hats off to the agency for 10 years of

amazing work on putting together a very complicated process, taking an enormous pile of information, of input, of organizing advisory committees to help guide, bringing in stakeholders, and then doing all that work on time and -- can we still say under budget?

MR. JONES: Oh, yeah.

UNIDENTIFIED MALE: Excellent. On time and under budget. So hats off.

MS. EDWARDS: Thank you.

MR. JONES: Thank you. Jennifer.

MS. SASS: On Slide 19, I just wanted to know what your data source was. This was the slide where you said that EPA's improving human health protection and you said there's been a percentage of decline in unintentional pesticide exposures and poisonings. What did you use as your data source or sources?

MS. EDWARDS: The source -- this is data from the American Association of Poison Control Centers and their (inaudible) exposure surveillance system. I actually have a paper here that was prepared by Jerry Bondell (phonetic) on this, but I don't have -- I don't know if it was public.

MS. SASS: I think that Jerry also used the 682, am I right? Is that incorporated into here?

MS. EDWARDS: I'm sorry, I don't actually know, but I do have the paper, I could probably just give it to you.

MS. SASS: The paper would be great, yeah. I mean, I'm glad that you're using the Poison Control Centers. I know that we had recommended that a long time ago and I'm glad to see -- I just want to know how many sources of data you're incorporating and then, of course, there's the quality control check on all the data sources.

MS. EDWARDS: True.

MS. SASS: So, I would just be curious to see that. On page 21, this is just a real quick one, from the ethylene oxide, I know that you're aware that the National Academies is beginning a review of this. Are you planning on waiting until that review is out or not? And I don't know if it will affect you directly, but they are looking at the cancer exposure.

MS. EDWARDS: I don't know what the -- is that separate from the SAB review?

MS. SASS: I'm sorry, it is the SAB. Sorry.

MS. EDWARDS: Yes, we're waiting for the SAB.

MS. SASS: Okay, sorry. Thanks. (Inaudible) I sometimes forget what building I'm in.

Okay, so you'll be waiting for that and just --

MS. EDWARDS: Yes.

MS. SASS: Okay, my last question is the most complicated. It's on Slide 24. It has to do with the data call-in process, the DCI process. What system do you use for tracking what data call-ins you've issued and whether or not you receive the data on those call-ins and whether that data fulfills the requirement for that call-in? And then how do you know that you've incorporated the results of that data into your assessment? Do you have a tracking system that someone like me can look at and say, okay, this RED is finalized and there was data call-in issues for this RED, how has that data been received?

MS. EDWARDS: We have a number of tracking systems and we're working toward having one through -- open that you would be able to do exactly what you're talking about. But for the most part now, we have a

number of separate free-standing tracking systems between RD and SRD and actually, to be -- it's interesting that you brought this up because in our staff meeting today, we were discussing a tracking system for DCI.

But I would say what you could do is if you're interested in any specific chemical, the status of where we are with that, you could simply ask us and we could provide you with that.

MS. SASS: So, each -- it would be chemical manager by chemical manager kind of (inaudible) right now.

MS. EDWARDS: It's not that bad, but it's --

MS. SASS: Well, I'm not saying that's bad. I'm just wondering -- it was just a question, where do I go?

MS. EDWARDS: Yeah, it's -- it's a series of separate tracking systems. It's not all in one tracking system right now I think is the best way to put it.

MS. SASS: Okay, then I do have a question on the OPs. You guys issued a data call-in for development of neuro-tox study data, the DNT data on all the OPs that were reviewed. You didn't receive most of that by the time it was issued. Now, by the time it was finalized,

my understanding is you had received more of those DNT data, but not timely enough to be able to review them for the final cumulative assessment. Is that right or how would I figure that out? Did you have all the DNT data when you finalized the OP cumulative risk assessment?

MR. JONES: We need to get back to you on that question because --

MS. SASS: When can I get -- who can I contact to find that out?

MR. JONES: (Inaudible) back here. It won't take us long to get the answer to that.

MS. SASS: Okay, thanks.

MR. JONES: Bob?

MR. ROSENBERG: Jim, I just wanted to echo what Adam was saying about the tremendous accomplishments of the agency in the last 10 years. On behalf of the IR-4 Program, and especially crop growers in the United States, I'd like to thank the EPA for the wonderful partnership we've had over the last 10 years. We've had -- I don't think by any coincidence, we've had our most productive 10 years of our -- decade of our entire program. We've got 5,600 clearances in partnership with

EPA on specialty crops and I think the doom and gloom of 10 years ago that products would be taken away from our specialty crop growers and not available has largely been dispelled thanks to the efforts of the agency and the IR-4 Program in registering predominantly reduced risk chemicals and safer chemicals for our growers to use.

And after spending a week, as I did last week in Germany, and hearing the hand wringing of what's going on in the European Union, I think the EPA can be proud that we have not only protected the environment, but given our growers a safer set of crop protection tools to use. So, thank you.

MR. JONES: Thank you, Bob. Caroline?

CAROLINE: This is just a clarification question. There were a couple references in the presentation to kids' food and I was curious exactly how that's defined.

MS. EDWARDS: It has to do with exposure from dietary surveys, what are the ones that they eat the most of. So, I mean, some of them are -- well, I can tell you what they are, apples, grapes, oranges, peaches, pears, potatoes, snap beans, spinach, strawberries, tomatoes and

wheat. That's based on the food survey data.

MR. JONES: Ray and then Michael Fry.

MR. McALLISTER: A couple of questions. I believe that the inert ingredient formed a certain small portion of tolerance reassessments, the work handled necessarily by your division. I'm aware that there's a block of the inert reassessments which are then completed with a decision document that are not yet available. Do we know when those will be made available?

MR. JONES: We'll have to get back to you, Ray.

MR. McALLISTER: The other question deals with special review. You said you're closing out all special reviews. Does special review now just go away?

MS. EDWARDS: No, we still have regulations, so we could, if we chose to, use them. But what we, I think, have found over the years is that it -- in order to get the mitigation we want quickly, it's better to work with registrants to get voluntary agreements, and if not, probably just pursue notices (inaudible) cancel because for the special review, as many of you know, these have taken years and we've kind of determined during reregistration that it made more sense to just

work these issues through reregistration. So -- but the regulations are still there if we -- if there was a situation that we felt that that was an appropriate path forward.

MR. JONES: Michael?

DR. FRY: Yes, just a clarification question again. On tolerance reassessments, good tolerances are established by the FDA, I believe. Clarify that for me (inaudible).

MR. JONES: (Inaudible) we establish the food tolerances.

DR. FRY: I beg your pardon?

MR. JONES: EPA -- OPP establishes food -- pesticide food tolerances; FDA enforces them, not exclusively, but we establish them.

UNIDENTIFIED MALE: (Inaudible).

UNIDENTIFIED FEMALE: Turn on your mic.

MR. JONES: Okay. Thanks, Debbie.

I understand Betsy Behl is going to give the next update, transparency around issue of impaired water bodies.

UNIDENTIFIED MALE: (Inaudible).

MR. JONES: Kevin, you're going to do it?

MR. COSTELLO: Yes.

MR. JONES: Kevin Costello who is filling in for Kennan Garvey.

MR. COSTELLO: Kennan can't make it today. I'm Kevin Costello. I'm with the Special Review and Reregistration Division. And with that, I'll give you an update on our pilot exploring how we might be able to obtain and use impaired water body data for registration review.

Now, Debbie described before with the essential completion of the tolerance assessment under FQPA and the end of the reregistration program in 2008, registration review will be the vehicle by which we will continue to assess pesticide registration to keep them current with the state of the science. And registration review is actually starting right now and will be a continuous program by which we look at each chemical every 15 years.

Now, one of the guiding principles of registration review is transparency and openness in the process, and we really intend for public participation to be an important part of the registration review program.

So, as such, stakeholders and the public will have opportunities for input and for consultation throughout the whole process starting, as Debbie said, with the opening of the dockets.

Now, one kind of the information that we're hoping to get is great information about water monitoring from the states. At the end of reregistration, the states indicated to us that they had been aware of water monitoring data marginally, but not completely, from their 3B impairment listings, that we hadn't included in our risk assessments. And the states and the regional offices have indicated their interest in making sure that they can make available this data so that during registration review, we will include it in our risk assessments.

In February, Benita Best-Wong of the Office of Water and Debbie Edwards of OPP agreed with this position and established a goal in a memo to develop an SOP to establish a process by which we could obtain this data so we could use it in registration review, and also set up a pilot between OPP and the regions and some states.

Go ahead. So, in response to the memo, OPP, the

Office of Water, four of our regions, Regions 3, 5, 10 and 9, and several states tested a process for gathering state water quality data. Now, in this pilot, we determined data location, not only from which state all of the data came from, but which databases, where we might find this data on the internet or such, and how accessible it was to us.

We gathered targeted water quality data for a particular pesticide, which I'll describe, and this data was submitted in the summer and then evaluated by the Office of Pesticide Programs.

We determined the extent to which the data, as presented, could be used in our risk assessment, and then based on our experiences, revised the draft SOP to identify the roles of the agency, the states and tribes in gathering this data for registration review.

So, the pilot then has established -- helped us to establish a process to routinely consider this water quality data for our exposure characterizations for ecological risk assessment and registration review.

Now, in order to be able to do the pilot in a short amount of time, since we're looking to start

registration review, as Debbie said, this year, we concentrated on two chemicals to start, malathion and chlorpyrifos. These pesticides were chosen for a couple of reasons, mainly because there were multiple impaired water body listings in regions and states, 35 of them for chlorpyrifos and a couple of them for malathion, as well as additional data for water bodies in Region 5.

It's very important to note that, again, this pilot was meant to give us an opportunity to see how we can gather this data and then figure out how we might be able to use this data. It was not meant for us to take a look at the data and decide whether we agreed that they were a good basis for impairment listings under the Clean Water Act.

So, the regions that I mentioned worked with the states this summer and sent the data that they had or links on the internet to us where we could obtain the data for chlorpyrifos and malathion.

Since we're trying to do it in a short time frame, we got what they were able to give us in that short amount of time. It's possible that there's more. But then once we had it, OPP checked the data, provided

feedback and -- both on our ability to get the data, understand the data, but also our ability to use it in risk assessments.

And now Betsy will give a little more details on how we took a look at this data.

MS. BEHL: Hi. The data came in to both Office of Water and to the Office of Pesticide Programs and after winding its way through the agency, landed in the Environmental Fate and Effects Division, which is the organization in OPP that does ecological risk assessment. We assembled a team of scientists, the folks who would generally look at data like this, to take a look at the websites and the other data sources and sort of screen it for information.

The list of checks that you see on this slide is sort of detailed. We attempted to answer questions like can we reference these data; when we look at the data provided, can we identify what the results are? I'll get into that in a little bit. Is there enough information associated with the data to describe the monitoring program to give us some of the context of how the data were collected and how can we use the data? Can we use

it qualitatively, can we use it quantitatively in risk assessment?

We recognize that, you know, this is a pilot, this was a first effort to gather this data and send it into the agency, and there's a lot of monitoring being done in states for a lot of different reasons, not just for use and pesticide risk assessment. So, we received a lot of different kinds of data sources and data links. We didn't always find the kind of data that we would need to use the data quantitatively in the risk assessment, but a lot of good data was submitted that we could use qualitatively.

This second bullet about 303(d) listings references Kevin's earlier comments, which we've heard in the end of reregistration about the availability of data related to 303(d) listings. One of the things we've tried to do is to see if we could relate some of this monitoring data back to those listings and we weren't really able to do that a lot of the time. I think it's possible that when additional information about -- and links to other data sources, we might have been able to do that. But based on what we received, we weren't able

to do that a lot of the time.

In some cases, only summary reports were available and not the actual data. And in the end, what we tried to do is go back to the standard operating procedure, look at our initial data request to the states and refine it a bit, and I'm sure there's going to be multiple iterations of that, to try to identify what are the minimum things we need. We know we need to be able to provide a bibliographic citation for where the data came from. So, we sort of subdivided the SOP into absolutely have to have kind of data that is what you see here in this list and other kinds of data that would be needed to use the data in a more rigorous analytical fashion.

One of the issues was that some -- the reports that we got sort of spanned a list -- a sort of spectrum of information and some folks submitted data where they had gone to look specifically for detections of the targeted chemicals, extracted it, sent that data in, which was a wonderful time saver, but you also need contextual to be able to interpret it. So, having both of those things is important.

The other end of that spectrum were websites with locations of lots and lots of data but not necessarily just on pesticides. Some included radiological data, mining data, and so, actually getting to the specific targeted compounds of interest was quite time-consuming.

There's potentially a lot of useful data, as I said originally, in here. You can use data in lots of different ways, qualitatively and quantitatively. For example, the middle portion of this slide gives some of the details of several of the submissions which gave us everything we would need to really use -- need in order to use those data in an ecological risk assessment. In other cases, a lot of follow-up was required to get enough of the contextual information to be able to (inaudible) data.

Kevin?

MR. COSTELLO: So, after going through the pilot, there were a number of conclusions that we could come to right away. First, as Betsy said, the data was of varying utility for us in our risk assessments, whether qualitatively or quantitatively. But a few of

the data sets met most of the data elements that OPP had identified and, so, perhaps could be used quantitatively. But several other submissions had the potential to be useful, either to a lesser extent or perhaps with additional information could be more useful.

We found that if a state provided links, it minimized the amount of time for us to find the data, but sometimes it led to very lengthy searches. It wasn't always a clear linear path to the information we were looking for.

Newer data, as one might expect, would be more likely to include the elements that we would need for a quantitative risk assessment. But the SOP, when we -- as we do iterations of it, as we work with the regions and the states, should help us in getting the voluntary submission of the data, and it will give advance notice of the kind of data elements that would be needed for us to be able to use the data in our risk assessment.

You know, the focus of what we will do will be on the near-term cases of the registration review schedule, which, as Debbie mentioned, is available on the web. And we certainly, again, as one of the main goals

of participation, encourage the states and the tribes to submit the water quality data that they have so that we can meet with the -- you know, resolve the concerns that they had at the end of reregistration.

And very importantly, you know, while providing the schedule, it's necessary that the data be submitted to us in time so that we could actually consider it, have the time to look at it.

The draft SOP, as it stands now, after going through the pilot, has different roles proposed -- we proposed for ourselves, for the regions and for the states. You know, the goal for those that will be submitting the data is that they would voluntarily submit high quality data that we could use in registration review. In order for us to be able to get the information on time and use it, that they take a look ahead to see which chemicals are due in the schedule.

While we were concentrating mainly on 303(d) impairment listings, other water quality data is also important, and from the biannual water quality reports under the Clean Water Act, as well as the (303)d.

We ask the states to mine existing data that

they've got in their own databases in order to be able to provide it to us, and then submit the data links or the data on specific chemicals as they come up.

Now, the role of OPP under the draft SOP would be we would consider the data in the characterization of our ecological risks when a risk assessment is needed and that we will seek public comment on the risk assessments and on risk management for each chemical, and develop appropriate risk management and monitoring options.

Oh, I'm sorry, I misunderstood this one. Then, again, to issue the proposed decision for comment. As was said before, all the different aspects of registration review, including proposed mitigation, proposed decisions, will be up for public comment before implementation.

So, in conclusion, we do believe, after going through this pilot, that the findings of this exercise will help us to gather water quality data we could use for registration review. The draft SOP that we have (inaudible) establishes the processes and provide guidance to all involved on what data we need and the form in which it might be provided to us.

And then we will use this process as soon as possible starting in this fiscal year to the extent that the data is available and is submitted to us.

Thanks.

MR. JONES: Any questions or comments? John?

MR. SCHELL: How do you folks -- do you have a plan in here to deal with some of the QAQC issues that come up? The 303(d) and some of those are -- they're pretty standardized. But you have down there, and you mentioned it a couple of times, other water quality programs, and there's all different kinds of monitoring programs across the U.S. And if you're compiling this especially for a quantitative risk assessment or -- is EPA going to provide a QAQC gate keeping role in this or are you just accepting data and that's the state's responsibility?

MS. BEHL: I think it's the responsibility of the study director to do the QAQC on their monitoring data. However --

MR. SCHELL: The state study director or --

MS. BEHL: Whoever does it. I mean, I think there's opportunities for states to submit data that is

derived from a variety of different sources. But one of the things I said is you can use data a lot of different ways. You can use it qualitatively, you can use it quantitatively. Monitoring data will generally tell you something if you're able to cite it and understand why the monitoring study was conducted in the first place. And in order to be able to use it in a quantitative fashion, you need to know an awful lot about the data, and QAQC is one of those things.

So, where we've got those kind of -- that kind of information, we can use data more quantitatively (inaudible).

MR. JONES: Beth?

DR. CARROLL: I had a similar question to John and I just -- I wonder in thinking about your answer, is SOP available and does it address any of these quality concerns?

MS. BEHL: The SOP is -- I think it's still under development. I don't think it's quite available yet. There was a brief discussion about that yesterday. I think there are a few steps that the Office of Water wants to go through before it's finalized. But it's very

close and I don't know the mechanism for dissemination.

MR. JONES: And, ultimately, we will make it available.

DR. CARROLL: And will you take comments on it?

MS. BEHL: Sure. I mean, it's a fairly straightforward -- it's an SOP not about how to do data, how to collect it -- how to collect data. But what types of information we would like to have submitted to the agency.

And there are -- to expand on it slightly, one of the things we did was we sort of separated categories of information into three parts. The first is, what do you need at a minimum? The second was what is really good information that you really ought to give us for us to be able to interpret this? And the third is what will -- ideally, what would we like to see coming with a data set to enable us to use it quantitatively?

MR. JONES: I think actually, Beth, it's in everybody's packet, the SOP.

DR. CARROLL: Oh, the SOP?

MR. JONES: Is that --

MS. BEHL: Yeah, it's Appendix A.

DR. CARROLL: Okay.

MS. BEHL: There's an Appendix A.

UNIDENTIFIED MALE: (Inaudible).

MS. BEHL: Right, right.

MR. JONES: Dennis?

MR. HOWARD: From the standpoint of a state lead agency, I really would like to let the agency know that we appreciate these efforts to try to obtain data that have often been pulled together by the states, but often also never really been actively sought for one reason or the other in the past in the reregistration process. The idea of setting up a process to obtain the data and for the agencies to consider it, I think will really help the registration review process if it's set up in a way that is more -- is active rather than passive where the agency sends out information to the states saying, this one's out now and we're looking for these data. I think that the Federal Register does that.

But if you make it more active to go to the water managers in both the lead agencies for water quality as well as for pesticides, that would help quite a bit.

And, also, I'd like to applaud you for working -- OW and OPP working together. I know you've been making a concerted effort to do more of that and the more cross program efforts that you take, the better off, I think, everybody will be for it.

And, finally, just a question about OW's role in this particular exercise. Did they (inaudible) the data that came in as well as he said? Were they part of your review team or what role did they play in this?

MS. BEHL: We discussed the findings of the data -- the data came in to OW as well. The analysis was done by (inaudible) largely because it's (inaudible) pesticide risk assessments which is not something they are routinely involved in. But we spoke with them several times in conference calls about the findings and follow-up to what we were seeing.

MR. JONES: Thanks. Jennifer and then Julie and then Ray.

MS. SASS: Yeah, my question is, in the Appendix A where you list your three tiers of data that you'd like, that's pretty good, I mean, especially the third tier, your metadata. So, my question is, what data are

you using now? I mean, if this is the ideal data that you'd like and if your pilot program sort of failed to collect that data in most cases, that you weren't able to collect data that you could use quantitatively, which is your third tier here, what are you using now?

MS. BEHL: Well, we have -- we've been looking at monitoring data ever since I've been working with the program, and a lot of those data are collected by state agencies. I think this is kind of a formalization of the process that we use right now to go through and screen data for various forms of utility in the risk assessment.

MR. JONES: But even if there is monitoring data, which there often is, we are going to model estimates and predict estimates using models, and if there isn't any monitoring data, obviously, we're going to have to model the predicted concentration.

MS. BEHL: Yep.

UNIDENTIFIED MALE: The list of the data elements that we were hoping to get was based on some of the data that we have seen and used in the past and some of the ones that we thought were the most useful to us in our risk assessments.

MS. SASS: So, I'm aware that you use models, and so, do you think that some of this data could be useful to you maybe if you didn't get the third tier, the quantitative necessary tier, could you use the data to help to truth test and improve the model? Could it be useful that way?

MS. BEHL: Yeah. I mean, I think we always try to use all available data. There's a lot of data that goes into the models in terms of environmental FATE data and climatic information. I know you're aware of that. And at the same time, we try to summarize all available monitoring data and describe its pros and cons, its uncertainties and we use both of those lines of evidence together in risk assessment.

So, this -- I sort of look at this as a more formal and broader request for monitoring data, casting a wider net, hopefully, to gather everything that's out there that we might have missed in the earlier stages. I think we've seen a lot of state monitoring data. The State of Florida, we've been in contact with for example and used a lot of their data in risk assessments. So, I think we're just expanding upon that.

MR. JONES: Julie?

MS. SPAGNOLI: Just a question on, you know, since there's data very specific to a particular area, how did you or how would you get the usage data sort of specific to that site? I mean, because you can't really tie the particular use -- I mean, because usually risk assessments are based on -- you know, a particular use. I guess I -- how do you correlate those if you don't have the usage data?

MS. BEHL: You have asked the $64,000 question. I mean, that is usually the hardest part of interpreting monitoring data is trying to figure out what was actually used so you can figure out if the concentrations being observed are consistent with that. I know there are a number of efforts to try to refine our capacity for getting more site-specific usage data, but that's the hard part.

MR. JONES: Ray? This will be the last question. We're going to have to wrap it up.

MR. McALLISTER: If I understand correctly, you're collecting this information or you're looking at how to collect it for use in the registration review

program, and then if something of concern shows up, you'll decide whether you need more information?

MS. BEHL: Kevin?

MR. COSTELLO: Sure. Again, as Betsy said before, monitoring data that we get from the states, as well as any other monitoring data that are available, will just represent one of the lines of evidence that we'd use in the total risk assessment. It's not meant to be some kind of specific trigger which is different than everything else we use. We just want to make sure we're using all available data, all the best data. But right now, there's no specific requirement to submit this data either from registrants or from states. Even in this case, it's going to be a voluntary program. We're asking for their help.

MR. JONES: There isn't an answer to the question. As we go through registration review, it's set up in a way that has enough transparency that stakeholders will be able to see early on how we're using it and be able to participate in how they think that we're using it, whether it's just for assessment purposes or ultimately (inaudible) risk management. And I think

it will be very case specific.

Okay, thank you, both of you, Betsy and Kevin. I appreciate it.

We are now going to hear from the Performance Measures Work Group who I mentioned at the beginning has developed a report for consideration by the full PPDC. Really the question before us is whether the full PPDC wants to adopt the report as advice to EPA.

Sherry Sterling, who is from EPA and the Pesticides Program, who helped to manage that group, is going to kick us off.

You all have a report that is dated 6/29/06 in your packet. It was also sent to you, I think, about two weeks ago electronically.

(Brief pause in the proceedings.)

MS. STERLING: All right, thank you. This is not a typo. This isn't just about the strategic plan. It's about strategic planning, which is the strategic plan and beyond. So, it's more to give you the update because at the last meeting -- and our work group has asked that we continue to keep you updated on what we're doing with this project.

The agency's strategic plan for 2006 through 2010 is not final yet. It has cleared EPA's chief financial officer; it has cleared OMB and it's now up on the Hill for review. It won't be final until the Hill completes their review of this.

I want to make a couple of important points for the rest of this briefing relative to the strategic plan, and that is that your strategic plan sets your budget structure. However that -- so, now that we've changed our strategic plan structure, we have to go back and change our budget structure. I'm not talking changing money; I'm not talking change the work that we do. I'm just saying that the headings that we use and the headings that will be used in the President's budget when it goes up for 2008 will have the new headings that reflect this new strategic plan.

So, let me just take a minute and tell you what's in the -- in the draft strategic plan that we have right now. If you recall, we have three mission areas. The first one of those is protect human health and it is listed as Protect Human Health from Pesticide Risk in the strategic plan. If you're into numbers, it's 4.1.3. And

there are three measures that we have in this strategic plan relative to human health. The first one deals with a reduction in the general population, and we're looking at that with the NHANES data. We're looking at specifically OPs and reductions there. So, that's our first one.

The second deals with maintaining a low rate of occupational exposures. And, finally, the last one deals with reducing some very specific occupational exposure chemicals that have the greatest acute list. And there are six of those that we've identified.

Moving on to Protect the Environment, I would say that this is the area that has changed slightly from the last time that you all have seen it. Last time, we had -- we did have this concept of looking at urban watersheds and agricultural watersheds against benchmarks. And back then, you might know this as the NAWQCA or National Ambient Water Quality Criteria Assessment database. It's a measure based on that database.

When we got to the chief financial officer and OMB, they actually asked us to pull apart and have one

measure for urban and one measure for agricultural. It just made it easier to follow.

The big difference here is that we have taken out the specific endangered species. We were saying look at endangered species. We'll be capturing that in other ways and I think this is actually -- what we have in now is actually more in line of looking with aquatic species in general as opposed to just the endangered species and the work group said, you know, you shouldn't be just looking at endangered species.

I would say, though, that we recognized, as the work group did, that, quite frankly, our next adventure will be into the realm of non-aquatic measures to use.

And, finally, Realize the Value from Pesticide Availability. As a result of the discussion from the group, this is no -- this used to be called Benefits. It's now Realize the Value. And I will say -- I want to make a very big point that this category probably wouldn't exist today without the work and the comments from the work group and the PPDC. In fact, at every level and every step of the way, people have challenged us about this realizing the value from this pesticide

availability. Not that they think that pesticides aren't valuable, but they think that it's not an appropriate, perhaps, measure for an agency, an Environmental Protection Agency. We've convinced them that, you know, safety is always there. It's not just that they're available, but they're safe and available.

So, we were able to point to the work that you all did in the work group and say, no, our stakeholders think that this is an important piece. So, I just -- you asked for feedback on how we use the report, this is a major way. This is a major way that it was helpful to us as we went through the process.

And here we have the avoided crop loss with the Section 18 Program. That's what the first measure here is, and the second one is looking at termite structural damage avoided.

So, those are the seven measures that we have in the strategic plan currently.

Remember I said it was real important that the strategic plan sets the budget structure. Well, in '07, on the right-hand side of this -- the left hand side of this slide, you'll see that the budget structure for '07,

what we're currently in, is the old structure, registration, reregistration, field programs. Those are very output kind of oriented areas or ways to look at things. And as you'll see, we're moving towards, we're transitioning towards FY '08 when we have a proposed structure that reflects the mission areas that we've just gone through putting the strategic plan.

So, what we're in the process of doing is tracking all the activities that were for registration and tracking those activities into the new structure. It doesn't mean we'll have different activities, it doesn't mean we'll have different money, it's the same money, same activities, just tracks the different categories to better reflect the outcomes, which are, obviously, protect human health, protect the environment and having pesticides available for use.

One of the things that the work group told us is, remember, you can't -- don't throw out the baby with the bath water. Don't throw out those output measures, and we have not done that. We've just augmented those output measures with our new -- with these new outcome measures.

And the seven that we just went through for the strategic plan are kind of, in a way, the tip of the iceberg. The strategic plan is like the big picture. We have a number of measures that we're still looking at and are very important. It doesn't mean that they're not important because they weren't in the strategic plan. It was just the strategic plan looks at kind of like an overarching sort of measure. We will continue with other measures that we're calling internal measures to distinguish them.

Okay, examples of the output measures that we have in place for FY '07, the year that we're in, number of new chemicals registered. That's a measure that we've had for a long time. Or the number of new uses registered, again, an old standby that -- really those provide the background for some of the outcomes that we're asking for. And the outcome -- I have listed here two examples of outcome measures that we're looking at that we will be tracking and will be reporting on in FY '07.

So, our next steps in OPP are really -- you know, we really kind of focused for a while on the

strategic plan, making sure that the strategic plan measures were accurate and that we had verification and validation processes for them and that we had all the back-up documentation that we needed to make sure that they were strong measures, to get them through to our chief financial officer and also through OMB. So, now we want to turn our sights on to the internal measures and really beef those up.

And, of course, the second bullet there is doing that budget crosswalk to the new structure for '08, that will go public in February when the President's budget comes out.

And I just wanted to follow up kind of with the agreement that we reached with the work group, and that is that it's kind of a work group in suspension and that until -- there wasn't -- until there's a need to have review of new measures or different measures, perhaps the internal measures, that's what I envision, it would be kind of -- the work group would kind of be asleep, if you will. It would be lying low. Like the equipment here we have, it goes into a sleep mode. So, that's what it would be like. So, you can go, shew, no work for that

one for a little while, until we get more involved in the internal measures.

So, that's kind of the update on where we are in strategic planning in a nutshell.

MR. JONES: Thanks, Sherry. So, the work group prepared basically a report, which all of you have got, and other than having questions for any of us up here around what you just heard, I think the principal order of business that I'd like to accomplish this afternoon around this topic is whether or not the PPDC as a whole wants to endorse this report to the agency as advice, which is the process we need to use for any work group recommendations. It's a pretty short document. Hopefully, you'll all have had an opportunity to have read it.

Personally, I thought it was actually quite well done. It hit a couple of the areas that we have been struggling with, from develop some better environmental outcomes to you need to be using a term other than "Other Benefits" and, frankly, you haven't captured the range of the benefits this program offers. But it is really up to this committee as to whether or not you want this to be

considered advice to EPA.

So, I see there a number of cards up, but they were put up before you knew what I was going to ask you. So, let's tackle this question and then we'll go to just general observations, questions you may have had on Sherry's presentation.

Would anyone like to move to recommend it or does anyone have a question around it or -- Bob, you want to move --

UNIDENTIFIED MALE: (Inaudible).

MR. JONES: That this report become advice -- the 6/29/06 report of the Performance Measures Work Group of the PPDC, whether this should be accepted as advice to the agency. Bob has moved to recommend that it be taken as advice. Does anybody want to second that?

MS. SPAGNOLI: I'll second that recommendation.

MR. JONES: Thank you, Julie. Is anyone opposed to this becoming advice to EPA?

UNIDENTIFIED FEMALE: (Inaudible).

MR. JONES: Okay, yep, sure.

MS. SASS: Well, I actually did read it over carefully prior to the meeting, and I don't have many

comments, so maybe it is really (inaudible) and maybe it's things that the work group considered and could very easily just say why they didn't include it or wouldn't want to or something.

On the part of general and process observations, it's page two in the written report, number two, it's important to recognize the risks and benefits of pesticides. There's no mention about long-term health risks at all, chronic exposures and maybe the cost of those. So, I wonder if the work group considered long-term health risks as opposed to the poisoning incidents.

Then number four in that same section, the group talk about regionally based impacts. I wonder if there could also be a mention of the highly exposed group, like worker and bystander exposures in those areas, which aren't picked up by national data, and what are the costs associated with those.

And then going on to number five after that -- no, actually I'm going to skip the number five comment because I can live with that.

(Laughter).

MS. SASS: Number eight, under Mission Area,

number eight talks about use of the NHANES. I'm glad that you're using the NHANES. I'm a big supporter of using the NHANES. But the NHANES isn't -- doesn't give you regional or site specific information and it is likely to underestimate highly exposed, vulnerable subgroups like worker populations in agricultural areas who are bystanders.

UNIDENTIFIED FEMALE: (Inaudible).

MS. SASS: And their children. And for some reason in here it actually says it could overestimate. I would like to know how it could actually overestimate because it's measurements, it's real measurements. So, I can't imagine how real measurement could overestimate. But I can see how it could underestimate by missing things. So, this seems to me to be a bias that actually only goes in one direction and it should be discussed.

The use of the Total Diet Study, that's the last sentence on the same point, eight. It is actually a less direct measurement than the NHANES biomonitoring data. It monitors what's on food and not what's in people's bodies. Just as something to consider.

It seemed to me the group might be talking

between the two and I'm a supporter for the NHANES, but with the caveat that it may miss sensitive populations.

Number nine, it says -- the first sentence, there was concern in the group that having measures that reduce the levels of pesticides without any qualification of that statement could give the impression that current levels are unacceptable. In many cases, they are unacceptable because FIFRA has the cost benefit trade-off built into it. So, as we discussed extensively yesterday in our spray group, with the example of Q4D, it could actually be biologically or human health or ecological health unsafe, but have, you know what Anne Lindsay called a FIFRA safety decision because the economic benefits are weighed into that.

So, you cannot de facto consider a registration of a pesticide to be an indication that it's safe for humans.

Number 10 --

MR. JONES: It sounds to me, Jennifer, that you're not prepared to endorse this as a recommendation to EPA.

MS. SASS: Well, not as is.

MR. JONES: That's my --

MS. SASS: If the group can discuss these and can convince me, you know, that I'm out of line or they could be included, then I'm willing to consider it. There was things I liked about it. I liked the use of human health and ecological and worker health indicators rather than numbers. But I think it needs more consideration of quality control of the data to really understand what you're considering.

MR. JONES: So, are there others in the group who are uncomfortable with making this a recommendation to EPA? Amy, uncomfortable?

UNIDENTIFIED FEMALE: (Inaudible).

MR. JONES: Okay. So -- Bob, you're not one of them if you're -- okay. I think we then need to go back one more time to this -- it was a napping work group that needs to be reawakened, and if I could ask that the people who are not comfortable, if you can either participate personally or coordinate with each other so that one of you can represent that perspective. I mean, you don't all have to participate and maybe you may not share the same -- if you don't share the same issues,

then you'll obviously have to participate personally. And it may be that we can do it in a conference call without having a specific meeting.

So, I think what we'll need to do is try one more time to see if we can get consensus around the recommendations before we give reconsideration.

UNIDENTIFIED FEMALE: (Inaudible).

MR. JONES: I think we start with the existing work group, and I saw Jennifer Sass, Amy Liebman -- and I'm sorry, I cannot read your card.

MR. KEIFER: Matt Keifer.

MR. JONES: Matt Keifer, sorry, Matt. Oh, and Shelley Davis and -- that looks like the public interest community. And Carol Ramsay.

UNIDENTIFIED FEMALE: Public health people.

MR. JONES: Okay, you're saved by a non-public interest community representative, and Melody. Double save. Okay, everybody who's already on that work group will also be -- will be asked to re-engage. Phil? Phil Klein? You have a comment?

UNIDENTIFIED FEMALE: (Inaudible).

MR. JONES: Well, I think that order of business

is taken care of. We have a pass forward.

UNIDENTIFIED FEMALE: Jim, could I make an additional comment?

UNIDENTIFIED MALE: Before you pursue that, you've got a motion and a second and some discussion. Is there going to be a vote or not?

MR. JONES: No, this isn't --

UNIDENTIFIED MALE: Okay.

MR. JONES: I see that a significant sub-population of the PPDC is not comfortable and that's enough for me to say that we're not going to move to accept it.

UNIDENTIFIED MALE: So, for a decision on that, you're waiting for a consensus.

MR. JONES: We're going to defer until we've had one -- at least one more session where some of these issues can be vetted.

UNIDENTIFIED MALE: Once the report and recommendation goes forward, what does EPA do with it? Does it make changes to the strategic plan?

MR. JONES: It will be advice to EPA.

UNIDENTIFIED MALE: Okay.

MR. JONES: That we'll take under consideration as it relates to the strategic goals that we've got in our strategic planning process, yes.

Okay, so, do people have other questions or are they prepared to move on to the next order of business? Sorry, Amy?

MS. LIEBMAN: Yeah, I just have some questions, Sherry, on some of the specificity, actually, with which the slides of your presentation were developed. There are some very specific numbers given in there in some cases, some very specific percentages and some very specific benchmarks, and I'm wondering if those -- to me, it indicates that these are now in the strategic plan or will be in the strategic plan. Is that --

MS. STERLING: They are indeed in the strategic plan. The things that are on slides three, four and five are what's in the strategic plan right now.

MS. LIEBMAN: Oh, those are the ones that I have the exact questions about, because it seems to me if you separate out into statements, it makes it -- hmm. Well, I guess I don't understand why one would set a specific percentage reduction for one case, but then just a

reduction in another case. What I'm really suggesting is the same thing that we've discussed before about giving a mis-impression that you have some indication that you need -- unless maybe you do. Maybe you know that you need to reduce it by 50 percent and (inaudible).

MS. STERLING: Yes. Actually, very, very good point. Because these are snapshots of what's in the strategic plan, they don't give the full statement. And, in fact, let's say perhaps your question might be, why in the second bullet under human health you say we're going to improve the overall rate, but the third bullet says you're going to reduce those specific six chemicals? And the reason is we chose those specific six chemicals because we found in surveys that they're the most acutely toxic agricultural pesticides, and that's going into a little bit more detail in the strategic plan and that's very well backed up.

So, overall, we want to maintain a low rate, but in particular, we want to focus in on those that are most acutely toxic that we found the most problematic. And that is not -- we do go into that more in detail in the strategic plan.

MS. LIEBMAN: Well, I sort of assumed that with the six pesticides that you identified, that you had reason there and that was not --

MS. STERLING: Right.

MS. LIEBMAN: -- unbelievable to me. But things like continue to avoid one and a half billion dollars in crop loss, so what if you managed to avoid only $1.4 billion in crop loss? Things like that. I just wouldn't put quite such --

MS. STERLING: Unfortunately, the world is such that you have to put numbers and you have to make it that specific. And that's just kind of the world that we live in. If we only reach, let's say, $1 billion in crop loss because that's what was appropriate and we did all the Section 18s that we needed to do and everything worked out, but gee whiz, we had a great year and we didn't need that many, then we'd just write -- it would be up to us to write that explanation in. It isn't that we're trying to create crop loss; it's, in fact, that we want to maintain the rate that we currently have, which we think, over the short term, that's not an unreasonable thing.

MR. JONES: Anyone else? Phil?

MR. KLEIN: I have a question. I sort of (inaudible) on your slide with regard to crops and termiticides and the value of pesticides and I notice you do pick up on (inaudible) for the application of --

MS. STERLING: Yeah, can you -- I'm sorry, I can't hear you. Thanks.

MR. KLEIN: You talked about the antimicrobial pesticides. I think that needs to be broadened out to insect repellants and other public health products that benefit against West Nile Virus, lyme disease and other diseases, and do we engage in performance measures with regard to those public health pesticides as well.

MS. STERLING: And, in fact, that's been one of the struggles. That's something that we'd like to do and we just really haven't had the data to really go after that and that's one of the things that we have been working with various members in the work group to say, hey, what other data can you bring to help us be set up, because, indeed, we would agree with you that that's the case.

MR. KLEIN: Just a point, we are working with -- on Capitol Hill with the American Black Caucus, with

Republicans and Democrats alike with regard to education with regard to West Nile Virus and lyme disease and elsewhere, particularly with regard to Deet and other products. So, I think it's vital that those products, from a strategic planning standpoint, get included.

I think it's also important, if you check on the website of the Center for Disease Control and look at (inaudible) diseases in the United States, it's a significant problem, and I think, again, as a strategic plan for EPA and working with other federal agencies, there should be some specific performance measures with regard to those products.

MS. STERLING: We'll definitely have performance measures related to those (inaudible) products. But I'm not going to tell you that they're going to be in the strategic plan. The strategic plan are kind of the seven that are set. That doesn't mean that other products that are not in here, the products that you mentioned and others, aren't important. It's just simply that they would be internal, they'd be tracked. We'd use them for other important documentation like our part reviews, like our performance reviews that we do in -- that we share

with OMB, with the White House, et cetera.

MR. JONES: Shelley?

MS. DAVIS: I have a quick comment and a question. I'm glad to see that the strategic plan includes measuring worker risk, but I actually think that the "low" level of worker poisoning is really an artifact of a couple of things. First of all, that workers don't get adequate training to recognize the symptoms that they have as related to pesticides. Secondly, that their health professionals aren't recognizing that the effects they're seeing as pesticide-related. And, third, that there is no national incident reporting system.

So, one of the things that's good is, I hope, that we will see in the next five-year period, an improvement in worker training. I hope we'll see an improvement in training of clinicians. I hope that we will actually see a national pesticide incident reporting system. So, when those things all come online, what you might have, if this is all working actually well, is you might have an increase in the number of worker poisoning incidents because you'll have more actual incidents reported. So, I think that kind of thing needs to be

taken into account.

My question is, if you could, what are the particular pesticides that you're measuring (inaudible)?

MS. STERLING: Sure. They are chlorpyrifos, diazinon, malathion, pyrethrin, 24D and carbofuran.

MR. JONES: Bob? Bob Holm and then Bob Rosenberg.

MR. HOLM: Yeah, just a quick comment. On the economic loss avoidance, it appears -- I assume that's an annual number and it appears to be low. I know we use EPA data for IR-4 supported Section 18s and we've averaged about a billion and a half dollars a year from 1998 to 2005. So -- and we account for less than 50 percent of all the EPA Section 18s. So, that number seems to be low.

The other comment is, I know there's a lot of focus on endangered species, but a problem we see emerging is invasive species. It seems to me the cooperation between EPA and the USDA on Asian soybean rust was a tremendous success story, although the problem didn't occur as many people anticipated. I know there are a lot of other invasive species that are causing

hundreds of millions of dollars of loss in irrigation canals and other things. So, maybe there's an opportunity to look at performance measure based on control of invasive species.

MR. JONES: Thanks. Bob Rosenberg?

MR. ROSENBERG: I don't want to comment on any of the specifics of what people have just talked about, but, you know, I think it would be worth saying that at some point, maybe like tomorrow, it would be valuable to have some discussion about the process of work groups. And the reason I say that is I think there's been a lot of good work conducted within the work groups. In fact, I think some of the best things that have come out of PPDC and TRAC and CARAT. But there seems to be some procedural flaws. I mean, it seems like there needs to be a point where there's some closure on things, and maybe there's some way that we could construct an internal process within PPDC or other advisory committees that would sort of give us a pathway towards closure so that it doesn't seem like it's always kind of on the verge of being adopted but never actually gets adopted.

So, if that discussion could occur, I think that

would be useful.

MR. JONES: Sure. Julie?

MS. SPAGNOLI: To add further to Bob's comment is, you know, the work group spent a lot of time working on these recommendations and I really want to stress, those things were discussed and, in fact, they're reflected in some of the recommendations where the group encourages OPP to solicit ideas beyond this work group for additional measures. I think, you know, there was a lot of discussion within the work groups on many things which is reflected by what they are recommending, which aren't actually specifically measures, but in some cases saying, we need to look to see how we can measure this and look for mechanisms for measuring, especially in the area of benefits. I think that's -- looking at quality of life, disease reduction, things like that.

The problem is is how to measure it and we didn't select that in the recommendation.

MR. JONES: Thanks. Matt Keifer?

MR. KEIFER: First, as an occupational medicine physician, I'd like to second what Shelley said about the lack of cases that get reported through the Poison

Control Center. I personally -- the last two cases I saw of pesticide overexposure, I didn't use the Poison Control Center. I don't need it. I mean, I don't use it necessarily to report and I don't use it to get information. I have other sources.

And then, secondly, I'd like to point out that Washington State has a big experiment going on called cholinesterase monitoring and we're actually tracking the data very carefully and it's going to be valuable information potentially for EPA as well. I think we're seeing some very interesting things there. And so, I'd encourage this to be incorporated potentially as one of the other sources or changes. I'd just encourage you to take a look at that.

MR. JONES: Okay, thanks. Well, I'm going to just address the work group issue now because it seems like the right -- I mean, you know, we'll go to great lengths to get good advice, and frankly, the reason we've been using work groups is because these issues are way too complicated to really bring around the level of understanding and have the dialogue that you need to in an hour, and we actually only had a half an hour for this

and I think it highlights you just can't really sort of get closure on anything in a half an hour.

And I appreciate that it is impossible for everyone to participate in every work group. So, we've got this balance of between providing enough opportunity for individuals to participate. At the same time, them having -- you all having to balance in the realities of your work life, you can't be everywhere at the same time. So, we will -- the way I'm going to strike that balance around this is we're going to take one more shot at it and convene either by phone or in person, probably have to do a combination of the both, too. People who can be here can be here; others, we'll make it available by phone. It's going to take more than an hour, though.

The issues that you've all raised are all very good. Some of them, as Julie mentioned, have already been talked about. Others may need further discussion and you can't really do it in an hour. It will probably be a half a day kind of meeting, and we'll see if we can get to the point where there's a consensus recommendation. And by the way, a consensus recommendation can say, part of us think A and the other

part of us think B. That's okay. Everyone can agree that their perspective is represented. That's part of the recommendation. I don't mind that at all.

So, we'll take one more shot at this one and see what we get out of it, after which we will -- if we don't have a recommendation, we don't have a recommendation. It's not like we're not going to keep plugging away at this. We have to. We have no choice around that. So, we'll take one more shot at it, and Sherry will work with the co-chairs of that work group to pull together another meeting and we'll make sure we've included all of the individuals today who have said that they would like to participate. So, absolutely.

All right, thank you all. Okay, another easy issue, the work group on worker risk. You all are really just pushing me, but I'm trying to rein in my obsession with timeliness. I'm letting it go a little bit and we're just going to have to be here late. That's all right. As you all know, we federal bureaucrats work long hours, we're not out of here at 5:00.

So, we are now going to move to a group that met this morning. The group on worker risk, and Kevin Keaney

from the Field and External Affairs Division is going to kick this off. Thanks, Kevin.

MR. KEANEY: What I'm going to present is a bit of background for those of you that weren't involved in some of the earlier presentations here at PPDC and then update them on what the work group has done. There's fairly extensive stakeholder involvement and extensive engagement following up on a couple of years of worker -- pesticide worker safety program national assessments resulting on a National Assessment Report that's on our website and it provides a framework for approaching the two regulations that are sort of the umbrella of protection for the band of labor that works with and around pesticides. So, it's the agricultural worker protection regulation and the regulation setting standards -- setting national standards for certifying pesticide applicators of restricted use pesticides.

In the PPDC meeting of February of 2006, we presented the outline and the strategy that we were to take to enhance the regulations that I just spoke of. We presented the range of options and areas that we were considering necessary for change, and as a result of

that, there was the need expressed for a PPDC work group to work with us. So, the work group was established.

We established the role of the work group, charged the work group with engaging with us on specific issues and giving us information and guidance on where we were going with the regulatory changes, and set a schedule to engage the work group at critical junctures in our regulatory timeline. By default, critical junctures came to be whenever the PPDC meets, which isn't quite a critical juncture in regulatory development, but we're working with that.

So, we established the work group, the work group charge, request for feedback and then provided the issues that we were considering as needing review or change.

At our second meeting, after the work group had dealt with the -- had the issues to work with and worked with us, we thought that some issues were much more significant than others, so we attempted a ranking session to determine the level of discussion that was necessary, that the work group felt to be necessary.

Generally, there was a request for more detail.

So, we established discussion papers that sort of expanded on a particular bulletized presentation we had made for the areas for regulatory change. And we established 24 discussion areas, as it were. They collapsed into 23 issue papers or discussion papers and we set up conference calls to focus on these points.

And in the preparation of those conference calls, we did ask for -- requesting for comments, supporting documents, any information that the participants in the work group could provide. And we came back and had a report back to the general PPDC at the June session presented by a number of the participants in the work group.

From August to November, we, as I say, engaged on these 23 issue papers or discussion papers. We had conference calls, ten of them, two hours apiece to clarify questions, encourage discussion and get comments back in. We asked that written comments be submitted within two weeks of the conclusion of the discussion of the particular issues.

The group that was initially -- you indicated that there were about 20 people that were interested in

participating in the group. We thought that was, you know, approaching the boundary of manageability. Well, now we have 70 people wanting to participate in the group. Not all of them come onto each conference call, but 70 folks are on our listserv and receiving our material, and depending on the issue, a large number or a small number participates in the conference call. And they do represent the full range that PPDC represents. You've got advocacy groups, industry, agricultural groups, state regulators, state safety educators and the antimicrobial network which constitutes a special concern for us, as I'll mention.

The antimicrobial participants have been separated off into a separate group because they are not our typical -- they don't fit into the typical model we have for ag (inaudible) structural, lawn and garden and so forth. So, we are going to deal with them specifically with calls to discuss their issues, specifically the issue of scope, if we're going to change the scope in the applicator regulation, it's very important to them the details and when we are describing uses of pesticides, applicators of pesticides.

The meeting we had this morning focused on comments that we have received in response to the discussion papers and the conference calls. We tried to compile our comments into a summary document that can be available to you. We're going to place the comments that have been submitted by the work group participants and the other comments that we've gotten from state regulatory and state education -- safety education training sessions, we'll put those comments in the docket. There are a few papers, a few issues that were raised early on that were apart from the 24 set that we had, primarily from advocacy groups, and they are going to frame out discussion papers for us to circulate to the group and have conference calls on them as well.

Our next step, we'll revise the discussion papers, the issues papers for the May PPDC, you know, using what we've learned through this process, and ask the work group participants for additional feedback on those particular set of papers. We'll have the PPDC work group critically involved with us in continuing discussion at critical junctures.

We will deal, as I said, with the antimicrobial

network in a separate way, working -- developing a specific focus paper for that network of work group folks to address their issues, and we'll fairly quickly hold conference calls with them on those issues.

As I said, we had fairly extensive public involvement through the stakeholder participation and assessment exercises for a couple of years. We've had this work group, which is very valuable in that contribution and engaged with us. Early on, we gave our schedule, our regulatory schedule which seemed to be in conflict with what we were saying was needed and valuable and the extensive stakeholder involvement. So, we had requested internally for a revision of our regulatory schedule, and Jim let us know that that was approved by the Deputy Administrator.

So, our new regulatory schedule is -- from now until the end of December, we'll have continue issue discussion that I mentioned and try to bring that to closure so that we can consider the inputs we've had, gathered further data, refine the issue papers, distribute the material to the work group and then bring them to the PPDC May meeting, having conference calls

leading up to that and have presentations at the May meeting indicating the work group feedback and where we are with these issue papers.

From June '07 to June '08, we'll be in the business of writing preamble language and rule language, internal agency review. There is multiple analyses that are necessary. Economic impact statements have to be developed, small entity impact statements have to be developed, small business impacts and so forth. We'll be in the business of options selection, on the tail end of that. We are required to have OMB review, Department of Agriculture review, and then reach the point of the Administrator signature for publication of a proposal for public comment, which we now are dating as December 31, 2008.

MR. JONES: Just for one second, if I could interrupt. What you're seeing up there represents quite a remarkable degree of pre-proposal participation, that is, involving basically this committee here and others through the work group, and I think it's just worth noting the degree to which we are trying to go into proposal with as much participation by stakeholders

around these two rules, short of doing a negotiated rule-making, which is not what we're going to do in this context.

It's pretty heavy lifting by everybody. Unlike the registration review rule, which is the model we're using, but it was a procedural rule, so I think it was a little easier for people to get their head around the issues and for some kinds of consensus to form. And we're not necessarily expecting consensus around the many issues that are being identified here. What we want to do is make sure when we go into the proposal decision-making part, we have our eyes totally wide open, we completely understand -- not completely, but we largely understand what it is that we're going to be putting forward and what the consequences of them are and what we'll achieve by doing it.

But this is proving to be pretty costly, I think, for everybody involved. It's been costly for the agency, as you saw ten conference calls of two hours each over a three-month period, very costly for all of you and the others in the work group to participate. We really do hope that this is an expansion or an extension, I

guess, of the model used in a registration review. But it is going to take a lot of time and a lot of effort by a lot of you, as well as us, to see if we can pull this off. I just wanted to make that point before we moved on.

MR. KEANEY: So, that's the picture of where we've been and where we intend to go. Now, I'd like to have folks from the work group give their perspective, and it will be Bob Rosenberg, Julie Spagnoli, Carol Ramsay, Dale Dubberly (phonetic), a state regulator from Florida, and Shelley Davis.

MR. ROSENBERG: I'd add just a couple things. One, even though I think you made reference to 70 people being involved; in fact, it's really been quite a bit more than 70 stakeholders being involved. What you all asked us as a subcommittee to do was to come prepared to represent your sector, and I know that there were a lot of subcommittee members -- I think the pesticide safety educators, Amy, Carol -- didn't just come to these meetings representing themselves, but actually had conferred widely with their constituents prior to those calls. I know that Wise Planet and NTMA convened

numerous conference calls to come prepared to speak on behalf of the non-ag applicator sector, and that, in some cases, involved 50, 60 other people. So, it's a lot more than 70 folks involved.

Well, anyway, thank you very much for giving us this opportunity. Obviously, we're not yet in a position to come today prepared to discuss any kind of committee consensus because we're not anywhere close to that point. But I think the idea, Kevin, and I'm sure you'll correct me without the least reluctance, was to try to get perspectives from some of the different groups within the work group. So, I guess I'm here kind of speaking on behalf of the -- well, the non-ag applicator sector. In fact, I expressly want to make clear that I'm not speaking on behalf of antimicrobial or agriculture. They have their own perspectives and are very capable of expressing those views.

So, in general, we just wanted to first offer a couple of observations. You know, I think most folks know that -- though I suspect sometimes things like certification and training have been a little bit of an afterthought and we're pleased to see it's moved to the

forefront of the agency's thinking. You know, we don't think there's anything that the agency can do, registration, re-registration or anything else, that contributes more to the safe use of pesticides than ensuring that the people who use the products are adequately trained, and we think this is an important step forward. In fact, we think it may be a once-in-a-generation opportunity to advance the quality of applicator training in the U.S.

It's been 32 years since these regulations were first passed. There was an attempt, I think in 1989, to amend them and it was abandoned. You know, it's 17 years later and we're trying again and we want to see this thing happen.

A couple of things about the current state of certification and training in the United States. Number one, the federal law, the regulations promulgated under the federal law are extremely narrow. It's basically that if a person supervises the application of a restricted use pesticide, they've got to be certified, period. That's it. There's not anything more to it than that.

Well, as it were, we obviously think it ought to be much broader than that, but so do most of the states. In fact, every one of the 50 states has adopted requirements that go far beyond the federal requirement. In fact, most of them go very far beyond. To give you some sense of it, of the states, 50 of them, every state in the U.S., actually regulates the commercial application of general use products. While FIFRA and the existing 170 regulations are confined to restricted use products. Fifty states are now regulating general use products.

Secondly, even though it only applies -- the federal law only applies to the persons who supervise restricted use products, approximately 42 states have requirements for either training, testing or some other credentialing for persons who act or are operating under the direct supervision of a certified applicator.

And then, thirdly, there are close to 15 states that have adopted some kind of requirement that -- occupational handlers, people like school janitors, hotel maids and folks who are applying (inaudible) to properties other than their own themselves be trained,

tested, credentialed or somehow have something more than just the ability to go down to Wal-Mart and pick something up and spray it in the hallway.

The second observation is despite the fact that states have gone way beyond the federal requirement, there is a dramatic variance in the quality and the substance of the programs being offered by the states. Some of the states do a remarkably good job. Some, frankly, don't do all that good a job. It's an enormous drain on the resources of the state to have to create certification categories, develop category content, develop fresh examinations, administer examinations, establish recertification requirements, evaluate coursework to ensure that the coursework complies with the state's CEU requirements, and the states are pretty much all over the map on that.

Some do a very good, some don't do a very good job. Some states do a very good job in some areas, but not in other areas, but there's nothing even remotely like uniformity.

The other observation we want to make is this. We think there is a certain amount of inefficiency in the

current system. You know, the folks that I represent, and I think a lot of you have heard this before, are pest control companies. So, I don't think this is unique to pest control companies. If there is a small pest control company with two or three service technicians and they're located in Crystal City, in all likelihood, that company and its employees have to be licensed in Maryland and Virginia and in D.C. and maybe they go to West Virginia or Delaware. Those persons, that certified applicator and those two service technicians, may have to have a core exam in each one of those states. The core exam may be different in each one of those states.

They then, because in structural pest control there are as many as five, six different categories. You know, some have wood destroying insects, some have fumigation, some have food processing facilities, general household pests, and you have to be credentialed in each of the categories in which you do business, and almost all service technicians have the ability to do business in multiple areas. The categories aren't the same in each of those states. They have to be credentialed in each of those categories, in each of those states. My

point is, if you're a small company just in this area covering a small regional area and you have three employees, it's not impossible; in fact, it's likely that you may have to be subject to 25, 30, 35 different credentialing standards.

It's inefficient for folks that I represent or anybody that does business outside of a single jurisdiction, but in our judgment, it's also inefficient for the state. There's 50 states that are each doing all of those things. It's an enormous drain on resources. States are having to do all those things like develop categories, develop exams, keep those exams fresh, administer the exam, check CEUs.

We have some observations. We think that, you know, to take a step back and, once again, Adam and Bob were so good sucking up earlier, suck up one more time and just say that the amount of (inaudible) and the amount of dialogue that's occurred has been refreshing and we very much appreciate it. We think it's been a very positive experience.

We think there are three key components that need to be addressed to take advantage of this once-in-a-

generation opportunity. The first one is expanded scope. Pure and simple, in the view of NTMA and some others, though not everybody, there ought to be one -- there ought to be a requirement that any person that applies commercial -- commercially applies pesticides, whether it's general or restricted use products, ought to be credentialed in some fashion or another.

Secondly, we think that every person who operates under the direct supervision of a certified applicator should, themselves, meet some kind of standard. There should be some sort of training or testing requirement.

And then, thirdly, we think that there ought to be, again, some kind of credentialing requirement for occupation handlers, the folks who do it in commercial properties, you know, property other than their home. We're not talking about homeowners treating their own houses, but we're talking about the person that comes into this building. If there was an EPA employee that did pest control in this building, we think that person ought to have some kind of minimum training standard. A, the scope ought to be expanded to go to all of those

categories.

Secondly, we think they ought to be tough standards. And one of the advantages to tough standards is we think it's not necessary for the agency to ask questions about things like direct supervision. You know, how direct should direct supervision be? Should somebody be within five miles or five minutes or so many feet from the application site in order to supervise or should there be a certification category, a credentialing category for certain high risk scenarios? Our take is, you know what, if there was a single tough standard, things like whether you're five miles or five minutes away from the job site don't matter. If the people on the job site have been trained well, then that ought to suffice.

And then, finally -- and this is the subject that I alluded to before -- we think there needs to be uniformity. EPA has said, and we agree with it, in those 23 papers, that they're looking for some uniformity in categories, they're looking for some uniformity in competency standards, they're looking for some uniformity in testing. And we have some thoughts on how this all

ought to take place and we think it's, again, an opportunity to really move things forward.

We believe that, number one, there ought to be, in all 50 states, uniform categories. If you're licensed for general household pests and it's Category 7A in Virginia, then it ought to be Category 7A in Montana and Wyoming and Rhode Island, every one of the 50 states.

Secondly, we think the content of that particular category ought to be the same state to state to state.

Thirdly, we think the examination ought to be the same state to state to state.

And, fourthly, we think the requirements for recertification ought to be the same state to state to state.

That kind of raises the interesting question for us which is this: Is there much efficiency to having 50 uniform state standards when, in fact, each one of those states already is over-burdened with what is a very costly, time-consuming process? If there's 50 redundant programs, then maybe there ought not to be 50 redundant programs. Maybe there ought to be a single -- and we use

the term "national clearinghouse." Maybe it's time to look at the notion that at least for the purpose of credentialing, that if you're going to have a single uniform standard, then instead of having to go to Texas and then go to California and then go to Wyoming and pass a test over and over and over and maybe it's a different test and maybe the contents are a little bit different, instead, one place where people can go. There's one set of categories. They have the test administered there. The states would have access to those tests. They would be able to make their own licensing decisions.

This is not a (inaudible). This is not saying that EPA ought to be in the business of taking over or re-federalizing the administration of certification and training, but rather some group, whether it's a consortium of states and EPA, or EPA itself, or some private entity, we think there ought to be a single place where the task of credentialing pesticide applicators occurs.

And then, finally, think that it ought to be -- well, if there is a uniform set of standards, if you pass the exam and you passed it in one place, then it ought to

count in another place. So, if you've got that little PCO in Virginia and you've done everything you need to do in Virginia, then it ought to be good enough to get him a license in West Virginia as well.

What we're not talking about is this: We're not -- you know, by suggesting that sort of a national clearinghouse or nationalizing of the certification and training process or at least the credentialing process, we're not talking about this, we're not talking about trying to create a single uniform training system. There is a wealth of excellent training programs available now, the extension services, the universities, chemical manufacturers, chemical distributors, state pest control associations. There are hundreds, if not thousands, of institutions in the U.S. that do a good job of training. We don't mean to suggest that there ought to be a single location where people go to train. We'd like to see the existing training continue.

Secondly, we don't mean to suggest that EPA ought to be granting certifications or licenses just handling the administration of credentialing. It's still the right for each state to collect a fee and grant the

license for an individual applicator. We think it's vastly more efficient to have a single set of tough, uniform national standards. It's a more efficient process, one that benefits, I think, applicators, state agencies, EPA, farm workers. We think it's an opportunity that won't recur again probably in my lifetime, maybe not in the lifetime of most folks. Would love to see us make progress towards that thing, expansion of scope, tougher standards and uniformity.

Anyway, that's our position. Thank you. If there's any questions, I guess, afterwards, I'd be glad to answer them.

MR. JONES: We'll use the work group process for the questions. If I can do two comments, Bob, for you and then the follow-on presentations.

What you presented, Bob, was very clear advice, which is very useful. I'm not speaking to whether or not it will ultimately be adopted. It's very clear advice.

For the individuals who are following Bob in this session, if I could just ask if you could try to be sensitive to the time issues of getting your clear advice across quickly. That will just, I think, help move us

along. But I very much appreciate that.

Why don't we take one minute, before we go any further, to introduce the Assistant Administrator and ask him if he wants to make any remarks before we follow on with the four additional presenters.

For those of you who don't know, Jim Gulliford, who's sitting to Anne's right, is the Assistant Administrator for the Office of Prevention, Pesticides and Toxic Substances, has been for the last five months. But he's not new to EPA. He was the Regional Administrator for Region VII, which in EPA lingo, Region VII is headquartered in Kansas City, Kansas, Nebraska, Iowa, I'm skipping a state. The Regional Administrator of that regional office for the first four and a half years of the Bush Administration.

Jim had the unenviable task of becoming the head of this office with about a month to go to the FQPA deadline, and I have to say he performed quite admirably, making a lot of very hard decisions in a very short period of time.

Jim?

MR. GULLIFORD: Well, thank you, Jim. I thought

for a minute he was going to say, well, now that he's here and sat down, let's go take a break or something like that.

(Laughter).

MR. GULLIFORD: I appreciate the opportunity to finally get to meet many of you. As Jim said, I came -- in fact, I recall it well. I got on a plane at 7:00 in the morning on July 10th. The reason I know that is because July 10th is my wife's birthday, and I don't care how long you've been married happily or otherwise, to walk out and take a new job and leave town on your wife's birthday is a mistake. And I made it, I paid for it and I'm still paying for it.

(Laughter).

MR. GULLIFORD: No, actually, it's working out wonderfully. I'm very pleased to have had the opportunity to join OPPTS. It was an interest of mine that goes way back, the subject matter that OPPTS deals with and particularly, again, the pesticide issues. I think many of you that know my background know that I do come from an agricultural background. I worked in soil and water conservation in the State of Iowa for 20 years.

I worked in many a project, many a program where our interests were at the time the wise use, the appropriate use of ag chemistry in the field.

We did a lot of projects in watersheds where we worked with dealers, where we worked with producers, where we worked with people concerned for pesticides in the environment, and had some very good projects in very productive ways, and in virtually all of those ways, voluntary solutions to real problems that existed.

That was why several years ago, in fact more than four years ago, as a Regional Administrator new to the job, and I was learning about how we have lead region responsibilities to work with headquarters, that I came to this Assistant Administrator and I didn't know very well whose name was Steve Johnson and made a pitch to him saying, my interests are the work that you're doing and I would like for Region VII, Kansas City, based on our interests, based on our priorities in the region, to be your lead region. And I don't know how hard I did or didn't lobby, but I was very pleased that we were selected in that role. I enjoyed working with OPPTS at that time and I think that was -- my deputy at the time

told me, be careful how much interest you show in this or you may find yourself in D.C. And I said, no, not a chance. But that was part of what led to my interest in this job.

I want to thank you for your interest in this job as well. The efforts that you've made as a committee, but also as interested public, to come and participate in this process. It's very helpful to us. You know the effort that you've made over the years where -- as we've worked on issues like FQPA and those responsibilities, you know the input that you've had to that process, the helpful nature that has provided us, helpful and productive part of the process that you have provided has been very important. So, I want to thank you for that.

I want to get to know you. I'm going to have an opportunity to sit here and observe the discussion, I believe it's after the break, on spray drift, what are the challenges that we have to deal with. But as I look at the agenda that you have here, it matches up with many of the priorities that I have for the OPP Program as well.

I'm not sure I ever got it out in a truly formal question to Jim, but one of the things that clearly ran through my mind -- as he had indicated, I came here a month before the FQPA deadline. As I thought about what would life be after FQPA, clearly it's been very apparent to me that we will always have new chemistries to review. I think that's a good thing because, again, the new chemistries are, in many cases, many ways, safer and better chemistries. But we will do our job to make sure that we review them in a complete and timely manner.

We also continue to have the non-food FQPA re-registrations to deal with, and Jim has got a schedule for those that is a very challenging schedule that we will work to meet. And as you know, also, now, we're transitioning to registration review and there's plenty on the plate. We're also going to deal with the challenges that you have before you as well, how we address (inaudible) responsibilities and the responsibilities of pesticides in general to the Endangered Species Act and also, the Endocrine Disruptor Program will have a place and we'll work on how to integrate that into our pesticide work as well.

There's a lot of very timely, very challenging, very important issues that are before us in OPP. I welcome those challenges. I think that it's appropriate that we address them in a productive and a protective way, and we will do that. And rather than take up any more of your time, perhaps I'll give you a chance to ask a couple of questions of me and then get back to your meeting and, again, the issues that you folks came here to address today and tomorrow.

Let off the hook so easy. I'll be around during the break. I welcome the opportunity to meet any of you individually and exchange a business card and hear your interests, your concern and any questions that you might have on a one-on-one basis. Given that you're a stitch behind on your -- that's a Midwestern term, by the way -- in your schedule, I'll just turn it back to Jim and let you get back to work.

MR. JONES: Thanks, Jim. As you have heard, we're a little bit behind on our schedule, but you'll have the opportunity of hearing some of the feedback around the worker protection and certification training rule where we've basically just started that

presentation. I think, Kevin, we're on to the second presenter.

MS. SPAGNOLI: And I'm going to speak, again, as Bob did. It's not specifically just for myself or for my company. This will really be representing a lot of the feedback that came about from the conference calls for the antimicrobial and consumer product industry and some of the issues that have been raised.

But, first, I want to say with regard to the process that I think this is a very valuable process, getting the stakeholder input up front and I think we identified -- some of the issues that were identified as a result of this process and maybe wouldn't have come to light as easily, identifying additional stakeholder groups -- I know one of the meetings, we thought of a group that hadn't even been engaged and that was veterinarians as pesticide applicators. So, via this process, I think they were able to reach out to a lot more stakeholders than might have otherwise been engaged.

MR. JONES: By the way, that was Julie Spagnoli with the Clorox Group speaking.

MS. SPAGNOLI: Oh, I'm sorry. I didn't put my

name on it because again this was from the whole industry's perspective.

Some of the background that was brought up in consideration of this is that currently general use antimicrobials are not subject to specific pesticide training and certification programs. Looking, I think, in particular, at disinfectants and sanitizers, they are generally not part of any training and certification programs for pesticides.

One of the other issues brought up was that in industrial settings, use of biocides and other antimicrobial products are not distinguished from other chemical use. That in manufacturing, if water treatment chemicals are used, they're generally not distinguished as pesticides, but they are included in any chemical safety and training programs.

But OSHA exempts the use of consumer products using the same manner that the consumer uses, and this would be what we would be considering, the incidental use of a consumer pesticide. It could be a teacher using a disinfectant wipe in a classroom, somebody applying an insect repellant before they go outdoors to do work, even

though it's an occupation -- it's within their occupation, it's really an incidental use.

Currently, FIFRA does exempt from the definitions of maintenance applicators and service technicians those who use antimicrobial pesticides and consumer ready-to-use products. So, there is some background -- when you're looking at the scope of worker training programs and pesticide applicators, there is some background where the scope has been limited for the antimicrobials and consumer products.

So, some of the considerations when looking at the scope that the inclusion of antimicrobials and consumer ready-to-use products and incidental use of consumer products would expand the scope of the regulations to virtually every business operation. Everybody -- almost any business is going to have a bathroom where they may use a disinfectant cleaner. So, again, this would greatly increase the scope.

We didn't really see it, there was essentially no evidence that a lot of the issues with the workplace use of antimicrobials are specific to the product as an antimicrobial. And looking at a product like

household -- like chlorine bleach, if there's incidence, is it related to them using it to whiten clothes, which is not a pesticidal use, versus if they're using it as a disinfectant.

So, it's very difficult, I think, in the case of antimicrobials, especially cleaners and other products, to say if there's any issues specifically to it as an antimicrobial.

Currently, we also feel that there's not a -- there's a lack of full engagement of the user community that would be impacted. This would involve restaurants, hotels, just greatly expanding the user community that would be impacted.

Looking at just the regulatory burden and costs, this would be an additional regulatory burden on, again, almost every business operation, including manufacturing, food processing, restaurants, hotels, motels, retailers, grocery stores that may use disinfectant sprays to clean off the belt where they put the food. It would also put an additional burden on institutions, including schools, healthcare, nursing homes or any public facility that might use antimicrobial products.

It's another additional burden on states to insure compliance because to insure compliance would increase exponentially, and I think we had some discussion this morning about enforceability, also, because the states would have quite a huge enforcement burden, too.

We don't really see that there's much benefit for workers or for public health to include antimicrobials and consumer products in any kind of training and certification programs. And, actually, there's probably a possible negative public health impact. If there's an increased burden by having to -- a regulatory burden for using antimicrobial cleaners, businesses might elect not to use antimicrobial cleaners or if it's difficult to, you know, use -- there's additional burden for somebody to use insect repellant, they might not use those products, and obviously, there's negative -- possible negative public health impacts.

So, it quickly became apparent -- and I think Kevin has already mentioned that there's -- the issues involving antimicrobials are quite distinct from conventional pesticides, and that a subgroup and issues

will be discussed and will be pursued. So, we're still sort of awaiting the agency's determination on the scope of inclusion of what, if any, antimicrobial uses will be included.

From an industry perspective, we don't really believe that there's enough stakeholder awareness and engagement, especially if the scope is expanded. And the benefit of expanding the scope to include antimicrobials and incidental occupational use of consumer ready-to-use products is really not apparent in order to justify the huge regulatory and compliance assurance burdens.

So, the main issue that the, you know, antimicrobial and consumer products groups have been looking at has been the scope. We really never got past Issue Paper 1A which was the expansion of the scope, and looking at, you know, how occupational use of pesticides is defined, we think it's going to be critical in determining what the burden is going to be and the cost and difficulty in implementing. Thank you.

MR. JONES: Thanks, Julie.

MS. RAMSAY: I'm going to go ahead and -- I'm Carol Ramsay with Washington State University. I'm glad

to be a member of the committee and be able to give some perspectives from extension. And one of the associations that represents the certification and education is the American Association of Pesticide Safety Educators. And as you'll see in one of these slides, it will comprise the members of that particular association, which includes the state lead agencies, cooperative extensions and industry folks that are involved in certification and training. Excuse me, and EVA.

One of the things -- Kevin went over the time line of how this committee has been working through these small number of issue papers. I think there's just a mere 24 or 25 of them. And one of the things that I'd like to applaud EPA in is the process in getting early involvement by the stakeholders in this particular issue, and when the issue papers were developed, they were given to us and we actually had a fairly tight schedule, but it was reasonable for us to have time and get it out to some constituencies and get comments to come back to these conference calls.

The second thing I'd like to applaud EPA for is they actually gave us a schedule of when these conference

calls were going to occur, what papers we were going to be talking about, and so, when we went to a call, we were more prepared than we would have been saying, what are we talking about today, oh, I haven't caught up to you yet. So, that was very beneficial and I would encourage you to use that strategy in the future.

As you heard, however, the scope of these are very large. They're very interrelated and so it was maybe frustrating at times because we didn't have enough detail on some of these issue papers, there weren't enough definitions to where you really felt like you could respond to, and so, really, more of it was input or have you considered this, have you considered this. It was really more a solicitation of considerations than it was, in my opinion, a response to an issue that was actually put forward.

Now, we do realize that the next step, hopefully, before the May meeting is that we will maybe have some more defined details, some more definitions to where we can actually give some critical response.

So, it's been very open to comments, they've been accepted. They've streamlined the system for

submitting the comments. One of the things that we found was critical, I was able to attend the prep course, which is a pesticide regulatory education program course, which was attended by EPA Region folk, EPA headquarters, state lead agencies and cooperative extensions to talk about these issue papers. We ranked them, gave them enough time for them, and so, we actually got a fair amount of critical, again, consideration and we discussed some of these considerations this morning in our work group.

So, both the work group and these other stakeholder dialogues have been very important. And the last thing that we'd request from EPA is that with the next set of issue papers, please remember, we need enough time. If it's a big issue, please give us enough time so that we can get it out to the group and for us to have time to collate those comments so that we can give you something that's not just here's everybody's comments all strung together.

Since I have the microphone, I just want to talk a little bit about the impacts of the scope of these changes that could occur. And when I talk about the impacts on extension, I want to bring in that this is not

just extension that does training across the United States. The state lead agencies are very involved, especially depending on what state you're in, and industry, depending on the segment of the community, whether it's structural pest control, whether it's turf and landscape, (inaudible) treatment, stored commodity, rights of way, you know, some of those are very well-represented by industry, some are not as well represented by industry. And so, when I talk about extension here, I'm really talking about an infrastructure for training.

And so, some of the impacts on that, it's really funding and time commitment. And I think you all have heard that statement. Most of the people that are involved with these programs, the training portions of these programs, whether it's writing manuals, helping develop exams, doing actual training courses, free certification training courses for applicators, continuing education, whether it's the lecture circuit, whether it's calibration clinics, whether it's workshops on integrated pest management and those sorts of stewardship things, whether it's train the trainers for handlers or train the trainers for county extension

agents to actually go out and do training and learn about some of the technology. That's really a funding commitment and a serious time commitment.

And the people that are -- the structure that's behind that is not just Carol Ramsay at Washington State University, though I do like to take credit for the 100 people that are on staff at Washington State University that are very much involved with that role. We're talking about myself, the pesticide safety education specialist, we've got a registration specialist, we've got toxicologists, lead scientists, plant (inaudible), entomologists, ag engineers, soil sciences, water quality (inaudible), hydrologists. They are all intimately involved in this program and putting hundreds and hundreds of hours into the program every year. It's not just -- excuse me -- but my pretty face.

So, realize -- and then you've got the extension agents, when we're dealing with the ag community or the extension agents that are using with the urban communities, because in Washington State, we have -- you know, four-fifths of our population is Seattle. A lot of our extension and a lot of our pesticide safety education

is targeted at that corridor over there, and we've got county agents that are definitely supporting that. Horticultural industry, urban forestry and those efforts, it's not just agriculture.

So, realize that when we talk about developing an exam, developing training, those funding and time constraints for train the trainer, it's this entire infrastructure that's supporting that.

Again, we service lots of different areas, whether it's in cooperation with industry. We co-coordinate lots of association meetings, lead association meetings, vegetable lead association meetings, structural meetings. We've got a new structural pest control facility. And so, it's a very large infrastructure behind that.

MR. JONES: Thanks, Carol.

UNIDENTIFIED MALE: Dale Dubberly. You want to work from down there? Dale's with Florida regulatory.

MR. DUBBERLY: Thanks, Kevin and Jim. And, no, I'll keep you back on track because I'm not going to do a PowerPoint presentation here. I think I can summarize my comments fairly quickly here.

Since I have supervisory capacity over the CNT program, the worker safety program and the enforcement program, it seems like we always kind of leave the enforcement side of this out here when we work on CNT and WPS, but believe me, the full circle ends at the enforcement side here.

I see Rick Colbert down here looking at me like, yeah, what's Dubberly going to say now, but anyway, I do want to say a couple comments on each one of these sections there. CNT is an important program for all of us. Carol covered it very well. All the involvement we have, it's not just state lead agencies, there's a lot of other aspects to those programs.

The worker safety program is one of the programs that's been very, very highly publicized, especially in certain states. We feel that there needs to be some definite changes in the worker safety regulations. We felt that when we started this process, Kevin, correct me if I'm wrong, back in 2000, I think, when we started some of the meetings in Florida, Texas, California, concluded in Washington, D.C. We've had expensive reviews of that program. There's been lots of recommendations made in

that program. But somewhere along the line, they have become stalled and we need to kind of move that one along, in my opinion.

I know since then we have kind of brought CNT back into the picture to deal with some of the WPS issues here with training and certification of applicators, handlers, workers, things like that. But somewhere, I think we need to break these back out and see if we can address worker safety issues, and let's see if we can kind of move them along, because I think it's pretty important to a lot of us.

2008 is a pretty long time. That means we've been working on worker safety changes for about eight years just to get a rule promulgated for a proposed change.

The last thing that I want to say -- or the last two things I want to say is that it's very important that we work on changes to the certification and training program, the worker safety program, that we need to test the enforceability of these, because we put a couple of these through some tests here recently, and I'm not sure they're withholding the actual proposals that are coming

out of some of the work groups here. I think if we're going to stick to what I heard here today, is have tough standards and make sure that everybody's on the same playing field, that we need to make sure that we have the definite enforceability language when we promulgate these rules.

It was also mentioned that the enforceability is probably where a lot of the funding issues actually have problematic areas. I know over the past years, we've actually taken reductions in some of our enforcement activities. So, if we're talking about adding on responsibilities here, then we need to address the funding aspects of this. There's a lot of different ways to fund these programs. You know, we're faced, not only in Florida, but other states, as I hear, of imposing user fees. It's our general revenue dollars (inaudible) this program. So, you know, you're only limited with certain options of how much money you can raise from certain aspects of other programs. So, we need to take those into consideration when we work on these rules.

But I would like to see that the worker safety stuff move along at a faster pace than the CNT stuff,

especially from a rule-making standpoint.

That's my comments from the State of Florida. Thank you. And I do want to commend Kevin and his staff and your whole group, Anne and Jim, for really receiving and taking the time for all the input, but I do think it is time let's move some of these things along. Thank you.

MR. JONES: Thanks, Dale.

UNIDENTIFIED MALE: Shelley Davis, Farmworker Justice.

MS. DAVIS: Thank you, Shelley Davis, Farmworker Justice. I think that -- I'm going to quickly echo a couple points that were made and then focus on what I think are unique to our concerns.

First of all, when the worker protection standard was issued in 1992, it was extremely weak and I think it was, in part, the product of a lot of resistance from the agricultural community to the need for worker safety and it weakened -- as a result, I mean, virtually every provision has loopholes that weaken it in very detrimental ways. And I think, as Bob said (inaudible) this is kind of a once in a generation chance to make it

right. So, we've got to really jump on that.

And I would say in figuring that out, there are a lot of issues on the table, there are a lot of issues that need to be addressed, but I think we should try to keep our eyes on the prize and focus on the most important issues and I think, as Dale said, make sure that whatever gets chosen is enforceable.

So, with that said, I'd like to quickly look at three different areas, because I want to focus on the folks that pretty much no one else has talked about, the agricultural workers, first of all, the post-application workers, the field workers in farms, greenhouses, nurseries, forests that go back in after an application; then some about the handlers, the people who actually mix, load and apply pesticides under (inaudible) supervision, the supervised applicators; and then a little bit about expansion of the rules.

So, let's start with the post-application workers because they've gotten the least attention so far. When you think about what they need, there's got to be improvements in training and information, ways of reducing their exposure, and then some of their procedure

rights.

I'd like to commend Kevin for having the stakeholder process, but I think we're all really anxious to hear EPA's proposal to get this really concretized, what is the agency really thinking about. So, let me just give you some ideas about what we think is really necessary here.

Training, right now, occurs once every five years. Usually it's about a 15-minute video. In no way is that adequate for anyone to be alerted to the hazards they face. So, in order to bring us into the 21st Century, farmworkers need annual training. It's got to be comprehensive. It's got to be interactive because these are generally low literacy adults, and it's got to focus on something they care about, which in this case is really protecting their families, especially their children. So, to the extent that the training really highlights the need to protect their children, and then I would say even, secondarily, themselves. That's going to be a way to get their attention. And it's got to focus on the actual pesticides they're exposed to. We've got to finally have hazard communication instead of have

information about the short and long-term health effects of the specific pesticides used in their workplace. They've got to learn about that. They've got to know that.

Now, somebody said, isn't that just like asking us to do individual risk assessments? I think that, on the contrary, that's like treating them like adults. In OSHA, we have a hazard communication standard and that's required that every worker in every industrial setting get information about the short and long-term health effects of the chemicals at their worksite. That's how we treat adults. Farmworkers should be no different.

They need notification. Let me just link this to the key barrier. The key barrier for field workers is the restricted entry interval. But the problem is workers don't really know when that is. So, that's got to be posted at every field, so, again, they are in a position to protect themselves, and so, the notification piece has got to come up.

We need -- the restricted entry intervals have to be actually barriered. Right now, there are a host of exceptions to that. They're very vaguely defined.

Limited contact, for example. Exactly what does that mean? The fact is there should be no exception except possibly for a freeze for our limited extreme weather emergency. But the basic ideas of having exceptions is really counterintuitive to this process.

Okay, I'd just like to give a little bit to the handler side just to give you a feel for the kinds of things we'd like to see for handlers. I think in the handler community, there's a lot more opportunities for engineering controls and medical monitoring, and again, to bring us up in agriculture to the area of the 21st Century, stuff that's very routinely available in industrial settings.

Okay, so, first of all, medical monitoring. A lot of this actually is utilizing the best of what's available already in the state. Matt mentioned that they have an excellent program in Washington State on cholinesterase monitoring. They have a program in California; recently enacted in Ohio. Okay, so this is now on the radar screen, but it's time we went national. We don't have to wait 30 more years for medical monitoring. So, this should be a national program.

Fit testing for respirators, that's also already in OSHA. Why don't we have that for pesticide handlers? We don't have it.

They need closed mixing and loading systems. You know, all of these engineering type controls would really reduce exposure.

They also need improved information. We know that our hired farmworker workforce is primarily non-English speaking, low literacy folk. They need to have information, foreign language labels, low literacy information just like the field workers in a pictorial or low literacy format so that they can understand it.

We'd like to see some expansion of the rules. Our areas of expansion are primarily in livestock farms and in landscaping, two major industries that use pesticides in an occupational setting where workers don't have the kinds of protections they need.

We'd like to see some increased procedural protections, for example, that workers have anti-retaliation protection that's actually enforceable.

But it comes back down to what Dale said actually, that if these regulations aren't enforceable,

then they're illusory and we're just pretending to these workers that we're going to protect them. So, we've got to construct a series of protections that really make sense, that give workers the information they need, provide barriers to the extent possible to reduce their exposure, allow them to get the protections in case of an emergency, and then allow them to participate in the regulatory process if there are violations.

So, all of these pieces have got to fit together and they've got to be enforceable. Thank you.

UNIDENTIFIED MALE: Thank you, Shelley. Are we going to take some questions generally?

MR. JONES: Actually, what I would like to do -- well, are there a couple of questions around?

Jennifer?

MS. SASS: Shelley, I've just been given the report by Dr. Jerry Blondell, the one that was used to gather the numbers for occupational exposures by the EPA presentation. But the thing is when you look at it, Dr. Blondell actually recommends that the numbers on unintentional exposures and unintentional poisonings be multiplied by a factor of eight. That's the account for

four-fold, he estimates, for under-reporting and he lists the reasons that you cited, and two, for lack of penetrates and that is not able to get to the populations that are likely to be of highest exposure. And he mentions all the things that you mentioned in that.

And he also says that although the poisonings, overall poisonings have gone down a bit, actually, if you look at this, it looks pretty flat-lined since 2000. The organophosphates have gone down and that's because of primarily what you said, the two major, chlorpyrifos and diazinon getting taken off the household market, but actually the pyrethroids and pyrethrins have gone up by almost the same amount, 12 percent for the poisonings.

So, I do think that it supports your argument that there's a reason to take a closer look at this data and not just cavalierly announce that we should keep -- that we're doing such a good job of preventing exposures and poisonings. I think we do need to be a little less cavalier and a little -- take a little more careful look at the data that's available to the EPA.

MR. JONES: I don't know if you are speaking about EPA in the cavalierness in the we, but we are not

being cavalier, and that's why we have the work group around performance measures to address issues such as that.

MS. SASS: Right. But there does -- I mean, I've sort of been bringing this up all along. But when looking at data, there does always need to be a data quality control aspect. So, rather than taking the headlines and the conclusions, actually looking at the data in there and being a little more thoughtful about what's there.

MR. JONES: We agree with that. Bill?

BILL: Jim, I guess -- I just want to give a little, you know, 30-second background. The scope issue, I feel the scope issue was already dealt with by Congress. Congress, 10 years ago, brought all the different players together, sat down, brought many of the users, also, that Julie talked about, and said, we need to develop a scope with regard to certification and training, and in developing that scope, they put the definitions of service technicians, maintenance applicator, exempting the antimicrobial products, all antimicrobial products, and exempting out the ready-to-

use consumer products.

I can generally explore where Shelley's going with some of the direction. There are certain avenues where we do think you need to have a certification and training. But I think we need to go back with regard to the scope of what Congress' intent was. I think we need to look at that service technician and maintenance applicator definition. They had brought the school association, the non-ag sector, the commercial applicators in, had already vetted all this among users and pesticide industry and others, and they established this bill. I think we need to go back to that and deal with that issue.

They were also concerned, and I'll just raise it, they were concerned that certain industries would look to build a market share through the legislative process and they wanted to make sure that didn't take place. And, again, I think we need to be very cautious as we move into now the regulatory process with regard to certification and training and having a floor. I think we need to go back and look at exactly what Congress intended. Thank you.

MR. JONES: What I'd like to suggest is -- well, actually, I want to reinforce what Kevin said earlier around the schedule that we're operating under, which is that this winter/spring, we're going to be, as Carol described, further refining those issue papers, and then we're going to be taking them back to the work group so we can get more informed advice around those 23-odd issues that we've talked to the work group about before.

I think that the challenge for all of us, sort of multiply the performance management question by maybe 100, is how to -- even though we've got over half of the full committee participating in the work group, how are we going to make sure the full committee has enough insight and knowledge about what happens in those work group meetings so that when we get the reports back, we're able to, in some reasonable period of time, digest it and give advice to the full committee.

And that's something I want to talk about with all of you tomorrow so that we're -- when it comes to the May time frame and all of this work will have occurred by the half or two-thirds of you who are on the committee, we're able to have a full committee meeting that's fully

informed, because we really do have a schedule here that we really need to keep.

The point of today's meeting was mostly -- it's an accountability for us, collectively. We were going to come and talk about how we were doing as it relates to the work group process, and in doing so had a subset of that group come and say sort of where they are, and I think we got a pretty clear sense from many of the participants as to what they think about where we are right now.

But the process has a little bit to go, six months or so, but it's six months of pretty intensive work. I, frankly, think the hardest question for us is going to be how do we take all of us, meaning how do we all meaningfully participate in giving advice to the agency without having all of us participate in the many, many hours that is going to need to occur between now and then amongst a subset of us? And, again, we'll spend some time on that tomorrow.

Cindy and Adam, did you want to make a comment?

MR. SHARP: Actually, just real brief, I guess from an agricultural side, we expressed I know a lot of

our concerns this morning, and I just wanted to say I think there's been a very good job done by the agency as far as teeing up in the work group, you know, with the number of conference calls and work that's been done to tee up the issue papers, and I think a lot of the key issues have been identified very well.

And I wanted to come back to actually the comment Bob made earlier here about maybe some focus of the work group actions from now and the agency's review now when he talked about three areas of scope, the tougher standards and uniformity, and I thought those were well done. I know he said he didn't want to speak for agriculture and others, but I thought that captured, actually, very well some priorities maybe of where we could focus. Thank you.

MR. JONES: Cindy?

MS. BAKER: Thank you, and I'll keep mine brief, too. I just would make these comments. One is that I think in looking at all those issue papers, it was quite surprising and quite pleasant to me to see how much agreement there was around a general goal. A lot of the discussion was about some of the subparts under each one

of those papers. But, by and large, you had a lot of consensus of the goals of what those issue papers were, and I don't think that's any small feat. I mean, I think that was an accomplishment that shouldn't go unrecognized.

But I guess I would also like to point out that there isn't a one size fits all answer to this. There aren't solutions that are going to be all one thing or all another thing. I mean, you can't say there is never going to be a circumstance, for example, where you would find some justification and some reasonable way to allow someone early entry into a field for a reason.

Does that mean everyone should be able to go in early entry? Of course not. Does there have to be real restrictions and understandings about why you do that? Absolutely. Just like not every product should be required to be in a closed system. There are criteria that the agency uses to look at those things.

And so, I would say as we look at this, we have to look at this from a standpoint of what are we really trying to do in protecting the workers and the workers' families and the people and what's reasonable in that

expectation to allow the activities that need to take place that have a significant benefit, not only to the crops and the structures and all of that, but the people engaged in those activities as well.

MR. JONES: Thanks. Okay, my last comment just before we go to the break is that the -- although the objective of this exercise is not to come to a consensus, to the extent that we identify a consensus through this process, EPA's very likely to attempt to occupy that consensus, accept it, in other words. To the extent that we don't have consensus, we will have the great value of understanding all of the perspectives so that before we make a decision, we're making those choices with that knowledge, and of course, then we will still go through the APA required process of notice and comments as well.

So, we're very hopeful that this process will lead to the best proposal that we can come up with. Hopefully, it will represent some elements of consensus even if it is just on principles, which I would agree is no small feat. Hopefully, it goes even beyond that. But there will still be the notice and comment process that will follow that as well.

So, thanks to all of you people who worked all morning on the -- in the work group and then particularly the five presenters. We'll take a 10-minute break and be back at 25 after 4:00. Thank you.

(A brief recess was taken.)

MR. JONES: All right, we're getting started here. Okay, we are going to get started now.

I just want to mention before we get started that Jim Gulliford, who is going to be here for most of this discussion, at 5:00 is going to need to leave to go to another meeting. So, if you're wondering why all of a sudden halfway through our discussion he stands up and has to excuse himself, you know.

And if anyone is interested in the public -- non-PPDC members, but anyone else, in making a comment, you need to see Margie Fehrenbach and let her know and she will -- okay, there's a sign-up by the table and you'll have that opportunity.

So, I'm going to turn it over right now to Anne Lindsay.

MS. LINDSAY: Okay, Jim Hanlon, who's the Office Director for our Wastewater Management office in the

agency's Office of Water and I are going to do a very brief introduction. The primary presentation is actually going to be done by Scott Shirtz (phonetic), who's sitting right here to my right, and Susan Kegly (phonetic). They're both members of our Spray Drift Work Group and they volunteered for this duty.

I don't know if I'll convince them to do it again because you'll see, it's actually a very good report and one of the things I'm most proud of is it's not just their report, but they vetted it through their whole work group this morning, and while you may recognize some words that are signs of compromise, either because it's vague or it really seems awkward to you and you can't imagine why people would string words together in that way, it does -- at least as of this morning when we left to go for lunch before this meeting started -- actually represent what the work group thought was an adequate representation of where we are at this point in time. That's a very carefully worded statement, just as an example.

For those of you who are new to the group or substituting for somebody else, this group was actually

commissioned by the full PPDC about March -- or we actually had our first meeting in March of this last year, March 2006. Commissioned a little bit earlier than that. It's jointly sponsored by the Office of Pesticide Programs and the Office of Water. I'm not going to go through the whole mission statement for the group. But so you know, there were four elements that the agency actually really asked this group to focus upon, the first of which was to try to improve understanding of those different perspectives stakeholders have with regard to pesticide and spray drift.

Those of you who've known us for a long time will know that spray drift is one of those issues that generates lots of strong feeling and perspectives in multiple different directions. So, the first was just to understand each other.

Second, to the extent that the understanding was achieved, to look for any common ground for working together that might exist with an eye to how we might actually minimize both the occurrence and the potential adverse effects that can be associated with spray drift.

Third, in areas where common ground exists, the

group was charged to look for options for work that would help achieve those areas of common ground, and then, finally, to explore the range and effectiveness of potential responses to unacceptable levels of drift off-target.

What you're going to get today -- I want to emphasize, you can see it in the title, is a progress report. The group is likely to meet one more time in full session, I think most likely in very late winter, very early spring, and will hope, at that time, to be able to actually put together a report from the group and it will either identify areas where the group pretty much coalesced and found common ground or areas where perhaps there are some distinctly different perspectives. But we will actually, I think, have achieved sort of a rich understanding of what those different perspectives are and that will also be captured in the reports that the group does, and that report will be destined to come then to the full parent committee when it next meets, I think, probably in May 2007.

What the process we'll use at that time for the full committee to decide whether you're ready to just

adopt the report, whether you want to discuss and debate it and recapitulate the experience of the work group, we'll have to think about that. I'll keep in mind what I saw happen earlier today with the Performance Measures Work Group because I've noticed, even within our own work group, we think we have talked an issue into the ground and then we all go away for a night and come back and discover in the morning many of us can start re-debating it again. So, we'll need to keep that in mind when the full report comes to this group.

But for today, it's a progress report. So, if you find something up there that you're really feeling like you want to debate, you don't necessarily have to debate it at this point in time because I think you'll get future opportunities. But if you do have (inaudible) focused thoughts, something that you just really see missing from the discussion at this point, for example, that you'd like the group to consider, whether (inaudible) that would be helpful.

So, before I ramble on more, let me turn to Jim Hanlon and see if he has a few remarks he'd like to make.

MR. HANLON: Very briefly so. As Anne said, the

Office of Water has the pleasure of co-chairing the group, along with Anne and her team from OPP. The work group has met four times now face-to-face in addition to individual telephone teleconferences. The approach was the agency provided background briefings in terms of Clean Water Act decision-making, regulatory programs, as well as the OPP programs in the first meeting, and sort of, that was our contribution.

I could say personally that I sort of learned a whole lot more than I provided by way of background to the group. It's been a learning experience, I think, for all of us. My sense was that through the conversations yesterday, the group was making real progress. This morning as they went to sort of put the words on paper, sort of some gelling needed to take place and you'll see the results of that this afternoon. So, without any further adieu, Susan, Scott, the floor is yours.

MR. SHIRTZ: Okay. Well, I'm Scott Shirtz and I'm representing the National Agricultural Aviation Association, and Susan Kegly will also be sharing the presentation.

Basically, what we will be doing is giving you a

summary of the last two meetings of this work group, or another way to look at it, what we've done since the last time we reported to the work group in June.

To start off with, we'll just basically remind you of the scope statement that we are looking at. Primarily, the focus is on the labeling which is, as we see it, the primary opportunity to influence the behavior of the application of a particular product. On the practices and equipment, I mean, that's primarily technology and how it affects drift. And then, also, training and stewardship as far as the opportunity to influence best management practices in the application of the product.

At this time, there's an agreement not to focus on the NPDES rule or misuse or volatilization since they're different factors. And I believe Susan has a comment to this.

MS. KEGLY: Hi, I'm Susan Kegly from Pesticide Action Network in San Francisco. The volatilization issue, I'd just like to add a little bit more on. This got separated out of the process early on. Spray drift being that which occurs during an application and fairly

soon thereafter and volatilization -- well, spray drift can be controlled through applicator action, to some extent. Volatilization drift, on the other hand, is an inherent property of the active ingredient in other ingredients in the product.

So, there was an agreement for there to be some discussion about how that gets incorporated into the risk assessment process instead because that seems like the more appropriate place to deal with controls for volatilization drift.

MR. SHIRTZ: Okay. Next, we have the summary of what we have done. The September meeting was primarily concerned with the label review of permethrin, and in particular, we did break out, based on application equipment and then also public health uses, the meeting yesterday and today focused primarily on the labeling issues for 2,4-D and then also what we term complex issues that basically were -- included what is harm or adverse effect, also the discussion on what is desirable on labels as far as whether it should be a defined standard or performance standard, and how regulation and labeling applies to local conditions, such as specialty

crops, and then, also, how to evaluate the real world impact of these pesticide labels.

And then the summary of what we've identified as far as problems from looking at these respective labels, the pyrethroid type and the 2,4-D case studies, is basically we do have inconsistencies, particularly where you have the same active ingredient that is labeled by different registrants or at different times. At many times, there are inconsistencies based upon when it was re-labeled.

And then, also, many times there are questions as far as what part of that label is actually enforceable and, you know, there are, at times, confusing, impractical or things that are just plain outdated on the label.

And then the final point is, you know, a lot of times people really do have to hunt throughout a lengthy label to find the actual restrictions on a particular type of application or a particular crop, and that does reduce the probability of actually complying with all of it when it is such a lengthy process at times you find that.

Okay, on the recommendations, basically, this first part has to do with how to communicate and implement the results of this, providing that, of course, the PPDC follows the work group's ideas and, basically, it does need to be sharper language, clearer. I think this was one of the big consensus as a group that it really would improve the effectiveness of the label if it was sharper and clearer, more concise.

And then, also, to apply the same standards on products, on, you know, many different products, particularly when they have similar active ingredients or the same active ingredients.

Also, this would require more steps to really change this and the clear separation of enforceable and advisory label statements would be a big help, and then, also, the -- back to the clarification situation, the separation of types of application equipment could be a huge help, which I'll turn it back over to Susan.

MS. KEGLY: So, Scott just told you about the things that we could all agree on, and there are some other issues that arose that -- so, there are other issues where there was some discussion, but not

necessarily agreement, but just questions in general. And, you know, the first thing that came up is, you know, the label is actually trying to be everything for everybody, which makes it very difficult for it to be effective for anything, actually.

The objective, first and foremost, for EPA is that the label is the law, and so, if -- so, it should make it easy to follow that law and enforce that law.

It's also used for consumer information, for applicator information. That's kind of the biggest intent. Manufacturer statements, best management practices, all of those issues are dealt with.

Labels are also used in training new applicators, and so, there's information on there that an experienced applicator may not need, but a new person might. So, we need to think about, you know, how can you best arrange the label so that you reach those different target groups and not make it so confusing that it's impossible to enforce.

The label is also connected to the risk assessment that EPA does. When doing a risk assessment, the label is -- the uses that you consider and when you

come up with your overall assessment to the toxicology, you go back to the label and use the label to get that information back out to the user to have them use it correctly so that risks are below levels of concern.

There are also issues of the label -- again, the label can be a training device or educational, but maybe a professional ag user may not need it, consumer users might need more of that, but overall, the enforceability has to be one of the most important criteria.

Another issue that came up is that the label also contains statements that are aimed at the grower and statements that are aimed at the applicator, and if the applicator has the label in hand, but the grower does not, how is that information transmitted from the applicator to the grower? And this came up in the context of, you know, there needs to be a vegetative buffer strip of 10 feet between the field and the water body, for example, and whose job is it to make that communication. Well, it's the applicator's job, but it's not clearly spelled out that it is and it's not uniformly done because it's not spelled out. So, you know, how can we facilitate that communication to make those -- get

those points across?

The other issue that came up is -- this came up in the context of the 2,4-D label. There was a whole label statement on sensitive plants and there was a suggestion that we also discuss sensitive sites like homes and schools and businesses and water bodies and wildlife for parks and things like that. So, just as something that might need to be added.

There were a number of complex issues where we knew we weren't all going to agree, but we thought it very much worth a discussion. As Scott said, basically, looking at what do we mean by harm from spray drift, looking at design standards versus performance standards, how do we accommodate local conditions, and then determining, you know, how does that label actually operate in the real world. We're going to go into these in some detail.

Harm, there's a couple of ways that you might go about defining harm. The FIFRA standard says unreasonable adverse effects on health and the environment, right? We missed the health part. The specific adverse outcomes. So, no bad things happen when

it's used properly.

No toxics in toxic amounts, and that's the Clean Water Act standard. And the minimized drift standard that you would get to from using best management practices. And then, at kind of the other end of the spectrum is any -- no drift period. So, no drift in detectable amounts. So, these are the range of options.

And what happened was that Dave Scott with the Indiana State Chemist's Office, Indiana has already moved on this because Dave is frustrated with not being able to enforce labels. And I wanted to read to you what they put together. It's a one-liner. We didn't quite get the quote right there, but a person may not apply a pesticide in a manner that allows it to drift from the target site in sufficient quantities to cause harm at a non-target site. And their rule basically looks at harm in the context of exceeding Federal or State standards, like water quality standards, or tolerances, if it drifts onto a crop. And, of course, if there's no tolerance, like if you drift onto an organic crop, obviously, there's a violation.

He also says that -- they haven't had much time

to check it out, but there are definitely -- you know, it's only been in place for this year, but certainly situational issues would contribute to the estimated potential harm; for example, application near a school would be viewed differently than an application next to just another cornfield.

Economic harm is an issue, and then, of course, anything observable, when something dies or people get sick or whatever. So, that was kind of the initial -- that's what they're doing. There was then a lot of discussion on that, what the law did well and what things might have been left out.

And one of the things that came up is that multiple pesticide exposures -- if you have a water quality standard, maybe that's fine if you're only exposed to one thing. But if you're applying a tank mix of, you know, two pesticides together or more, you're not -- your risk assessment doesn't tell you much about the interaction of those two pesticides. That might need to be taken into consideration.

And then the fact that we don't routinely test for endocrine disruption and we don't have a good method

yet. Hopefully, we'll be working on that. And that developmental neurotoxicity as two examples of where risk assessments aren't necessarily complete.

There was concern that just because you detected a pesticide, that that not be the standard of harm, because our detection limits are getting more and more refined and we're able to see smaller and smaller amounts.

There was a comment that we should think about utilizing the FIFRA standard of no unreasonable adverse effects, and in terms of what you'd normally do in good agricultural practice. There was even comments about the costs of drift are not borne by the people who benefit. And so, a typical cost benefit analysis may not be the most appropriate thing there. And then there's also concern about -- again, this kind of comes back to the risk assessment. There's a lot of variability in different humans that -- intraspecies variability and sensitivity to toxics that that factor of 10 that's normally used may not cover.

You want to jump in?

MR. SHIRTZ: (Inaudible).

MS. KEGLY: Okay, other considerations, one thing that came up is, you know, how would you write this law so that if you were on the other side of the fence, you'd be happy with the results? And, again, there's a lot of situations where the person applying the pesticide doesn't necessarily ever end up on the receiving end of the potential harm.

There's also issues of residues that persist, like maybe you might spray a schoolyard on the weekend and then the kids come back and play on the swing set that might have residues on it. That needs to be considered.

And then another proposal was, well, Federal standards are limited, they're not available for a lot of different chemicals. So, with the risk assessments, we now have a kind of toxicologically allowable concentrations in the population adjusted doses, and those might be some other values we might want to compare with.

There were concerns from a trial representative in Washington that some highly exposed groups have really different circumstances. The example he used was a

person there might eat salmon 15 or so times a week because that's one of their main staple foods, and so, highly exposed groups may need some special consideration.

And then there was also a comment that problems can be minimized with some notification in advance of an application.

MR. SHIRTZ: Thank you, Susan. Back to the design and performance standards. As mentioned earlier, basically, what we tried to look at was whether it's preferable for a label to say how to do something or telling the user what it needs to end up. And we tried to look at it on the basis of enforceability and benefits, you know, what actually would end up doing the best job of mitigating drift, and then, also, measures of compliance.

Now, the thoughts on this, the development on it, the commercial applicator representative -- I preferred the performance based standards primarily because it allows the use of experience, and I've found that many times the design standards actually tend to increase potential instead of reduce it. And that's, I

think, a very important thing. It's not to actually end up with a label requirement that increases drift potential.

And then the other important part about on the performance based standards is that it ends up being related to actually an adverse effect.

Then the regulatory representative really preferred to have a combination of those because, particularly in the case when the complaint might be somewhat delayed on when it was called in and responded to, that would give them more leeway on enforcement action.

One other main point that came out is that the private applicator situation really does need to be explored more.

Then something that came up on the 2,4-D study, in particular, is the local need situation because you may have a label that generally permits it and then in the 2,4-D case, of course, there's certain sensitive crop areas that changes it, and how this plays on a national situation is a real question. In fact, 2,4-D does have the label that does require that. And in this particular

case, of course, it is for sensitive crops or those types of things as related to that particular product.

Going a little farther with this, generally these local conditions, whether it's a sensitive crop or that combination with the product, typically trigger more restrictive conditions. Of course, in the 2,4-D situation, typically there are blackout dates or areas that at a certain time that can't be sprayed.

Then, also, the 303(d)-listed water bodies, already take those into consideration. That may be something incorporated under the labels. Also, we currently have the endangered species regional bulletins. And then, basically, this is the statement that created a lot of our concerns on the 2,4-D label.

Okay, then continued on the local conditions, it is thought to be best working with the local regulatory entities and when they're knowledgeable of it.

Mapping is something that definitely has the potential to help publicize this. It is already used in some instances and this is something that has a lot of potential to communicate that. And then, also, there are some existing tools that may be included.

And then my last part of this -- okay, okay.

UNIDENTIFIED FEMALE: (Inaudible).

UNIDENTIFIED MALE: (Inaudible).

MS. KEGLY: The fourth difficult issue that we were dealing with was looking at real world impact and getting feedback into EPA on how the label is actually working, is it doing what they intended when they wrote those restrictions on the label?

This means looking at risk assessment models and see if they're giving you accurate information; determining the impact of labeling on the user's behavior, and this means, you know, does the user actually read the label, and if they do, do they understand what you meant by what's written on the label; and then, also, looking at whether people are actually complying with the label.

So, our thoughts on those particular issues are that some iterative testing of models against real world conditions, and this might be water sampling or air sampling, would help you ground treat your models and see that you're really proposing something that's effective.

It would also help to have more data that was

mentioned earlier in terms of gathering poisoning incident reports to see if you're being better or more effective at preventing this incident. The AAPCO survey -- American Association of Pesticide Control Officials, is that what it is? Something like that. They work together in many states to put together a survey and get it back in to -- I guess Dave Scott ran it -- to look at what the problematic chemicals were and types of incidents. That could be enhanced to, you know, look at what types of applications, what chemicals cause, you know, more of a problem than others, and you could target your enforcement activity on those situations.

A common theme was that if the states are going to be asked to do these kinds of things, they need more resources, states and tribes, and this encompasses all kinds of activities, including enforcement training, applicator training and certification and monitoring.

There was some discussion about more monitoring, preferably done by an objective entity. There was some discussion of having the registrants do some of the monitoring and maybe some of the communities that are affected by drift assist with some of the monitoring, as

well as the states. So, I think there's some agreement that we'd all prefer an objective entity to be doing those tests.

Then there was a discussion of, you know, do we need a new EPA process to test and develop labels? Can we do focus groups with actual pesticide users to see whether the label is communicating what we'd like to communicate? Surveys and perhaps a new person in EPA with expertise in kind of communicating this kind of technical information that needs to be accessible to people who may not make it -- well, everybody gets overwhelmed by too much information.

And, finally, basically where we're headed next, EPA's going to update the work group on the permethrin and 2,4-D labels. We are going to revisit some of these issues that need more discussion, and we'll begin a report for the PPDC.

MS. LINDSAY: Well, it's 5:00 and -- which you all know, you've probably been looking at your watches.

(Laughter.)

MS. LINDSAY: I think that there's probably time for a limited amount of discussion, I think particularly

if you see an issue that you just couldn't recognize in the presentation that Scott and Susan gave that you think would really be important to add to the list of issues. That's valuable to us at this point.

So, let me open it up. I see, Matt, you've got a --

MR. KEIFER: We in Washington State have a pesticide incident reporting and tracking panel which follows pesticide poisonings in the state, and each one of our pesticide poisonings that gets reported and meets certain criteria is investigated by an investigator from the Department of Health. They do an excellent job of doing this investigation, and one of the things that we on the PIRT recommended that they do a couple years ago was to try and design a fault analysis of each time somebody got overexposed.

Oftentimes, we learn more from our failures than our successes, and one of the things that pesticide poisonings represent or pesticide incidents represent is a failure. So, we should be looking at each one of these things, which means prompt response, thorough investigation, but a lot of states don't have the support

to do that. So, I think EPA maybe should start thinking about how they can support the states. I know they do the sensor project now, but sensor -- and sensor is good, but it doesn't necessarily have a focus on the label or on the recommendations, on how it might be failing, and that's, to some degree, because of who's doing sensor.

But injecting that kind of -- an understanding of fault analysis into the process might be very helpful.

MS. LINDSAY: Okay, great, good suggestion. Dennis?

MR. HOWARD: This isn't so much a comment about what's left out, but more about what was done with the work group. I had the opportunity to sit in yesterday and just watch the conversation. I thought it was actually a remarkable dialogue. I haven't seen anything like that, in my experience before, where you had a very constructive dialogue going back and forth in several different directions, but primarily between folks with a regulatory vent and those with -- on the applicator side of things and both with real world experiences to share.

What struck me was that the focus being on the label as it was, it just brought to mind the fact that,

sure, there are problems with drift statements on labels, but those are just a microcosm of the kinds of problems that applicators face when they try to interpret labels, and the idea that the label is supposed to be all things to all people, I think, is a strong observation. It seems to me like labels have been around as long as pesticide regulations have been and they've evolved over the years. But I don't know that the agency's really ever had a chance to take a strong look at what the label actually is doing and how it's constructed now, and the idea about having focus groups to look at its ability as a communication tool, as well as a legal tool, I think is really valuable.

I would just recommend that that line of thinking be considered further by the committee.

MS. LINDSAY: It looks like I might have intimidated everybody else that's not speaking, but the comments were actually very good.

MR. JONES: Thanks. I want to thank Jim Hanlon and Anne Lindsay for their leadership of this work group. They're not done yet, and as the next steps slide indicates, they're going to have one more meeting -- as

they indicated, they're going to have one more meeting which will result in a report that comes back to the full committee. I think the same -- as Anne mentioned in her opening remarks, the same issue with this work group as applied to the worker certification and training work group, which is what do we need to do to make sure that we can have an expeditious dialogue around the consideration of the work group report without having to repeat everything that the work group did.

And we'll spend some time -- I'll think about that tonight. I ask you to do the same. We'll spend some time tomorrow seeing if we can come up with some ideas about how to achieve sort of fully informed -- having fully informed advice without, again, sort of reliving the whole work group process, which I don't think anyone's going to want to do, either those who did live through it the first time or those who didn't.

So, we'll close this (inaudible) part of our process right now and look forward to your report at our next meeting. Thanks very much.

Thanks to Susan and Scott, as well, who are not members of the PPDC itself, but were obviously very

active members in this subcommittee. I appreciate your not only taking your time to participate in the work group, but your time and your hutzpa to come and talk to the whole committee. I appreciate that very much.

Okay, so, Margie --

MS. FEHRENBACH: No comments.

MR. JONES: No comments. Well, what was I worried about being on time?

(Laughter).

MR. JONES: We are now officially ahead of schedule. I'm a man who likes to be ahead of schedule. So, we are going to call it a day and we'll be back here 8:30 tomorrow morning. Thank you all.

(Day 1 was adjourned.)

DAY TWO

NOVEMBER 9, 2006

MR. JONES: We are going to get started this morning. I think I'll wait until later in the morning to

talk about some of the work group issues and how we can manage so that we don't -- people don't feel the need to, as I say, relive the work group in the full committee and how we can make sure people have an opportunity to have their views expressed without, again, everybody being on every work group or this full committee having to relive every moment of every work group. We'll have some dialogue around that later this morning. I've got some ideas. So, we'll talk about that later in the morning, and if you can also continue to think about that through the morning.

Are there any points that -- I know we sort of ended the day yesterday where people seemed to have gotten a little bit tired and I wanted to make sure any points people want to make, clarifying or questions regarding any of yesterday's presentations before we start on this morning's agenda.

Carol?

MS. RAMSAY: Jim, I'd like to retract my concern for the report. It was actually a concerns for the measures I had, not a concern for the report. So, I'd like to retract that.

MR. JONES: Okay, I appreciate that. Anyone else?

(No response).

MR. JONES: Okay. So, we're now going to talk about registration review, which is our new old chemicals program. This work group was quite instrumental in helping us to develop the regulations that will -- we will need to operate under for registration review, and we want to give you a sense as to where we are in implementation and we also are going to be proposing to have a work group of the PPDC help us focus on implementation early on, so we don't get one, two, three, four years down the road and, at that point, people begin to feel uneasy about how we're making some of the early decisions in registration review. And by decisions, I don't mean chemical regulatory decisions, but how we're actually planning on -- what we're going to assess and what data do we think we need.

So, Debbie's going to take you through all of that and then we'll talk about this work group further.

MS. EDWARDS: Okay. As Jim said, I'm going to take you through, actually, a relatively short

presentation because mostly in this hour, we want to hear what you have to say.

So, as I mentioned yesterday, the what's next, a big piece of what's next for the old chemicals program is registration review. The FQPA set this up for us by modifying FIFRA 3(g) that requires this periodic review of pesticide registration. It covers all pesticides as opposed to the way reregistration was set up. In other words, reregistration was set up for pesticides registered prior to 1984. This covers all the pesticides.

The goal is to have every 15 years, at minimum, each pesticide re-reviewed within the program.

With your help, we got the final rule in place and effective last month, and one day later, we announced the schedule. The rule requires that we post at least three years, we actually posted four years. That's not a schedule for completion of these actions, it's a schedule for opening of dockets because you don't know yet when the schedule will be for the individual chemicals until you finish that process.

The final rule, if you haven't read it, it's a

good rule, I think. So, I recommend that you do read it. I like it. It describes a very flexible, transparent and very open process to do this work. It includes a robust public participation process that's modeled on what we learn from the existing public participation process. I'll talk in a minute about some of the differences there.

And, again, it ensures continuity. It's continuing. It would be every 15 years until and if that rule is ever revised or the law is revised.

We're planning to run this a little bit differently than reregistration. The way it's set up now, we would need to be opening and closing 45 cases, at least, every year. That's a lot of work. In addition to that, we believe that, for the most part, particularly with respect to tolerance assessment, we're already up to speed. You know, we've reviewed all of these chemicals since 1996, except 84 tolerances. So, we think we can look at this a little bit different way.

What we're planning to do is do a fairly significant problem formulation, we call it, up front for these chemicals, which we would present in the docket,

and questions we're asking ourselves is we're going to pull up all the most recent assessments on these chemicals and say, what's changed, if anything, since our last assessment in both dietary, drinking water, worker risk, residential risk, ecological risk and so forth.

If anything's changed, how significant is it? Would we need new information for these chemicals? And probably the most important question we'll be asking ourselves as we do this problem formulation is this last one here, which is, is the regulatory position likely to change as a result of any new information we might think we would normally need, and if not, we probably won't request it.

Just to give you a comparison, I think many of you have seen this before, but I think it's good to see some of the differences here. Like I just said, registration review is all pesticides, 15-year review as opposed to that one-time review. I just mentioned 45-plus pesticides a year. It depends on how many additional ones we register and how many drop off the plate as the years go by. This process was set by rule as opposed to law. The law has a very brief piece about

this process, but it did say you had to have a rule in place and we have that now.

Again, I just mentioned as opposed to comprehensive start-from-the-bottom reviews, we intend to update existing reviews, add to what we know, and we anticipate much fewer data needs than in the past because we've called in an enormous amount of data, as many of you know, through the reregistration process.

In terms of public comment periods and the public participation process, it is a little different. In reregistration, the first public comment period was on the risk assessment. That's not going to be the case here. The first public comment period occurs with the opening of a docket in which we -- I'll go into it more in a little bit, but basically it describes what we know and what we think the path forward is and asks all of the public to comment on that. So, it's actually involving the public in the development of our work plan for each individual chemical.

Then the second comment period, which will happen for most of the chemicals, except for very low risk chemicals, would be on the Preliminary Risk

Assessment, to the extent that any new ones are needed. That wouldn't always be the case.

And another new thing, actually, that we'll be doing here is we're going to be seeking public comment on our decisions. So, they'll be draft decisions as opposed to right now, we put out decisions, sometimes we seek comment on them if we think that's appropriate, sometimes not. But in this situation, the regulation actually provides for a comment period on all of the draft decisions.

And there will be other comment periods as needed. There could be one on proposed mitigation options that's in the rule. It's not a requirement. It may happen occasionally, even before we do a proposed decision.

I'm actually not going to go through this. This is in your materials. You can look at it. But it's basically the decision logic for how we move through this process, and it's pretty much described in the talk I'm giving here, but it's kind of for you to look at later, I think.

In terms of transparency, we have some things

we're going to be doing to try to make it very transparent. We're going to use the same docket numbers throughout the whole process for a given chemical. So, if you go into the docket, it might have up to three or four comment periods, but we'll be using the same docket. You can go in and see the whole history of how we get to a decision. We think that's important.

And, in addition, much like we've had with reregistration, we're going to have a website that shows schedules, the status of each chemical. What we're planning to do right now is once we close these dockets and evaluate the comments, we would post our work plan right on the web so people can see what the path forward is for each chemical.

I went through some of this yesterday, so I won't belabor it, but we are ramping up into registration review. We still have a fairly significant amount of work done to complete reregistration. I mentioned yesterday the non-food REDs, finishing the tolerance reassessments. There's a lot of RED implementation work and, obviously, product reregistration has to be completed, DCIs and so forth. So, this year, we're

ramping up not opening up 45 dockets, but rather 25 and then hopefully next year we can go ahead and open up the full 45.

This is a list of the conventional that we'll be opening this year. There are 15 of them listed there. Obviously, these are chemicals that were registered very shortly after 1984. Probably that first year, actually.

The next page here shows the antimicrobials that we'll be opening this year, because we're opening a total of 25 dockets. So, you'll see that there are several antimicrobials and biochemicals and some microbials that we'll be opening dockets.

In terms of the first steps, this is a lot of the work we'll be doing this year. Like I said, we're going to open the dockets and get your comments. That's a 90-day comment period we'll be providing early this year. We'll see if we'll continue that or move that back to a 60-day at some point. But -- for efficiency's sake. But, for now, we think it's appropriate to have a 90-day comment period. People are not used to this process yet.

Obviously, as I said, we'll review all the comments and additional information. This is an

opportunity not just to comment but to provide us with additional data that maybe we just weren't aware existed. At that point, we'll determine what exactly is needed to be done to complete the registration review case for the chemical and develop the final work plan and then proceed with that work plan. We'll schedule it out. So, we may need DCIs, we may need to do risk assessments, we may be able to move directly to a proposed decision. But that remains to be seen for each one, and that's why the schedule on the web right now only shows docket openings.

We're currently working on several dockets. The goal is to open some dockets this quarter, and if not this quarter, early next quarter. I think many of you that participated in some of the previous work on registration review know that we had a feasibility study on what this might cost, how it might go with a few chemicals. We're seeing that what we're doing on these first dockets is tracking pretty well with that. For the most part, the human health risk assessments look fine. We may not need to do any additional work on many of these chemicals.

In the ecological area, obviously, we're going

to need to probably do some additional work to come into compliance, in many cases, with the Endangered Species Act, and so, in some cases, there may need to be more data submitted in order to complete that.

Our goal is to, like I said, get some open this year, and those would serve as a model for -- we're going to learn by doing here.

Again, not to belabor this again, but what we're going to do in the docket is explain where we think the path forward is for the chemical, okay? What risk assessments we think need to be done, what data we think need to be generated, what data are missing. Maybe they don't need to be generated, maybe you can show us that they already exist. And we're going to give our full thought process for all the potential pathways of risk and pose questions to you for comment. In particular, we're going to be very interested, because of the Endangered Species situation -- and Steve will talk about this much more in the next session, I think. But we're going to be interested in as specific as possible of use and usage information throughout the country for each individual crop.

So, people, once they see our schedule, which, like I said, it's posted on the web for the next four years, can start working on that well in advance, and we're probably going to have a relatively standard set of questions that we'll have on that kind of information, grower organizations and so forth can begin working on.

This part, I'm just continuing to describe the steps in preparing the docket. I pointed out previously two of the biggest areas that are going to be big issue areas for registration review, obviously, are endangered species, which Steve will talk about in a few minutes, and then endocrine disruption, which is actually the topic of another session later today. So, those are going to be two key areas for us.

I don't think -- I think the rest of this slide is pretty much redundant. So, let's move on.

I'm going to give you an example. This is a theoretical example, although it's based somewhat in fact and experience. We've been working through and developing some dockets for chemicals. This is an herbicide and this is kind of what we have found. I won't say which herbicide it is. It can be a test

question for once you look at the schedule and figure out which one.

But we looked into this particular herbicide to see what we thought the appropriate path forward was and what we determined was, as I mentioned before, this is going to happen often, we think, we don't think any additional human health risk assessment is needed. Dietary risks are below the levels of concerns, including drinking water. There are no residential uses for the chemical. All the worker MOEs are, again, below the level of concern.

We think we have adequate data. There's not a great deal of uncertainty in those assessments. We considered any new policy changes and methodology that had come into place over the years and we're confident that we've taken care of -- that the current registrations are fine with respect to human health risk basically.

On the environmental side, however, it's an herbicide, so what would you expect. It poses acute risk to terrestrial plants and there are some incident reports actually describing harm to terrestrial plants. There

have been some fairly significant buffer zones put in place to protect plants. Those are actually on the product labels, but they don't take into account all formulations. So, we're thinking we may need to do some additional buffer zone assessments to look at all the different formulations, possibly using some of the new air models if it's a pretty volatile chemical.

In addition to that, the risk to plants, at least the (inaudible) level assessments show potential chronic risk to mammals and acute risk to some aquatic organisms.

So, obviously, we have predicted risk, the non-target organisms here and screening level basis. There may be effects on endangered species, but that's just the initial screening level assessment. And so, we'll need to do a more refined risk assessment that looks more carefully into some of the things I've just described, the different formulations and the actual potential risks to endangered species, including an indirect effect. We haven't typically done a lot of those kinds of assessments in the past.

What happens then with this particular chemical,

like I said, we're going to put all this out. There's going to be a document that describes this. There are going to be all the supporting materials there. We're going to seek comment on what we've described as what we believe is the appropriate path forward for the chemical.

I think in this particular case we're not even saying that we think we need any additional data; we just think we need to do additional assessment so we'd be able to move forward with risk assessment.

In terms of your input, obviously, as Jim mentioned, we benefitted greatly from PPDC input on development of the regulations for registration review. We're also interested in getting some advice on how we're going about this problem formulation and docketing process and work plan development. So, Jim mentioned earlier, we kind of like to consider -- maybe we can get some feedback on that here in a minute -- some subcommittee to discuss a couple of these case studies, some of the early dockets we're going to be opening.

We would do this probably during the comment period and continuing afterwards, if need be, to work towards -- we put all our information into the docket and

then we could have some meetings around the information and the thought process that went into preparing that docket with a subcommittee and work toward development of a work plan for those chemicals, and that would help us then in the future with all the rest of the chemicals we have to do. So, hopefully, we'll get some good feedback on that.

So, in conclusion, we're up and running on registration review, just barely, but we're up and running. We're going to begin that transition and, hopefully, next year move into full 45 docket openings. We want to make them as transparent as possible. We want to get good comments and we want your feedback. Thank you.

Oh, by the way, this final slide shows -- these are the addresses, you see the bottom link there is for the schedule and the next to the last link is for our registration review webpage, which, by the way, I think is a very good webpage. So, you should probably take a look at that.

MR. JONES: Matthew?

DR. KEIFER: One thing that I'd like to share

with the group is that as a clinician seeing farmworkers in clinics, I'm constantly frustrated by my inability to confirm diagnoses. I'm frustrated by the fact that patients come to me with complaints about exposure and I'm, effectively, without tools to confirm that this is not the flu, that it's not some other kind of illness, but in fact it relates to the chemical that the worker proposes is the cause.

So, what I'd recommend is that the Environmental Protection Agency consider in the registration process the expectation that the registrant develop or assist the development of clinical tools -- biomonitoring techniques and clinical tools to confirm or refute the exposure. It seems to me that having looked at the registration process, there's a number of places where those tools could evolve out of the toxicological information that's provided to the EPA and become a useful clinical instrument. I think it would not be that great an expectation beyond the registration process to ask that to happen and it would be particularly -- it would be enormously useful for us to have those tools available.

MR. JONES: Gary?

MR. LIBMAN: That was an excellent presentation. Just a couple of questions on it. On the one slide, slide number six, where you talk about the public comment and the three different dockets, if you will, or the three different comment periods, it might be helpful to see almost a time line continuum to see what -- you know, how -- what is expected -- obviously, things can change. But it would be helpful for certainly registrants to have a sense of how long each of these comment periods are expected to be.

MS. EDWARDS: Right. I mean, right now, we're anticipating that we would have the 90-day comment period on the docket opening and then probably the 60-day comment period that we typically have now, bearing in mind that there would be some distance between when you would open -- let you know the various time periods.

And then, in certain cases, when more time is needed, you know, we're able to do extensions, if that's appropriate. But I think you're right. What we hope to do for the -- when we start publishing work plans is show the whole time line. In other words, the work plan is these are the things we have to do and this is how long

we think it's going to take, and this is when we think we could make a decision.

MR. LIBMAN: I have another quick question, too. On the chemicals and the biologicals that you've chosen, the 35, was it arbitrary or was there some logic to the antimicrobials and the biochemicals and microbials and the conventionals?

MS. EDWARDS: It's just based on when they were registered in these particular cases. For this year, these were all registered, you know, very shortly after 1984.

MR. LIBMAN: Oh, okay. I wouldn't mind being involved in the case study things that you're doing (inaudible). When you do your case studies, are you going to be doing it by maybe two, three products? I don't know how you're going to work it out, but are you going to have it like in broad categories? One would be conventionals, one maybe biologicals, one anti-microbials or something?

MS. EDWARDS: That probably makes sense. We haven't really gotten that far.

MR. LIBMAN: I think that would make sense, so

that would be my suggestion.

MS. EDWARDS: I think the first ones we're planning to do would be conventionals, but I don't see any reason why we couldn't do case studies on them. We probably should do at least one on anti-microbials and microbials.

MR. LIBMAN: Thank you.

MR. JONES: Cindy?

MS. BAKER: Thank you, Jim, and thank you, Debbie. I was part of that original work group, and so, I'm pleased in both reading the rule and what just recently came out, and also, the way that the agency explained how they addressed the comments that came in. While I wish some of those comments had been the way that we submitted comments, it was very helpful the way that you explained why you didn't do what you did when the comments came in.

And I think if you read through that, Gary, you'll see there's a lot of explanation in there about how they're going to do these things. I think it's very useful in that respect. I think the website is very helpful to go to and pull those things through.

And I just wanted to make two comments. I think, one, I'm pleased to see in your presentation today, and also, in the way that it's written up in the rule that fast track off category that we talked about to save the agency resources in those cases where you have the kinds of things that you laid out there, because I think you will -- not so much in this first round, in fiscal year '07, but surely as you get into '08 and '09, you're going to have chemicals where you've already done quite a bit of work, and so, there might be specific areas that you come to.

And I, like Gary, would like to participate in this subgroup. I'm lucky enough to have two actives in that fiscal year '07 list, and so, I'd be interested to see kind of how those go through.

MR. JONES: Thanks. Ray, then Susan, then Caroline, then Beth.

MR. McALLISTER: I have a couple of questions. First off, in developing the schedule for registration review, have you folks consulted with the services, the Fish and Wildlife Service, the National Marine Fishery Service, regarding the priorities for endangered species

review?

MS. EDWARDS: Yeah, we have discussed the schedule with them.

MR. McALLISTER: Okay. The other question I had was in your problem formulation phase and posting the information in the docket, you may or may not identify additional date that you feel might be needed. But in addressing the particular issues that show up in the problem formulation, one or more registrants may feel that there are additional data that could address those, data that don't yet exist and would need to be generated.

Now, the agency may feel, we can go ahead without data, but if -- how would you handle that situation where a registrant feels additional data would be helpful, but you don't feel that it's absolutely necessary? How do you build time into the whole process to be able to generate that data that does not yet exist?

MS. EDWARDS: Well, let me give you -- I don't know, this is a little bit simplistic answer, but let's say we're missing some data but we can make some, what we often call worst case assumptions, you know, that lead you to the high end of uncertainty around that and we

still don't show a problem, even in the absence of those data. We might say that, you know, from our perspective, we can make a safety finding without actually having additional data.

On the other hand, if we don't think we can make a safety finding without those additional data, we would likely issue a data call-in, unless during the comment period it became clear that there were data available to address those uncertainties.

MR. McALLISTER: Okay.

MR. JONES: Okay, Susan Little.

MS. LITTLE: I just have a quick question on finalization of guideline requirements. There are several out there, specifically the 158 Part W that's going to drive a lot of the data development in the next phase. Where's the agency on finalizing all of these different guideline requirements?

MR. JONES: The 158 for conventional will be finalized in this fiscal year, FY '07. The proposal for 158W is likely to be -- it's likely to be proposed in this fiscal year. So, it's a little bit off before we actually are finalizing the requirements for anti-

microbials. We're also going to finalize, this fiscal year, the requirements for biochemicals, 158L and M.

MS. EDWARDS: And just to add, those are actually the rules which specify the date requirements, the test guidelines, the protocols as to how to do those. There were a number -- I think the largest set was in the environmental (inaudible) arena where we have been in the process of harmonizing those guidelines, both within the U.S. and internationally, and the vast majority of them, at least 16 out of 17 -- and I think the 17th may actually be very close to completion and we would expect to actually publish notice of that in the very near future. So, I think almost all of the critical test guidelines underlying both Part 158, the conventional chemicals, as well as in other areas are pretty much done.

MS. BAKER: Thank you.

MR. JONES: Caroline Cox?

MS. COX: One question, when you talk about looking at what's changed since the last risk assessment, is that going to include kind of a search of published peer reviewed literature that pertains to the particular

chemical?

MS. EDWARDS: Yes.

MS. COX: Great, I'm really glad to hear that. And then, secondly, I wanted to really support what Dr. Keifer said and add to it. I was thinking one of the things that's really likely to have changed in the last 15 years or more for some of these chemicals is the development of better analytical equipment and analytical technique. We have some pesticides that we don't have good analytical technique for in all media and it seems like that's something that should definitely be included in this registration review, to get those techniques all worked out and available to the public.

MR. JONES: Thank you. Beth Carroll?

DR. CARROLL: You mentioned more specific use and usage information as you were talking about the goals for the docket, and I just wanted to be -- to understand where the IMS information fits into this and how it's going to be updated for the endangered species assessment?

MS. EDWARDS: I actually think that probably in the next session that's a better question for Steve

unless we -- if that's all right with you.

DR. CARROLL: Okay.

MS. EDWARDS: Because it's going to be a critical part of the kinds of things he's going to talk about.

DR. CARROLL: And then, my assumption is you'll take a look at that first before issuing the DCI.

MS. EDWARDS: We will look at all available information, of course, before we would issue the DCI.

MR. JONES: Okay.

MS. EDWARDS: The goal is to get to decisions as quickly as we can and issuing DCIs prevents us from doing that.

MR. JONES: Julie and then Dennis Howard.

MS. SPAGNOLI: I, like Cindy, was part of that work group and I want to share, as she did, that we're really pleased. I think we put in a lot of time and a lot of -- I think it was about three years that work group was together, and so, we're really, really pleased with what we're seeing, that it really reflects -- pretty much, you know, the group had their discussions, but really kind of came to a consensus and that this really

reflects the -- I think we addressed the concerns from all stakeholders and this reflects it, and I just see that as a good model.

Now, I think we're seeing the same thing with the work group protection rules, that by engaging people and kind of making sure we've got all the issues on the table, in the front, it really helps come up with a better product and I just wanted to say how pleased we are with this.

MR. JONES: Thanks, appreciate that. Dennis and then Mary Ellen.

MR. HOWARD: Well, I was going to ask about usage, but since that will be deferred to Steve's discussion, maybe, Debbie, could you help me understand the linkage between the talk we had yesterday on water quality impact (inaudible) FATE were going to be speaking, that's going to come before that first comment opens, right?

MS. EDWARDS: To the extent that it can, yes. I mean, what we want to do is work with the regions and states and with the schedule that currently exists. I mean, you could look right now at the schedule and see

the first four years of docket openings, to the extent that people can begin gathering those data so that the data can be available to the entire public in the docket when we open it, that's the goal.

Having said that, the data, if that's not possible for some reason, could be submitted during the time that the docket is open and even thereafter. But the later it gets submitted, you know, the more difficult it us for us to use it in the most effective way. But we have a very predictable schedule now. So, we should be able to work very closely with people and get the data up front.

MR. HOWARD: Right, that would be helpful. Do you anticipate that there will be other types of information that state lead agencies could be trying to pull together for you to help with your assessments beyond water quality?

MS. EDWARDS: Yeah, incident data, any kind of monitoring data that exists. I mean, we want to hear about everything, to be honest. I can't think of any kind of data or information that we don't want to see. So, we can continue those conversations.

MR. HOWARD: Should they assume that incident data that we may know about, the agency may not know about?

MS. EDWARDS: Exactly.

MR. HOWARD: Okay, thank you.

MR. JONES: Just a further point of clarification with some of the questions. When we open this docket, it's going to describe all of the data that we've got in front of us. It's not only going to be the standard, you know, 158W or conventional or an L and M, but incident data, water quality data, any other monitoring data from any other source, and also describe sort of how we -- we need to do this assessment, this assessment, and we think we need this additional data. So, you'll all be able to -- the general public will be able to say, you don't have this data over here or we think you're doing too much on that or you're not doing enough on that and I don't understand why you have to get this data, but I think you need that data.

So, the public will have an opportunity to let us know if they think we've missed something that they're aware of, or if we're overreaching or if we're asking for

data that we don't think we have or we're not asking for enough data. So, you'll have -- and that will be unique to registration review that did not happen in reregistration, and I get the sense from some of the questions that that's not sort of filtered through yet, which I -- you know, it's very abstract, I realize, which is one of the reasons we want to actually have a work group go through that part of it with us where we're sort of explaining how we came to certain conclusions about we think we need this assessment and that assessment and we think we may need this data and that data, and we base those choices on this body of knowledge we had in front of us. So, I just wanted to provide that further clarification.

Okay, Mary Ellen and then give me Robert.

MS. SETTING: I just wanted to compliment the agency on the website and the depth of information that you've been providing on the process and the questions you've raised and the answers you have obtained. It's incredibly invaluable to us as state lead agencies when we get requests from constituents either concerned about products used by industries or by our own agencies, and

it's just invaluable to have that information. It's very easy to navigate and find the information. I (inaudible) appreciate it.

MR. JONES: Thank you, appreciate the comment. Dr. Roberts?

DR. ROBERTS: I mainly wanted to reiterate one of the things that Dr. Keifer said, as well, speaking as a clinician. I'm a pediatrician, so both in child health and adult health, we do need more biomonitoring techniques available to us. One of the other issues is, you know, we spoke a lot about acute poisoning and recognizing it. Clinicians don't recognize this enough and I think a lot of other -- like our opinions anyway, as far as the average clinician, so that having the tools available are important. And in addition to the acute poisoning, I think it's equally as important to gather as much available data on the chronic effects from pesticides to actually recognize or refute these medical problems as coming from a pesticide or not.

MR. JONES: Can I ask a clarifying question, Dr. Roberts, of you and Dr. Keifer? You're referring to diagnostic techniques. Do you mean sort of the ability

in the clinical setting to draw blood or urine and be able to say, oh, that's what's happening biologically? So, for example, a cholinesterase test would be such a thing. Is that what you're saying or --

MR. KEIFER: That's probably the best example of a diagnostic tool that can be of us, but has limitations. Some of the things such as to bolster cholinesterase monitoring, which has a recoverable half life that's predictable and we know about how long it's going to be depressed, and sometimes we don't know whether cholinesterase, for example, is depressed because the wide range of normal of cholinesterase, the person can come in with a depressed cholinesterase and we can't recognize it unless we have a baseline. And so, what we need is something to augment that, such as the work that Dana Barr at CDC is doing, where she's actually looking at the decorator protein. She's trying to look at whether we can identify the inhibition of the enzymes and connect it to cholinesterase or the decrease in activity of the enzyme and connect it to a pesticide by identifying the unique tag that a pesticide would give to cholinesterase or other enzymes. So, there's a lot of

different opportunities to look for alternative verification methodologies and diagnostic tools.

Sometimes, just the physical exam finding complex that we would use in a diagnostic situation is unique enough where we can say, oh, well, this is a pesticide poisoning or this is for a particular manifestation of this chemical. So, it spans the spectrum of diagnostic tools that clinicians need and can use, and I would encourage that there we have some effort invested in clarifying what those would be.

This is up, again, if I have enough (inaudible).

MR. JONES: I thought I understood the point both of you were making, but I just wanted to make sure that I did. Thank you.

DR. ROBERTS: And I have a little extra clarification.

MR. JONES: Sure.

DR. ROBERTS: In addition, we're talking about cholinesterase testing, but that's for just the organophosphate or (inaudible). And so, with the pyrethroids, there really are no tests that you can do with the exception of testing the metabolites in the

urine. But that's only going to be for a class of them, it may not be for one specifically. And then, it goes on to the larger number of newer compounds that there are not even any types of tests for.

MR. JONES: Thanks. (Inaudible).

UNIDENTIFIED MALE: I just want to point out that one of the things that I have concern about in this process is the degree of public participation of the public who have the direct -- who suffer the direct impact of some of these chemicals, and by that, I would identify farmworkers, particularly, machinists and biocides, the biocides that are put into lubricants to control overgrowth of activity, which for occupational medicine physicians is a relatively common problem for us to see, that machinists come in with complaints of biocides or of issues related to biocides in lubricants. I'd also add hotel and restaurant workers who use disinfectants relatively frequently.

What I would encourage EPA to look at is the environmental justice community based participatory research portfolio of both NIOSH and EPA and NIEHS, which has given unique access to these populations and really a

unique voice to these populations. It has energized the ability of these communities to connect to science and there's been a significant investment in this process, and I think that EPA should look at the opportunity that's created by this connection and potentially use it to obtain better participation from those who might be willing to participate were they to understand their opportunity.

MR. JONES: I appreciate that. We will definitely look into that. It's always been a desire on our part to be able to get as much public participation by as many of the affected parties as possible and we recognize that sometimes we've not been able to be as effective in that as we want and having insights as to where it may have been -- where someone else may have figured out how to do that can be quite useful. So, we'll certainly look into that. Thank you.

Jennifer?

MS. SASS: Yeah, just a question, the data from the Jerome Blondell paper yesterday that I was looking at indicates actually that 26 percent decrease in exposures and poisonings, the unintentional pesticide poisonings

and exposures, is actually all pre-2000. It's from 1995 to 2000. That's where that drop is. That would be pre really effective FQPA actions. And since 2000, in the five years after, the reason why that line flattens out is because the decrease in cholinesterase, in OP poisonings, is actually balanced by an increase in the pyrethrin/pyrethroid poisonings minus 1 percent. You actually get only a 1 percent decrease overall from 2000 and 2005.

But you obviously get a difference in the severity of the poisonings, right? Moving from the chlorpyrifos diazinon poisonings pre-2000 into the pyrethroid pyrethrin poisonings post-2000. So, my question for you maybe, Matt, and others at the table is, do we have a way of diagnosing -- of detecting and diagnosing those kinds of poisonings or is this something that the PPDC could recommend that EPA (inaudible) some of its funding sources for to try and develop those kinds of detection methods? Because EPA actually is -- I mean, you're right, Jim, EPA is the leader in this area with NIHS and these kinds of things. I wonder if you could do that.

UNIDENTIFIED MALE: I think that's what we were talking about before you came in the door.

MS. SASS: (Inaudible).

UNIDENTIFIED MALE: Exactly. Well, talking about encouraging EPA to assist in the development or expect from registrants the development of the tools necessary to make diagnoses.

MS. SASS: Maybe that's something that we could -- as a group we could put forward as a recommendation.

MR. JONES: Melody?

DR. KAWAMOTO: During the work group on worker protection, we had talked about the surveilling the sensor program and somebody brought up the fact that it was known to be flawed and one of the reasons that it's flawed is because it doesn't really capture all of the poisonings that are occurring, and what they're saying -- what Dr. Keifer and Dr. Roberts are saying is one of the reasons that that may be true is because people don't recognize -- number one, people don't recognize that they're being poisoned and, number two, if they do recognize it, there's no way to really document that that's what the cause was. So, this is really an

important issue.

MR. JONES: Thanks. Caroline?

CAROLINE: I see a couple of issues here. One is we need a better understanding of what kind of communication documents go out to the clinical community so that they -- even if a person walked into a clinic and doesn't realize he or she's been poisoned, maybe we can do a better job of at least putting out, you know, written communications about what to look for. You know, like the simple things you see in the newspaper, you may be having a heart attack if. You know, just some simple things that people can understand about looking for symptoms, right?

And the other thing is, what kind of information do we require for the old chemicals when you're doing the re-review that deals with their composition and figuring out their methods and so on? I mean, that's been an issue for a long, long time. I guess I'm asking Debbie that question. If we don't have tests -- I mean, there's -- we don't have tests right now for some of the chemicals to really determine their -- the methods that they operate by, right, for some of the old chemicals?

MS. EDWARDS: Are you talking about the mechanism of action?

CAROLINE: Yes.

MS. EDWARDS: I don't think we require that.

CAROLINE: Well, that's one question I have is, why don't we require that? And then the other question is, if we can develop -- if we do need to develop methodologies to deal with acute poisonings, then we ought to ask the registrant to participate in that process to develop those methodologies.

MS. EDWARDS: Um-hum. Yeah, right now, you know, the analytical methodologies that we get have to do with the ones that I'm sure you're familiar with, detecting residues in food and water and making sure you can detect it in the animal studies you're doing and so forth.

CAROLINE: Right.

MS. EDWARDS: But I don't -- I'm not aware of exactly what you're talking about.

CAROLINE: Well, there's detection issues with some of the chemicals and we don't have good information.

MS. EDWARDS: Right.

CAROLINE: I'm just wondering why we don't ask for.

MS. EDWARDS: Well, we do. I mean, I think if we don't have that information, we do ask for it.

CAROLINE: You do ask for it?

MS. EDWARDS: That's part of a --

CAROLINE: And is there a connection between that and getting information on how to detect these poisonings? Is that helpful to get that?

MS. EDWARDS: I would think there would be some connection, but I think you need to have separate methods for detections in urine and blood and people and that sort of thing. You'd need to modify the methods somewhat. But, you know, I mean -- what I'm saying is it's not part of the 158 requirements --

CAROLINE: Right.

MS. EDWARDS: -- or even part of the requirement within a given study because that study is not required.

CAROLINE: Right.

MR. JONES: There's a confusion between clinical techniques and methods and methods that allow you to measure a chemical in air, water --

CAROLINE: I don't know if it's a confusion on my part, but it's -- there's a lack of understanding about how the two might connect.

MR. JONES: There's the potential for a connection, but we have not routinely required the submission of methods for clinical diagnosis.

CAROLINE: Right.

MR. JONES: We have routinely required the development of methods for -- can you measure it in food, in water and other environmental media.

CAROLINE: Right. Well, given the spirit, at least, of the FQPA, is this something that we should be thinking about asking for as part of the (inaudible) program?

MR. JONES: That's something -- so far, that has not been raised in the dialogue that we've had around registration review. But as we go through some of these examples, that may provide a forum for people to say, why aren't you asking for a clinical method? Now, for a lot of chemicals, I think people will come away not feeling the need for one. There will be other chemicals where you say, gee, you seem to have a lot of incident data

here. Can you actually -- can this be measured in a clinical setting?

CAROLINE: Right.

MR. JONES: Where it may be more appropriate to ask that.

CAROLINE: Thank you. That's where I'm going.

MR. JONES: Okay. And Michael and Julie and then Ray.

MICHAEL: I think that clinical diagnosis versus residue analysis is particularly important with something like rat poison where there are about 20,000 incidents per year reported to the CDC, but hotly disputed by the industry because there's no residue analysis to back it up. And, you know, either they're poisoned or they're not. And I think that level of poisonings per year is really significant and we need to do something to be able to get quick, easy confirmation of the poisoning.

MR. JONES: Julie, Ray, Amy.

MS. SPAGNOLI: All right, just speaking from past experience, generally, when we do metabolism studies to see what the effects or what the FATE of a chemical is in an animal, it's done in animal. We do rat metabolism

studies. The only one -- I know when we did insect repellant, we did do a human dermal metabolism study because the product was intended for application to human skin and, therefore, could measure how much was absorbed, how it was excreted, how fast it was excreted. But I think the most conventional chemical studies are done in animals. So, there is some data to indicate how it will be metabolized and whether it will be found in the blood and the urine. But it's going to be based on animal data.

MR. JONES: Ray?

MR. McALLISTER: Those same animal metabolism data would require methods for detecting the chemical in urine and blood.

MR. JONES: Okay, Amy, last comment, and then we'll talk about this work group idea for a second.

AMY: To go back to Caroline's question about what information goes out to the health care community and health care providers, there are some state pesticide safety education programs that are involved in doing some of that. There's also EPA's own initiative on the pesticide strategy. There is an initiative in Minnesota

that I've been involved with working with the insurers for health care providers to get it into continuing education units ongoing. So, all of these strategies could be effectively used as models and developed for other states.

But, again, it's a matter of resources and funding, as well as the issue that both Jimmy Roberts and Matt Keifer has brought up about we can make folks aware of the kinds of questions that they can be asking and that is really key, but we don't have further tools to help them diagnose. So, that would be even better if we could work all that together. But there's a lot of work, I think, that could be done to further this process of helping the health care community recognize and begin to rule in and rule out the possibility of pesticide exposures for both acute and chronic type of problems that they may be seeing in their clinical practices.

MR. JONES: Okay, so, what we would like to do is to ask a subset of this group to sit down with us in the winter, early spring time frame to actually look at, in detail, how we're teeing up the first couple of -- they might not be the first actual -- literally first,

but of the first 15 to 25 we're going to be doing, two or three or five, depending on the capacity of all of you to hang on it, chemicals as we sort of walk you through, here is the thought process we used in determining what additional assessments we wanted, if there is additional data, we want to have data or not, giving feedback around that, and the basic path forward that we're going to spell out for a couple of chemicals so that there's some early awareness on the part of stakeholders as to how we are coming up with our plan for a specific chemical, and for us -- that's what's in it for you.

What's in it for us is that we're getting very early feedback in that initial thought process. So, before we've done 50, 60 or 70 of them, if there are some appropriate adjustments that could be identified now, we could make them now and not wait until we've gotten so far down the road before we realize that there isn't a lot of buy-in to the approach that we're talking. Not that everybody's going to agree on everything, but as I like to say, I like to make my choices with my eyes wide open as opposed to not doing something because I didn't know that it raised an issue for a group.

So, it sounds as if, from some of the early comments, there's an interest in that. I don't know if you have any further questions around it. You don't necessarily need to raise your hand now, but if you are interested, it would be important to let both Margie Fehrenbach know and Debbie Edwards, if you want to be on the -- other than the ones we already have heard. I mean, a couple of you have already expressed an interest in doing it. It is important, as in all our work groups, that we have a range of participation across the various stakeholder groups.

I'm guessing from your silence that nobody really has a fundamental objection to this. I'll accept your silence on that, that nobody has an objection. But that is what we will do. Again, if you're interested, if you would let Margie know and Debbie Edwards. If we see that we don't have a nice balance on this group, that it's -- no one in from a certain part of the stakeholder community, then we'll do some recruiting of our own and see if we can achieve that. Again, in a work group, you don't have to be a member of the PPDC to participate, so there's a little more flexibility in reaching outside

this group to make sure we have that balance. So, we will do that.

All right, Debbie, Kevin, thanks very much.

All right, well, as Debbie mentioned in her presentation, the endangered species considerations are going to be a very big part of registration review. I anticipate that in the months and years to come, endangered species and how EPA gets into compliance with it will be a topic that we routinely bring to this group for some advice.

Today, we're basically just going to give you an update on where we are as it relates to our efforts to get into compliance meant to be somewhat of a way to help provoke amongst you some thoughts about how PPDC could be engaged in our endangered species work in OPP, which is that's really what we're trying to do is not only just update you on this is what we're doing, which is an important thing for us to be doing with the stakeholders, but also get you thinking about how there can be a broader engagement in this area.

With that, Arty Williams, who's the Associate Director in the FATE and Effects Division, along with

Steve Bradbury, who's the Director, are going to take us through this.

MR. BRADBURY: Thanks, Jim. What Arty and I would like to do is spend maybe 20 minutes or so and give you an update status report on where we are in the program on a number of different facets of the program and then we should have plenty of time for questions.

What we want to do is spend a little bit of time just reviewing very briefly what the Endangered Species Act is, what FIFRA is and that interface between the two. We're going to spend a little bit of time reviewing where we are in implementation, both in terms of -- implementation in terms of registration, reregistration, registration review activities, as well as implementation of the various risk assessment tools and analytical tools that are associated with making an endangered species effects determination and the context of doing a FIFRA risk assessment. We'll spend a little bit of time reviewing where we are in the implementation of the field program to wrap it up, and then, like I said, we should have plenty of time for questions and follow-up as we see fit.

I've taken notes on some of the questions that came up when Debbie was up here and between Arty and I, we'll try to get those questions answered as we go through, but for sure if we miss something, we'll catch it during our question and discussion period. With that, I'll turn it over to Arty.

MS. WILLIAMS: Thank you and good morning. As Steve said, I'm going to remind you a little bit about what ESA and EPA's program are all about, but then basically try and give you an update of where we are, what the status of our efforts are in developing and implementing this program.

As a reminder, the section of the Endangered Species Act that we're most concerned about in terms of getting this program going is Section 7(a)(2), and this is a section that applies to all federal agencies, not just EPA, and it states that all federal agencies have to insure that actions they take, carry out, fund or authorize or permit -- there are a whole bunch of permissive words in there -- we have to insure that those actions are not likely to jeopardize the continued existence of a listed species which is a threatened or

endangered species, or adversely modify a habitat that's been designated by the services, Fish and Wildlife and National Marine Fisheries Service, to be habitat that's critical to that species.

Some time ago, Congress indicated that EPA, in carrying out this program under its FIFRA authorities. Those are our authorities to do anything with pesticide registration. That in carrying out this program under those authorities, we also should be complying with the ESA, and at the same time, minimizing the impact on agriculture and other pesticide users.

Some of the characteristics of the assessments and the potential use limitations that we may be putting in place to protect listed species, that speak to this mandate by Congress, are that we, as always, are going to be using best available data and science, but in addition to that, our assessments for listed species are becoming more and more spatially and temporally explicit, which means that we are able to look at a use limitation and narrow it down geographically and on a time line to those times and that geography when it really is a concern for the listed species.

I think I've spoken to you about this before, but our overall implementation approach is to address listed species issues during the course of our normal registration -- I use that term broadly -- activity, which includes registration, what's remaining of the reregistration program and then registration review program, which Debbie spoke with you about this morning.

As a reminder -- those of you who are new may not have seen this, but those of you who have been on this committee for a while have seen this graphic and it's just a graphic to demonstrate that through 2008, there are really going to be three major processes running, all of those that I mentioned. At 2008, the reregistration program will be winding down and we'll still have the registration program and registration review program where we're taking actions on pesticides and where we will need to be looking at endangered species issues.

The little line at the bottom called Species Specific unusual circumstances process is a process that would run parallel to those others. We were trying not to run parallel processes because it's not real

efficient, but there may be situations in which we need to take something out of that normal registration or reregistration or registration review queue and look at listed species issues outside those standard processes. Some examples of this would be chemicals that, as a result of litigation, the Court has told us we have to look at on a particular time line or if we're just going about our business and some information comes to light that shows something we thought perhaps was not a problem turns out to be a significant problem, we could take something out of queue to look at that issue.

The process that we're going to be doing these assessments by is articulated in a document that we shorthand call the overview document. I think the name is Overview of Ecological Risk Assessments for Endangered and Threatened Species or something like that. But it's the overview document. And this document was discussed -- and I'm sure a lot of you were there -- at a public workshop back in 2004 and it was an all-day workshop that basically walked through all the steps in our risk assessment process.

Again, in October of that year, we took

metolachlor, which we've been working on at the time, and had another public workshop, went over the same risk assessment process with the public, but used metolachlor as kind of a case study and showed how the generic aspects of the overview document actually applied in real terms to a real chemical.

Our assessments are consistent with the processes and the scientific methodology outlined in the overview document, and as a result of that, the services, after a lot of time looking at that document and having discussions with us about our methodology, deemed that if we follow this overview document, the results would be consistent with results they would anticipate they would get were they doing the assessment for listed species effects.

The overview document really outlines the methodology for two levels of assessment and we call those baseline assessment and the species specific assessment, and I want to just talk about those a second.

The baseline assessment, which is what you all have seen if you've looked, like over the past year and a half, two years, at assessments that have been issued for

public comment from the reregistration program. Look at the toxicity and fate of the chemical. It calculates pretty conservative estimates of environmental concentration using models that don't get you that spatial and temporal aspect that I spoke of before. And it provides a pretty coarse spatial analysis.

The species specific assessment builds on the baseline assessment, and rather than identifying (inaudible) of concern, so rather than birds or fish, it would identify individual species of concern, so a particular bird or a particular fish that's on the threatened and endangered species list.

This assessment, too, is based on the toxicity and fate of the chemical, but employs refined estimates of environmental concentration and refined spatial and temporal analysis based on specific species information and a variety of other factors, including particularly where the crop is grown, how the pesticide is used on that particular crop and things like that.

When we were developing the overview document and having discussions with the services about our processes, there were a couple of areas in which we

included enhancements over what we had been doing prior to the overview document. One of those -- and these apply to both the baseline and the species specific assessment. We articulated in this document that we would not only look at direct effects to the species, but we would look at indirect effects. So, we would look at effects to things other than the species that may impact the survivability of the species itself.

Again, in using best available data, the overview document articulates that we will not only use data that's provided us for the purposes of registering a chemical, but we'll also use scientific literature and the methodology for us obtaining that literature is through ECOTOX, which is a search engine maintained by our Office of Research and Development. ECOTOX is available to the public online. You can search it for different types of information, and one of the big enhancements that we're doing for our assessments is we're not only using what's online, but we also, for each assessment, are coordinating with our Office of Research and Development, and they're going back through all of the files they have of public literature that they have

not yet reviewed and coded and put online for the public, doing that review for us and providing us that literature as well. So, it's a pretty broad base of public literature.

MR. BRADBURY: Right here I'll jump in and see if I can capture a couple of the questions that came up about registration review. There was a question about making sure we were taking a look at not only registrant submitted data, but also information published, the (inaudible) literature and the ECOTOX search engine is the process by which we're scouring the public literature to include that information with the registrant information, as already mentioned.

It's our intention, maybe not with the first few chemicals going into registration review, but once we get fully ramped up, that when we open the docket, we would not only be summarizing the information that was submitted to the registration process by the registrant, but also the information that we're seeing from the ECOTOX search engine, so that the public could see all of the information that we have in front of us, and this would be a way just to double check one more time that

there isn't a paper that we're missing or maybe a paper that published a couple of months after the last time the search engine went through the open literature and just to make sure people know what we've got. If there's anything we're missing, to get that in.

Some of the first dockets, we may not have had time to quite get this organized with ORD, so we're capturing what's in the online version and then we'd be catching up over time with other information that would be in there.

The question about the IMS and the information that did come to bear there or there was a question about water monitoring and other kinds of information, I think I'll just jump in here and Arty will give you some more specifics about some of those kinds of information. But there are hopes that when the docket is open and people are sort of -- are taking a look at this problem formulation and sort of seeing how the risk assessment for this baseline level is sort of shaping up, to the extent groups or individuals have more site-specific (inaudible) the explicit information about where the crop is, how the product's used, when it's used, what

application methods are used with that product, when that docket's open, that would be a perfect time for that information to come into the agency because then we'd like to be able to start with all the information that people think is out there that's relevant to tackle the risk assessment and the effects of (inaudible) because it will be more efficient and more effective to start with the information that's out there rather than try to play catchup over time.

So, for example, the IMS information, when that docket's opening, it would be a perfect time for that information to be made available. So, why don't I turn it back over to Arty. But we can come back around on those concepts again when we wrap up.

MS. WILLIAMS: Thanks. Finally, in terms of the baseline and species specific assessments, one of the things that we have agreed to do and have been consistently doing, and also will be doing with these -- I don't know if we used the term this morning, the snapshot documents or reregistration within the docket -- is to provide a really clear explanation of why we have rejected certain public literature in terms of not using

it, but also just basically providing more transparency and better explanation of any gaps in our assessments.

In addition to all of those for the species specific assessments, there were a couple other enhancements. One is that the action area, which is the area that we believe there could be effects to a listed species, years ago, included only an area where direct effects may occur. The action area now is including the area where both direct and indirect effects could occur.

Additionally, in terms of critical habitat, we traditionally have looked at potential effects to critical habitat as a habitat. But in the listings that the services do, they actually publish Federal Register notices to designate critical habitats. They also indicate in there something called principle constituent elements, which are very specific aspects of the geographic habitat that they believe are critical to the survival of the species.

So, for example, if you were talking about an aquatic species that required water with a certain flow rate through shallow streams, that would be a principal constituent element, would that be that flow rate of the

stream.

So, in addition to the geography, the critical habitat, we're also evaluating whether the pesticide has any potential implications to each of these principal constituent elements that kind of make up why that habitat is critical to the species. And, again, I think I just mentioned this, but all of our assessments are containing more robust explanations of any uncertainties in our assessments, so the public can see where we've made conclusions, whether those are based on the actual data that we have or whether they're based on assumptions that we've been forced to make because data don't exist or methodologies don't exist.

In terms of applying the processes and methodologies in the overview document, since it was issued in, I think it was early 2004, we've begun to incorporate that into our assessments. Assessments that were started long before then, but issued after that time, you probably would not see application of the methodology in the overview documents. But those that were started around that time, around the first of 2004, we began to incorporate these methodologies, and we've

used them in those assessments that we've done for both registration and reregistration.

But I do want to point out that probably what you're going to see most of right now is that baseline part of the assessment. I said there were two parts, the baseline and the species specific. For registration and reregistration chemicals that were started around that time and issued in the last year, year and a half, you probably are likely to see work up to the species specific assessment, maybe a little bit into that, but not completely through that whole process.

So, a lot of those will say, here's a taxa (phonetic) that's of concern, we've identified the species that are in that taxa that may be affected, but the assessment stops at that point. Those should, also, articulate that we recognize we have further work to do and (inaudible) to do that work.

We've also applied the principles and methodology in the overview document in terms of a couple of informal consultations that we're engaged in right now with the Fish and Wildlife Service and National Marine Fishery Service. These are on the chemicals, Aldicarb,

Carbofuran and nine active ingredients, which I can never remember all the names of, used in rodenticides. We have -- we did some time ago write to the services requesting an informal consultation on each of these chemicals for purposes of technical assistance and they are actually part of our work group to look at these chemicals and help us assess the potential impacts of these.

And then, finally, the overview document is being applied to litigation driven assessments as well.

I want to kind of just point out the litigation driven assessments that we're working on currently. There are currently 21 species we're assessing the effects -- this is a bad sentence -- to of atrazine. Let me try that again. We are assessing atrazine as it has potential effects to 21 listed species in three, four different geographic areas of the country. We've completed the first area, which was the Chesapeake Bay and the Alabama River, and that assessment is online. And, again, I point that out because if you wanted to see one of these that completely goes through the endangered species specific process, those are some good models to look at.

We also are applying the principles and methodologies of the overview document to the review of atrazine, metolachlor, simazine, carbaryl, diazinon and prometon relative to their potential effects to a species down in Texas, the Barton Springs salamander.

We are beginning the process of reviewing the potential effects to the California red-legged frog from the use of products containing any of 66 pesticide active ingredients. And for those chemicals that we assess relative to Pacific Northwest salmonids several years ago and for which we're currently in consultation. During that consultation process, the services and we are discussing how to incorporate some of the newer methodology and the new way of viewing assessments into those consultations. I think we have one of those lines as well for metolachlor.

Outside the overview document, some other program enhancements that we've been working on are listed there on this slide, and let me just explain what a couple of those are. With our Office of Environmental Information, we are working on a project to establish a geospatial data warehouse which is a fancy name for a

central location where we can store and access not only GIS, geographic information system data layers that we develop during our assessments, but that other offices in the agency may be developing for other purposes, that are available nationwide.

So, for example, it would be a place where if we worked with the services for them to identify for us on a map in GIS the critical habitat of the species. We could store this information in this geospatial data warehouse, and if we needed to access it, it would be readily available in a form that we can use and overlay with other information, such as where water bodies are, where there might be environments that are particularly sensitive to the pesticide, where groups are grown or use patterns occur, and it will tremendously, as this warehouse gets populated, heat up our ability to kind of do a coarse assessment of where all the geographic things meet up and causes the problems. So, it's going to be a pretty big time saver for us once it's established and populated.

We're also working on some data extraction tools which are tools that allow our modelers to access

information that they currently access, but in a way that when they access it, they then don't have to do anything to it before they can plug it into the model. So, again, it's a time saving tool for us.

We're working on some automated watershed delineation work which includes the ability to automatically delineate on a map not only watersheds but -- I don't know if this is the right term -- but sub-watersheds, kind of little watersheds within watersheds.

We are building internal to the Office of Pesticide Programs, what we're calling an endangered species information repository. When I mentioned that we were currently looking at aldicarb and carbofuran and eight rodenticides, one of the kind of common things among all of those pesticides, if there is one, is that they have very broad use geographically, and as a result, have the potential to intersect geographically with a lot of different species. And as we go through those and get information on these species, we want some way to capture that information so that when another chemical is being assessed that has the potential to impact that species, we don't have to go out and do that species research

again.

We've been discussing with the services whether they have databases already like this because we certainly don't want to duplicate, but it doesn't appear that things like GIS layers for critical habitat or species location or things like what the breathing cycle is of species are captured nationally anywhere, but held in regional and field offices. So, we're in a position where we're having to communicate with those field level people to get this information and, again, once we do that, we want to capture it somewhere so that the next time we have to look at that species, we don't have to recreate that whole process again.

And then, finally, we are putting in place internal tracking systems which may not seem like a program enhancement, but from our perspective it is. If we've looked at a pesticide and then, for some reason, two years from now we have to touch that pesticide again for some reason, we want to know -- we want to be able to readily see what it is we've assessed so that, again, we don't recreate any information that we don't need to. Maybe that a new use comes online and this system will

allow us to go back and say, well, the geography of this use precisely overlaps with the geography we looked at for this other crop, you know, two years ago. So, we've got a base to start from. We don't have to start from scratch.

I want to talk just a second about the counterpart regulations. I think all of you know that the services issued counterpart regulations relative to our regulatory program for pesticides, and these regulations contain optional alternative consultation processes for us to use and use of those processes was dependent on two factors. The first is that effect determinations made by our office to determine whether or not a particular pesticide has the potential to harm a species had to be signed off on or done by people who had been trained by the services to do this and certified able to do this.

The second factor is that risk assessments being conducted had to be conducted consistent with the overview document. This regulation, I think, had the potential again to save a lot of resources and time and actually in the long run put us in a position -- us, the

Federal Government -- of being able to provide protection to listed species sooner because we didn't get ourselves hung up on multiple processes.

But this regulation was challenged some time ago. I don't recall the year of the challenge, but the case was just decided recently, and the judge in this case determined that there were some flaws in that regulation. That court decision has been appealed by both the Federal Government and my understanding is the industry interveners in that case as well.

I want to explain a little bit what the implications of all of this are. Under the standard service regulations, the regulations that have been in place for years, if an agency -- or if we found that there was no effect to a listed species, we were done, we didn't have to do any further assessment. If we found that the pesticide was not likely to adversely affect the species, we had to engage in informal consultation, which is consultation where we ask the services to concur or non-concur with that determination.

If they non-concur or if we determine that the pesticide was likely to adversely affect the species, we

had to engage them in formal consultation. The result of that process is the issuance of a biological opinion by them that indicates their assessment of the potential impact of the pesticide to the species and recommends procedures to reduce the potential risks.

Finally, under the standard consultation regulations, Section 18s are viewed as any other agency action. It had to go through all of these consultation processes as appropriate.

Under the counterpart regulations, the first change that was made was rather than engaging in informal consultation for not likely to adversely affect determinations, those regulations said that if we conducted our assessments based on those two criteria I mentioned, that no further consultation was needed on these actions. We could just move forward with any risk mitigation that was appropriate.

The second big change that the consultation counterpart regulations made was that it indicated that Section 18s under our statute could be viewed as emergency for purposes of consultation under the Endangered Species Act, which would put us in a position

to actually allow a Section 18 use to go forward and consult as soon after that as possible rather than doing all the consultation work prior to the 18.

The court decision basically took away our ability to forego further consultation for not likely to adversely affect. And in terms of Section 18s, it said that Section 18s sometimes could be viewed as emergencies under the ESA if they met the very specific description of emergencies under the ESA. So, basically for like public health emergencies, those would still be permissible.

I guess I wanted to show you that because really it kind of puts us almost where we were 10 years ago when we were trying to implement this program save for being able to use the emergency consultation provision occasionally for Section 18s. So, there was a couple of years to kind of come full circle.

The final area I want to touch on is field implementation. Everything we've been talking about is kind of implementation of our program, and by field implementation, I mean the part of the program that's the process of effecting change actually out in the real

world among pesticide users.

There are four components of field implementation that we kind of keep track of at OPP and those are education, creation, execution -- which is a really bad term to use, but execution, and enforcement. I want to make it clear that field implementation takes place once we've done our assessment, we've decided there needs to be mitigation and we've identified that mitigation. There are several opportunities, and I hope Debbie mentioned some of those this morning, during registration review where people have the opportunity to have input into the mitigation and how we've identified the risks. This is after that. So, you're not going to see a lot of public opportunity in this process.

In terms of education and training, we're starting that process by holding a workshop actually next week, Wednesday and Thursday. It's a regulatory partners workshop. It's not a public workshop. And it's to work with our state and regional regulatory partners to develop information that they can use and to carry on training for applicators -- certified applicators and the public.

We're going to be looking at four specific areas at this workshop. The first is, again, kind of basic educational and outreach materials. We've got some fact sheets we want them to help us finalize, a canned PowerPoint presentation that we're hoping to finish development of at this workshop that they can use then to go educate other people about the program.

The second area we're going to be focusing on at this workshop is Section 18 guidance. For Section 18, states have been requested to demonstrate -- let me see if I can get this right -- demonstrate that they have made a credible effort to identify and address listed species issues when they submit their Section 18 requests. There's not a real good description of what that means at this point. So, one of the things that we're going to do is share with them a draft of what we believe it ought to mean, see what implications that has for them, see if we can even make it stronger, if that's appropriate, and hopefully come out of this workshop with a really good draft of what that credible effort is.

We also are going to be demonstrating for them the web-based system where the public can access

bulletins. We'll be showing them how we are going to be creating bulletins and how this system will be of value to them in enforcement. And then we're also going to be discussing enforcement, specifically what their role is, what the Office of Enforcement Compliance expectations are of them enforcing these limitations once they get out in the field.

This, again, is kind of our first step to educate them so they can start educating and training other people, but we're certainly open to other opportunities to work not only with our regulatory partners, but the public in general, if that's appropriate, to provide further information to the public.

The second area, creation, this is actually the creation of the bulletins which will articulate the limitations that we find necessary to protect the species. One of the things that we have done in our computer system that houses the bulletins is create kind of a back door to it that only EPA will be able to access, and we will be able to access it actually to create these bulletins. This back door has a lot of

information in it, including things like county lists, species lists, base maps, and what it allows us to do is basically create bulletins in real time. A lot of the elements from standardized pull-down menus to minimize errors, because I know every time I even type my name, I type it wrong. So, it will provide a really good way to ensure that we're being consistent in naming species and how we're describing chemicals and it will provide for real-time updates of the information.

The bulletins themselves employ some really nice cartography, which we think makes them a lot easier to understand than our attempts of the past. They will be very geographically specific and they'll contain text, as well as explain what the user has to do. This is one area where there will be some input after the decision is made that a limitation is needed. But, again, it's not input to that decision or to the specific limitation, but rather a review by the state, who can engage others if they choose, to make sure we haven't messed up their maps, to make sure that we've articulated the limitation in a way that's appropriate for the people in that locality, so we're not telling Virginians to identify

their township range and section because Virginians don't know what that means.

And, finally -- no, not finally, next to finally, execution of the bulletins. The way that these bulletins become effective is that the product of the label will contain a generic statement -- the label of the product will contain a generic statement that tells the users in addition to what's on the label, they have to comply with the information in the bulletin. This makes the bulletin information enforceable and administers provisions of FIFRA.

The bulletins will be accessible in two ways. The primary way we hope will be from this website that we're going to be launching in the near future. But we also will be providing a toll-free number that pesticide users or the public can call to obtain a bulletin if they don't have web access. We're also going to be providing an online tutorial that walks a potential user of the bulletin through every aspect of use of it, again, as part of our training of the public.

Now, finally, enforcement. I did mention that the bulletins -- the provisions in the bulletins are

enforceable under the misuse provisions of FIFRA. Because the bulletin is referenced on the label it essentially becomes like labeling and that is enforceable.

The bulletin system also is going to be providing access to our state regional regulatory partners to carry out enforcement activities. They'll have access through some sort of password-protected thing and what this will allow them to do is access bulletins that may no longer be valid, but for which they need to see what the valid bulletin was time wise for an enforcement action they may be taking where the action occurred in the past.

So, we think that success in launching this program and getting it out in the field can be measured in a couple of ways and these are the ways that internally we're going to determine whether or not we've been successful, whether we have the ability to come into full compliance with the ESA while continuing to make timely and scientifically sound regulatory decisions; the ability to work with stakeholders and partners throughout this process and make sure we're using best available

data and to make sure we're adequately characterizing the potential risks to listed species; to minimize the scope of limitations where we can while still providing the protection that the ESA calls for; and finally, to make an effective -- and it doesn't say it here -- but I consider that also to be easy transition for the pesticide user community from their current way of doing business to this business of having to look at bulletins to determine how to use the pesticide.

And with that, I will stop talking. Thank you very much for your attention.

MR. JONES: Questions, if anyone has comments? Caroline?

CAROLINE: Yeah, on the slides, on page 12, there's a bullet where you talk about atrazine, metolachlor, simazine, carbaryl, et cetera, in relationship to the salamander in Barton Springs.

MS. WILLIAMS: Yes.

CAROLINE: So, how do you deal with cumulative impacts in this context?

MS. WILLIAMS: We are not trying, at this point, to look at cumulative effects of pesticides in the

environment for listed species or anything else. Maybe Steve can speak to this better, but my sense is, you know, we recently have figured out and are pursuing looking at cumulative effects in terms of human health. I don't believe that we have the methodology to do that consistently for environmental cumulative effects in the sense that you're talking about, and I think that's the sense you're talking about, multiple pesticides in one place.

CAROLINE: Yeah.

MS. WILLIAMS: The Endangered Species Act does say that if we determine that a pesticide is likely to adversely affect a species, we do have to look at cumulative effects.

CAROLINE: Um-hum.

MS. WILLIAMS: But the definition of that in the ESA is very different from the traditional definition that we think of as cumulative effects. What ESA means by that is we have to look at the effects of our actions, which is that pesticide registration, in combination with other actions in that area that are not ours -- so, for example, if somebody were -- when we're doing our

assessment, we'd have to look on the ground and see, okay, somebody's building a parkway through here. They're damming this river, the forest is timbering next year. What's the cumulative effect on the species of the potential insult from the pesticide, plus the potential insult from all of these other non-federal activities going on? That's how the ESA defines cumulative effects, and we will be looking at that if we have a likely to adversely affect.

CAROLINE: Interesting, thanks.

MR. BRADBURY: Just to follow up a little bit on the other way we all use cumulative more in the context of the human health risk assessments and looking at mixtures of chemicals, that was an area of quite intense and good discussion with the services as we developed the overview document and we all thought through, how do you assess the mixtures of chemicals on aquatic life or wildlife? And that topic and a few other topics, we all agreed that sort of the state of the science is such that we don't really have an accepted scientific peer-reviewed methodology to tackle that. So, let's tackle aspects of the problem, let's make sure that we get the chemical

specific assessment nailed down properly, and if we get into the situation that Arty described with the other definition, we'll deal with that.

In the meantime, we're working with the services to establish a joint sort of effort to do research to try to build those tools that we'll all be using and to try to tackle some of these tough questions.

MR. JONES: Thanks. I was so engaged listening to the answer, I forgot my duty as moderator and I didn't see in which order the cards went up. So, I'm just going to start with Ray and go around this way. If subsequent cards come up, I'll take them after that. Sorry about that.

MR. McALLISTER: My notes are kind of disjointed, so I hope I find all my questions. On the slide that discussed the explanation of rejection of literature, do you have clearly established criteria, is there an SOP involved in that acceptance or rejection of the literature?

MS. WILLIAMS: No.

MR. BRADBURY: There's, again, two aspects for the word "rejection" in that slide. One of the important

parts of the Endangered Species Act goal is to collect best available information and sort of defining available information and defining best available through the two-step process. The first process is have you documented that you've reasonably captured all the information that could be out there and then what's the process you went through to zero in on the data you think is really relevant and appropriate for your effects determination or risk assessment?

One of the facets of using the ECOTOX search engine that we worked out with the services was to use what ORD calls a rejection group. In other words, if they look at a study and it's not clear what the dose was in the study, it's not clear how the study was actually done, they don't code it up and put it on the website for the public to look at. But they do keep track that they captured that paper in their literature search and they document why it wasn't put on the website.

So, in that context, we're ensuring that in the appendices of our effects determinations that we acknowledge that that paper existed and here's the rationale why we didn't use it as part of the best

available information to move forward. So, that's one aspect of the rejection term, ensuring that the service is understood, that everything that the search engine picked up we were aware of and what was the rationale for not even bringing it into the next step, I think what you're getting at, is what if there's a study and they've got some (inaudible) using some sort of (inaudible). How do you decide if that data is going to be used in a quantitative or qualitative fashion?

I think it's fair to say that any data that makes it through that first (inaudible) coarse rejection tool, that it's pretty unlikely -- it's very likely we're going to qualitatively try to bring together the information that we've got. But one of the first filters we're doing is taking a look at the effects information and maybe in a peer reviewed journal article and comparing that to the information that would be in the registrant's submitted data. If the registrant's submitted data indicates that the chemical may be more potent than what's peer reviewed, public literature is saying, they'll move with the registrant in that case or they may qualitatively describe this other body of

information or quantitative assessment with a focus on the registrant's data.

Now, if there's situations where there's open literature, which suggests that (inaudible) are maybe more potent than what was suggested with the registrant's data, then we're going to be going through some of the same basic kind of aspects that you go through in reviewing any high quality (inaudible) going back to ASTM, American Standards for Testing Materials were at the EPA and all the scientific communities worked on them, what are the attributes of a high quality wildlife study or aquatic toxicology and then you go to the peer-reviewed literature and the protocols and procedures that are used, which are pretty similar to what we use when we take a look at the registrant's submitted data and evaluate and test the quality of the study.

And we're working through some SOPs now and trying to get that streamlined and documented.

MR. McALLISTER: In the sources of data and the approaches that you've described, I didn't hear you mention -- and I may have overlooked it -- the large body of data that should be available on endangered species

(inaudible) from Fish and Wildlife Service, National Marine Fisheries Service. Do you have access to all of this? Is there any problems in utilizing it?

MS. WILLIAMS: That's a real good question. I didn't really touch on that. There's two -- let me talk about the two kinds of information, if I could, and one will be very, very quick, and that is where the services or the National Marine Fisheries Service, for example, might actually be doing research or a field study of some sort and they publish that. That actually would be captured in the ECOTOX because it's now public literature. But in terms of simply information about the species, you know, where the species is, how it behaves, what it eats, when it eats, whether it's dependent on some other species for its survival, you know, whether it has one food source, all of that kind of information that we look at to make our determination more spatially and temporally explicit, in many cases, is available from the services.

In new cases that we've worked on so far, is that easily accessible? Again, this is one of the areas where there doesn't seem to be a database of information

that we can access, but instead, we find ourselves going back and reading through, you know, ten Federal Register notices to find out what we can find out about the species. So, there's a lot of information there. It's accessible, but not from our need in a very user-friendly manner.

There's some information that we've tried to get on a couple of things that nobody has, not even the services. For example, one of the things that was key to an assessment we were doing was whether some particular plant species were wind-pollinated or insect-pollinated, and nobody knows. The world experts about these plants don't know how they're pollinated. So, I guess the answer to your question is yes and no and yes and no.

Did you want to add to that, Steve?

MR. BRADBURY: I was going to say part of the work with aldicarb and carbofuran with the services helping explore how they're storing and capturing information that will be useful or beneficial to all the parties.

MR. McALLISTER: One last question here. You showed the one slide with several assessments you've done

as the litigation driven assessments, and from the outsiders looking in, it appears that has completely dominated your efforts in endangered species assessment. How are you going to transition from the litigation dominated situations to being able to do nationwide endangered species assessment and registration review? You don't have a court telling you do this chemical in these counties or these two species, but you've got potentially an entire nation to look at for a dozen or more uses and all of the species that may be out there.

MR. BRADBURY: Correct. That is the challenge. And some of the tools and technology that Arty described is part of the solution. Part of the solution is being able to access information sufficiently and being confident with the information that's collected. And I think our experience thus far -- not to minimize the tough risk assessment challenges about a riparian zone and an effect on salmonids are scientifically challenging, but I'd say a pretty hefty amount of our time right now is spent collecting information. Once we have the information, we can start to very quickly zoom in on which parts of the country one needs to focus on.

Right now, the big challenge is getting information efficiently and effectively. So, my responsibility, to get back to the first part of your question, is to make sure we meet our quotas and deadlines and with timely registration review, and we'll do it. That's what we're setting ourselves to accomplish (inaudible).

MR. McALLISTER: I found one more. On the county bulletin system, we want to really applaud the innovation that that demonstrates. I think it has a lot of potential. We're looking forward to seeing how quickly you can get enforceable bulletins online. I'd just suggest that that approach may be applicable to other types of labeling information and regulation.

MR. JONES: Carol?

MS. RAMSAY: Arty can probably guess what my question is. She's heard a few times before. What are you looking at for time lines for implementation because I'm assuming that if you have a training session next week trying to work on some of the training materials, you're -- I'll let you answer that one first and then I'll follow up.

MS. WILLIAMS: Time lines for field implementation, which is --

MS. RAMSAY: Training implementation (inaudible).

MS. WILLIAMS: -- actually putting enforceable bulletins out on the street is really dependent on our time line for assessing chemicals. We don't have like 59 of them ready to go. When we complete an assessment that needs geographically specific use limitations, we'll develop the bulletin and put it online. But because it's kind of a new approach for pesticide users and the bulletin system will be up and running soon and people can go and access it and look at the tutorial when it's up and running, even if there are no limitations right off the bat.

We want to start the training now so that when people are talking to pesticide growers maybe in certification training or something like that, they can tell them about the website, you know, explain the program to them, tell them there's a tutorial, and then when we start getting this out in the field, people will be familiar with it. There won't be like mayhem and

panic in the streets.

MS. RAMSAY: I guess my follow-up on that is realizing that right now it's November of the year and for most of the northern tier states, our training agendas have already been set, they've already been approved by the State Departments of Agriculture for credit, and so, to bring new topics into those would be awkward for anything that was going to take place November, December, January and February, which are going to be your horticultural meetings, which are going to be your vegetable seed meetings, the lead association meeting just took place last week, the forestry meetings are taking place this week.

So, the window of opportunity for us to put those into the normal training system for 2007, unfortunately, is almost -- is behind us.

MS. WILLIAMS: Um-hum.

MS. RAMSAY: And so, I think, if we're looking at some sort of implementation that's going to occur in 2007, when we're going to try to get this out, we're going to have to look at some novel techniques to get it out to the rangeland communities, to the ranch

communities, to the user communities, the turf and ornamental. So, I think EPA, when they put together the training module, need to look at some train-the-trainer multipliers, work with APSE (phonetic), for example, to get the educators trained to where they can bring in county agents, to where people don't actually come to a room, but you can do a fair amount of internet communication type training, but we need that soon enough.

And then you also probably need to look at popular articles and farm journals and things like that for getting it out because chances are that this is going to start unfolding next spring when (inaudible) is not on the ground and people are in the field and they're not going to get it until the following year.

MS. WILLIAMS: So noted, and absolutely. We actually have a couple of extension coordinators who are going to be at the partners workshop because it is so heavily focused on training materials. And, again, the presentation that we're putting together probably would be a good basis from which to start discussions with APSE specifically for like certified applicator training, and

we'd be happy to engage APSE in a discussion like that and how we need to move this out to make sure it's effective.

But I understand your concerns. I appreciate your bringing them to my attention.

MR. JONES: John Schell and then Beth and Gary.

DR. SCHELL: First of all, Steve, I want to compliment you on acknowledging that there are no good ways to do cumulative risk assessments yet. We really need to do single chemical risk assessments well before we start branching off into the really complex cumulative risks. We're struggling with that on the human health side as well and it's very difficult to do. So, I'm glad you're, right now, trying to get the process worked out for the endangered species using a single chemical approach.

My question is going back to sort of the earlier one and it's the data that you're using, from what I understand, it's primarily the published scientific literature that's posted online that you would use, and there's also additional reports. But how do you know -- if it is additional reports, how do you know that you're

capturing all of the information that other federal agencies, state agencies and NGOs are reporting and even things like other risk assessments, like eco risk assessments that have been done? Is there a way of going through that? And if you do, how do you do the peer review on that, on all of those varied reports coming from a whole bunch of different sources?

MR. BRADBURY: Okay, so let me go through --

DR. SCHELL: Yeah, I just -- you don't have to worry about --

MR. BRADBURY: I'll get -- I just want to start with -- the first comment is that, you know, the core set of information that we're going to be looking at is the information submitted by the registrant through the pest guidelines and just related to Part 158 information. So, that's sort -- that's the core, that's the kernel of information that we first get our heads around.

The Endangered Species Act is saying, good, use that information, by all means, that's part of the best available information. But let's make sure that we've done a reasonable effort to see if there's anything else out there that may pertain to the way you're looking at

or influence the way you're looking at the potential risks of the compounds and using the search engine to take a look at what else is available in addition to what the registrants have submitted.

Now, the search engine itself, and it's on the website, www.epa.gov/ecotox, if we go there you can see in gory detail all the SOPs and all the (inaudible) processes used in that search engine. And some of your questions are related to the strategy that that search engine uses. It not only is accessing papers published in scientific journals, it's also accessing federal reports, the gray literature, if you will. So, it's scouring all the gray literature in terms of federal reports, in terms of state reports. It's also -- we're also (inaudible) the EPA with OECD, so we're accessing information that's being published elsewhere in the world in many OECD member countries that put their data into this database. So, we also have (inaudible) for that kind of information.

Part of their search strategy also includes literature review articles or the dossiers on a risk assessment for a chemical or a group of chemicals.

Now, the database, itself, doesn't store secondary information. It will only code and store primary information. But it uses literature reviews, it uses risk assessments and other publications, and goes to those bibliographic sections and double checks to see if the computer activity that's been going through the literature has missed anything that may be in some of those citations.

So, in working with the services and then playing around with some of the techniques they use, everyone was comfortable that this approach is capturing best available information. The Endangered Species Act doesn't say that you haven't gotten best available information if there's one paper that slips through your fingers. Its point is, have you made a reasonable effort to try to capture the preponderance of information. And when we do registration review and open the dockets and say here's what we know, here's the information that we've seen through this ECOTOX search engine, is there anything out there that we may have missed? And that will be one more way we can just make sure that they're aware of everything that's out there.

MR. JONES: Beth?

DR. CARROLL: I'd like to thank you for all the work you've done. It's a tremendous amount of change since 2004. And I'd like to follow up on Ray's question about the information that the services have. I'm still unclear -- so, you have this information and it's not user-friendly. Is there anything being done about that? Is that where your data extraction tools come in or is that something the services need to be doing for you?

MS. WILLIAMS: The data extraction tool is more a tool, for example, to go into 30 years of national weather data and pluck out the right data for a location and put it in the right format for us to use in a model. So, starting at the back of your question, no, that's not what that's for.

We are, again, in our own work, trying to capture information as we get it and put it in a way that we can then later access and will be user-friendly in the endangered species information repository that I mentioned. We have begun the discussion with the services about tools that are available at the services and at EPA that we might be able to build on and gain

some efficiency from. But the fact of the matter is, to the best of my knowledge, the kinds of information that we need to look at just because of the different approaches of the agency and different focuses is not kept on a national level at the services, but rather out in field offices where the species actually exist.

I don't know if there's a move to consolidate all that at this point. I know there is an effort underway to map critical habitat, which will be of help to us on a nationwide basis. But in terms of other efforts underway at the services right now, I'm not familiar with any at this point.

MR. BRADBURY: And a quick follow-up, in developing the overview document and working through the methodologies, we talk about cumulative effects in the context of mixtures of chemicals as a future need, something to work on. This question was also identified as a -- Arty said a tool. That future activity where the services are realizing that's something they're trying to work on to help their efficiencies as well so they have a knowledge base that they can access with this information.

So, we're beginning to have a dialogue on how we can work together to create that kind of infrastructure.

DR. CARROLL: I think it goes back to Jim's question as to how can PPDC be engaged in this process and maybe this is something where we could have some impact on moving the services or whoever needs to be doing this to get the information pulled together so it's in a usable form.

And I just have a follow-up. I'm still a little confused on the IMS data. I'm actually a little concerned that it's not in here. Are you going to use the IMS data prior to opening the docket? It sounded to me like, Steve, when you answered that before, that would be something that would be submitted after the docket was opened.

MR. BRADBURY: No, I would -- in my opinion, if you wanted it provided before the docket opened, as you see the schedule, that would be fine. As we talked about with the water quality monitoring data yesterday, our goal would be to the extent possible to get that information. If the states are willing -- are able to provide it before the docket opens, then that can be

built into the problem formulation that we'd be doing and making that available to the public for comment. So, in that context, in theory, it would be nice to see whatever information -- IMS is an information management system which some of the registrants are putting together to better understand co-location of crops, where the pesticides will be used and where the habitat of a species may be.

Yeah, I think to the extent some of that information can be available before the docket opens, that could help focus the problem formulation and help with other public comments and input (inaudible) helpful.

MS. WILLIAMS: Could I add to that? You still look like you have a puzzled look on your face. Let me add to that something.

DR. CARROLL: Sure.

MS. WILLIAMS: One -- for those of you who don't know, this information management system contains information from the ag census in terms of location of where crops are and ultimately will provide access to -- what's it called -- nature serve information on where species are actually located on the ground, not in terms

of county or sub-county, but actual location. Like I saw it here on the corner of this table.

Once all of that information is populated into the system, we're viewing the system as one where we could do kind of a second screen. Our first screen is, is the county and the crop anywhere near each other? This -- I mean, the county and the species -- the crop and the species anywhere near each other. What this would allow us to do is do kind of a second screen which is to say, okay, with this refined species information, is the species anywhere near where the crop is grown, not at a county scale, but at a much finer scale.

And we intend to employ that internally in our assessment process, but we aren't doing that currently because our understanding is that the entire nature serve data set is not integrated into the IMS yet. I think there's a meeting of the group that's working on that in early December and we'll see what the status is then. But once the location information is in there, we'll be using it as a second screen and you will be seeing, in the docket information that we put out, that we have accessed that to kind of do a second level screen of

where the species and the use might be.

DR. CARROLL: Yeah, and there's a method to my madness. I'm kind of curious as to when the docket opens, will you have a fair idea of what kind of DCIs need to be issuing?

MR. JONES: Beth, that's going to be one of the things that in this work group -- we think we will, but we're going to sort of work with all of you through sort of how we come to our conclusion and we're going to take comment on it as well.

DR. CARROLL: Okay. And then just a couple other comments. I would like to encourage you to make guidance on your criteria for either acceptance or rejection, whatever you want to call it, available to the registrants. It's something that we really need.

And I would just ask the question of, since the overview document has been in existence since 2004, a lot of changes -- I mean, a lot of work has gone into this and I wonder if it needs an update.

MR. BRADBURY: My opinion, no. I think it still reflects --

MR. JONES: That's a good answer, Steve.

MR. BRADBURY: I think it still reflects the best available scientific methods and techniques to do these kinds of risk assessments. As I mentioned, though, before, we all know that science marches on and we all -- parts of EPA and the services want to make sure that science continues to march on. So, having said that doesn't mean in a different venue we aren't assertive and good partners in trying to advance scientific techniques. But in another version the overview document (inaudible) those techniques (inaudible).

But I'd say in my opinion we have the best available scientific methods and methodology used for the procedures used here.

MR. JONES: Gary?

MR. LIBMAN: My question is on the Section 18s. I may have missed some nuances there, but it seems like I guess a doughnut hole. How much of a problem has that been on the Section 18s? You say that the states have to demonstrate that they've done some analysis and ID'ed listed species and so on. But is there a federal follow-up even after the Section 18 is issued and can you then reverse a Section 18 decision?

MS. WILLIAMS: Well, you know, Section 18 is so short-lived that by the time we were done there would be nothing to reverse. The use would be over with. They're generally very time-limited for -- there for a season at most and the applications usually take place, you know, based on certain criteria in the 18. For example, it may be a Section 18 for a use on an insect and the Section 18 request is if the insect populations reach this level, we're going to need to use this, and they use it and then it's over with. They don't use it again. So, in terms of that, I guess the answer is no because they are so short-lived.

Here goes my job. Technically, any 18 that we issue should go through the full endangered species risk assessment process. We have 50 days to look at Section 18. Under FIFRA, we have to balance that (inaudible). So, it's a real conundrum for 18s and the thing that makes it so difficult is that 50-day window. I don't think there's a person in this room who could do an adequate species risk assessment in 50 days.

So, what we're trying to do is get the states to provide us with what coarse information they can provide

us. It may be, for example, that they're willing to limit the use to a certain geography to just completely avoid a species, and see what we can come up with to try and protect species in the face of these agricultural emergencies that we determined are true agricultural emergencies.

I don't know if that answered your question.

MR. LIBMAN: No, it does answer it. The only thing is that some Section 18s do last more than one season, so you'd get a chance for the second year.

MS. WILLIAMS: (Inaudible) if they reapply. Right, right, and the theory --

MR. JONES: The 18, itself, is for a year, but it may be issued --

MS. WILLIAMS: Two years in a row.

MR. JONES: Exactly.

MS. WILLIAMS: Right, right. The theory behind how we were going to operate when we had the ability to move forward with the 18 and then consult afterwards under the counterpart reg would have addressed that precisely. What our intent was was to do what we could for the 18. If we didn't get it completed, to continue

that so that should it come back the next year, we would be prepared with an assessment relative to endangered species.

But because the counterpart regs are no longer valid in that context, we are supposed to do the entire assessment for any 18s issued.

MR. JONES: Melody? I got it under control now. I got the order down.

DR. KAWAMOTO: Okay, thank you very much. I really appreciated your recognition of the need to clarify definitions and assumptions because I find that that's the problem that I encounter a lot, especially when you're dealing with multiple stakeholders, especially diverse multiple stakeholders. I also really appreciate your approach to assessing the impacts on endangered species and I feel that this can really be relevant to other populations and with regard to human populations. I'm particularly concerned about workers.

What I really like about your approach is the recognition of the variability related to space and time within micro-environments. I think that recognizing these multiple factors are really important because

that's something that we recognize within the workplace and we call them worksite specific micro-environments. So, as Ray McAllister had said, you know, what you've done, I think can be applied to some of the other areas of OPP.

I would like to clarify one thing because I keep seeing over and over again, even with worker protection, that there seems to be a reliance on education and training. So, my assumption was that you were really meaning that the target audience would be the applicators, is that true?

MS. WILLIAMS: For the education and training?

DR. KAWAMOTO: Right.

MS. WILLIAMS: Yes, ma'am. We, actually, for this program are going to be relying on the fact that the limitations are enforceable use limitations.

DR. KAWAMOTO: The education and training, we are hopeful will put growers and pesticide users in a position to understand that they have those obligations, how to access the information and how to comply with it. The training, yes, is targeted to pesticide users, not just agriculture, however, because I will point out that

this program knows none of those bounds.

DR. KAWAMOTO: Right, right.

MS. WILLIAMS: If it's an outdoor pesticide and it has the potential to harm a species, the user should be following a bulletin if there is one.

DR. KAWAMOTO: Right. I do have a concern about that because it seems that this puts a tremendous burden on the applicator or the user which basically, in most cases, means that they're workers. And there's -- I guess yesterday, particularly Kevin Keaney had or somebody had put up all the different expectations that we have from the label and also from training, and sometimes -- I mean, when you started talking about that, I was thinking, well, maybe all applicators and users should be Ph.D.s or something like that.

And so, actually, I'm going kind of beyond the box in saying, has EPA been thinking about ways to educate and train people before they become applicators and users? And I'm really talking about K through 12 education. And, you know, what kinds of things should children be learning while they're going through school that would serve them in the future? And it's not just

OPP, it's really all of EPA and actually all of occupational safety and health, too. And what kind of tools should they -- knowledge and tools should they have before they graduate from high school, before they enter the workplace that would really end up protecting our environment?

So, I just want to open that up because I feel that there is a tremendous reliance on education and training of the workers and really the burden should either be eased by starting them off earlier rather than having to expect them to know all of this that sometimes we have trouble figuring out or understanding.

MS. WILLIAMS: Um-hum. Just real briefly, Melody, we do actually have a number of efforts underway that are aimed at those sort of K through 12. Probably the best example I've got are some of our IPM in school programs where within a local school district, for example, the goal would be for the school district to actually adopt IPM techniques for pest management in all of their buildings. But one of the ways you go about doing that is actually through the education and engagement of the kids who go to school there. So,

you're both improving the quality of their school environment and you're reducing costs to the school district. The schools that have done this successfully have documented big reductions in maintenance costs associated with pest control and you're also teaching kids basic, I would say, IPM skills about how to decide, do you have a pest? If you do have a pest, what are your choices for dealing with it and how to select approaches that actually are more sustainable. So, that would be an example.

DR. KAWAMOTO: I think that's great, but I think it should be integrated more into like the sciences so that they understand all of the different things that's going into it, because an IPM leaves me thinking, well, you know, what is the chemical that's used for (inaudible) or can we have other alternatives? It's not just chemicals, it's biology and impact and, you know, in this case, it could be an economic impact as well.

MR. JONES: Thanks. Michael and then Joe.

MICHAEL: I want to follow up some on Carol's question and that is for the time lines on these things. It's my understanding from the February workshop that we

had six months ago, seven months ago, that individual chemicals will be incorporated into this process during their registration review, and that is a 15-year process. So, the endangered species protection won't be completed until 2022.

Now, there are two elements that really need to be done here. One, when you do the registration review, is that the time that the label is updated or is the label updated prior to that? And because someone uses the chemical, if there's no notification on the label, they won't know where to look at the website. But there's, I think, a real problem built into the website, and that is, that if there are a large number of chemicals that can be applied to a county, but the county information is not updated for those chemicals, an applicator can go to the website and look at the county and find no information for restrictions of use of the chemicals until like -- presumably until 2022.

So, you're actually -- are you, in fact, reducing the protection for endangered species until this whole system gets completed?

MS. WILLIAMS: Let me answer part of that and

then I'll let Steve answer the other part of that. Whether we were putting limitations in place via a website or via specific information on the pesticide label, which is how we have to regulate pesticides, the timing I don't think would be any different. We aren't going to be requiring limitations until we've done an assessment for a chemical that leads us to the conclusion that a limitation on use is needed and what that limitation is and where it is.

What the bulletin system allows us to do, as opposed to putting specific mitigation measures on the product label is a couple of things. It allows us to update that more quickly. If we review another pesticide or if we get new information about the species or the toxicity of the chemical, we can very quickly update the web-based system.

The other thing it allows us to do is be far more specific in terms of the limitations on the use of the pesticide. I mean, frankly, pesticide labels are running out of room, and if we've got a pesticide that has limitations in 50 different geographic locations probably the absolute outside we could do on a pesticide

label would be to say this has limitations in these 50 areas. There's no way we could describe the habitat around which it's limited. We couldn't provide information about the species being protected. There just isn't room. So, that's another advantage that we see, anyway, of going with the web-based system.

So, in terms of the overall 15-year schedule, I don't know if you all want to comment on that or not.

MR. JONES: I think that it is what it is. It's like we couldn't get in to compliance with FQPA nor does that (inaudible) require us to the day after the law was passed, we're not going to get into compliance with ESA like that. There's a thousand active ingredients. We can't possibly do them all at the same time. Maybe if we go 800,000 FTE we could figure that out, but we don't.

MICHAEL: And I do --

MR. JONES: And I'm going to have to move this along. We are very time-constrained here.

MICHAEL: I just wanted to say I do appreciate that you're taking specific classes first in the reregistration review, carbamates, OPs and pyrethroids. So, you may eliminate a lot of these problems earlier on,

but still, I still see a problem with the REDs (inaudible).

MR. JONES: Okay. There will be plenty of opportunity for that kind of specific -- around specific chemicals for those observations to be brought to bear.

Okay, Joe and Matthew and then we'll wrap this session up.

MR. CONLON: First of all, I'd like to, on behalf of the American Mosquito Control Association, commend you on a job well done. It's an extraordinarily difficult problem to address.

My question is, to what extent are these county bulletins going to be usage specific? And I'm asking that because, at least in mosquito control, what's done with one chemical, even according to the label specs down in Florida, could be totally different from what is being done in red-legged frog territory in California. So, how specific is that going to get?

MS. WILLIAMS: Let me make sure I'm understanding your question, because I always get my terminology, use and usage, confused. Are we talking about in Florida it's used for mosquito abatement and in

California it's used for a different use or --

MR. CONLON: Negative. Both the same except the parameters of application are different.

MS. WILLIAMS: Used differently for the same use. That's a real good question. We have to regulate for endangered species based on what's on the label, how it could be used. So, let me just give you a hypothetical.

For mosquito abatement, the product is registered to be used at -- give me a rate. I don't even know how you talk about those rates.

MR. CONLON: About an ounce per acre.

MS. WILLIAMS: An ounce per acre, okay. And that's the maximum rate on the label for that, and an ounce per acre we decide is a problem, we're going to have to limit the use in a particular geographic area. You call me up on the phone and you say, but in Florida, we never use it at that rate, we use at a half an ounce an acre, and we'd look at that and we'd say, okay, half an ounce an acre is not a problem.

We have the ability to do two things in that instance. It's not geographic, but we could go back to

the registrant and say, you know, if the maximum anybody needs is a half an ounce an acre, why don't you change your label and we're golden, there's no problem at half an ounce an acre.

If they go, no, because in California, they really need it at a full ounce an acre, what we could do through the bulletin is say, if you're using this product at more than half an ounce an acre, then these limitations apply. So, we can address it. It wouldn't be geographic specific, but it would be use specific.

MR. CONLON: Thank you.

MR. JONES: All right, Matthew, last question.

DR. KEIFER: I just wanted to make a point that I felt doesn't relate specifically to this topic, it relates to the previous discussion and I'll try and make it quickly. But I felt there was -- we had not come to a conclusion on that. I would like to make -- I would like to state that the PPDC should make a formal recommendation to the Environmental Protection Agency to pursue the development of diagnostic and biomonitoring tools related to the discussion we had before. And I'd like to make it a formal statement so that we keep it on

the table. And these will assist in the assessment of exposed individuals and populations, and the tools should extend to the diagnosis of acute and chronic effect and the biomonitoring of workers who have exposure.

In addition, the EPA should actively support the delivery of these tools into the hands of clinicians, researchers and public health professionals. I would like to make that as a formal recommendation for the PPDC to consider to endorse.

MR. JONES: Well, I'll do what I did yesterday, does anybody want to second that?

(No response.)

MR. JONES: They're not quite prepared to endorse that. So, perhaps we'll have more dialogue around that later. I think actually I know one place we'll have more dialogue on that and that is when we get into the registration review work group, that specific issue can be something that we talk about when we're looking at a specific chemical. There may be others for us to have that further dialogue as well.

UNIDENTIFIED FEMALE: Can I propose then that we keep that on the next agenda to have some kind of an

update at that point and maybe get into that discussion?

MR. JONES: You can propose that. What I think I'm inclined to do is to see how the dialogue goes at the work group level around that topic, which I think we'll have an experienced -- fact-based experience to talk about, which is a little more concrete.

Okay, so that's, obviously, a very difficult issue, endangered species, that we are going to try to figure out ways to bring the committee more -- get the committee more engaged around it. It is clearly a very big part of what we're going to be doing in registration review. I think that one of the things that -- just like all other elements of our program, it really does meaningfully engage, it requires a significant investment on the part of the stakeholders to understand what we're doing, and I think we've provided not only a nice overview here today and in other fora like this, but we're using our website in other ways in which you can become familiar with what we're doing. I think Arty's suggestion of looking at, actually, one of these assessments can be one of the best ways to inform yourselves of how we're at least doing the assessment

aspect of it.

All right, well, thanks to Steve and Arty, I appreciate it.

We are going to take a two-minute break -- no, I'm just kidding. We are going to take 10 minutes. So, it's five after 11:00. We will reconvene --

(A brief recess was taken.)

MR. JONES: All right, we're going to get started. The issue of nanotechnology was raised by a couple members of the PPDC at our last meeting with just sort of a curious question about what is EPA, OPP in particular, how are we thinking about nanotechnology. We had, at the time, just begun to form a work group inside of the office because we were also, as many of you are, we're reading the newspapers, we're talking to our colleagues and understood that nanotechnology was an issue that was likely to confront us sooner rather than later. So, we wanted to get a little bit ahead of it. Arguably, we're still a little bit ahead of it, but we have yet to see an application for a product of nanotechnology.

Our colleagues in the Toxics Program actually

have the lead in EPA and, as you would imagine, industrial chemicals generally is where EPA is first likely to see applications of nanotechnology. So, what we're going to do here this morning is the chairs of our nanotechnology working group in OPP, Jack Housenger and Betty Shackleford, who I think are familiar to most of you, are going to walk you through sort of what our initial thinking is around nanotechnology and then we'll open it up for some feedback questions. So, Jack and Betty.

MR. HOUSENGER: Thanks, Jim. There was some speculation by some of my friends about why Jim chose Betty and I to head up this work group, and there was some thought that maybe because we were both short and that's --

(Laughter).

MR. HOUSENGER: But I think --

MR. JONES: You guys aren't short.

(Laughter).

MR. HOUSENGER: So, I drew the nano straw and I'm doing the presentation today. Betty's my clicker.

(Laughter).

MR. HOUSENGER: The first slide just tells about the scope of the presentation. I wanted to give you some background on what nanotechnology is, how it's being used, what's the Federal Government's role, what EPA is doing, and finally, the good stuff, what we're doing.

The definition -- the working definition that's bantered about a lot is really three parts. One is the size, 1 to 100 nanometers in any direction; unique properties, enabling novel applications; and the third part is deliberately engineered. So, when we talk about nanotechnology, if it's naturally occurring, it isn't considered to be part of that.

This slide is virtually in every presentation that I've seen, so I thought I needed to include it in this one. It just kind of gives you a scale of things, both manmade and naturally occurring. Next slide.

Again, this is just putting things into perspective. You can see carbon nanotube that I'll talk about a little bit later down at the bottom. It gives you a sense of how small we're talking about. Next slide.

In terms of the current application, this is

just a chart that lists a lot of them. My favorite here is the nano pant that actually are self-cleaning, water resistant, stain resistant. I haven't found any of those yet, but I guess you wash them in your silver ion washing machine.

As you notice, too, there's a lot of cosmetics and sunscreens that are used in nanotechnology or have nanotechnology application. Next.

Future applications, the more I read, the less smart I think I am, and I was talking to one of my colleagues about -- you know, you read about all the things especially in terms of cancer treatments and things like that that are planned for nanotechnology, and I say, I feel so dumb. There's a lot of smart people out there. And he reminded me that there are a lot of stupid people out there, too, which made me feel better.

(Laughter).

MR. HOUSENGER: But in terms of some of the future applications, biological sensors; detection of specific compounds in the environment that could lead to more rapid human health and environmental protection; food packaging, that nanotechnology would be a part of

that would warn consumers when food isn't safe to consume; pesticides, where nanotechnology is included in a pesticide and it won't release its pest-killing abilities until it's inside the targeted path; and then in cancer treatment where you take a silica sphere coated with gold, inject it into the bloodstream, it goes into and targets the tumor. They zap it with infrared light, it heats up and it kills the tumor.

So, it's pretty amazing all the applications that are at least on the horizon.

So, those are kind of the up-sides of nanotechnology. We're going to talk a little bit about our concerns and questions. Because of their size, the exposure could be an issue. In other words, if you breathe it in and it gets deep into your lungs, then it could cause responses that larger inhaled materials don't. They're so small that they can penetrate the skin more easily and actually get into cells and affect viability and potential immune system effects.

On the environmental side, we also have issues, issues regarding many of the nano materials are more durable and, therefore, they remain in the environment

longer after they are used and disposed of. We're also uncertain about the effect on beneficial microbes from nano materials with antimicrobial properties. We don't know about how this is -- how plants uptake it and the effects that result from it.

So, what is the Federal Government doing? In December of 2003, the 21st Century Nanotechnology Research and Development Act was signed which ultimately resulted in the creation of the National Nanotechnology Initiative.

The NNI, as it's called, establishes research and development goals and priorities for the Federal Government. It invests in research and development programs and coordinates federal nanotechnology programs.

On the budget side, in terms of federal budget, nanotechnology budget has been increasing over the years. In 2001, $464 million was spent, whereas today over a billion dollars is being spent every year. Agencies with the biggest budgets include Defense, Energy and the National Science Foundation. Spending has been in two major areas, environmental health and safety issues and education and research on broad implication.

The environmental health and safety spending has been steadily increasing from about $35 million in 2005 to an estimated $39 million last year and a request for $44 million this year.

EPA's budget on nanotechnology is estimated to be about $5 million in '06 and a request from the President's budget for $9 million in '07.

Total U.S. spending, which includes the feds, the states and private industry, is estimated to be about $3 billion a year.

So, what is EPA doing? In 2004, the Science Policy Council created a cross-cutting work group to develop a white paper. The work group was chaired by ORD and OPPT and had representations from all major programs, as well as the regions and the Office of the General Counsel.

The white paper described the environmental benefits, identifies risk assessment issues and research needs and provides recommendations for next steps. It's undergone both public and peer review comments. We've revised that paper, and on September 25th, the Science Policy Council approved it. It's currently being

prepared for publication.

This slide lists some of the key recommendations in the white paper. Some of these recommendations have changed in the most recent version based on peer review and public comment, and as I said, that document will be published in the near future.

Other EPA offices' activities include the Air Office, under the Clean Air Act, is reviewing an application for registration for nanosized diesel fuel. OSWER held a workshop this summer on nanotechnology and waste management practices.

Probably the office most involved or most activity with nanotechnology is OPPT. Many nanoscale materials are chemical substances as defined by TSCA. Those not on the TSCA inventory are new chemicals and a pre-manufacturing notice is required before it can be manufactured. There's presently no similar requirement for those chemicals that are already on the TSCA inventory.

Some of the needs that OPPT has identified are listed on this slide, a mechanism to get the data needed to perform solid risk assessment; an interim approach to

obtain better informed decision-making on new chemicals and realize oversight of existing chemicals; and an industry stewardship in the manufacture and use of new and existing nano materials.

So, for now, OPPT is receiving, reviewing pre-manufacturing notice submissions on nano materials. However, some have met the size parameters, most haven't met all three parts of the definition. In other words, they haven't met the unique properties and/or the deliberately engineered criteria. So, they aren't considered technically to be nano technology.

OPPT has met recently with several companies on pending new chemical nano materials and their general approach thus far has been to permit limited manufacture of nanosized new chemicals under appropriate controls through the use of consent orders and significant new use rules.

In June of 2005, OPPT held a public meeting to hear suggestions how it best could manage the risk from nano materials. NPPTAC, a federal advisory committee, asked that it be allowed to provide additional input through a public process, and in May of this year, an

agency work group was established to explore the concept of a stewardship program.

On October 18th, Jim Gulliford sent a memo inviting public input on the stewardship program. You can see the components of it here. Participation would be voluntary. It's viewed as a complement to OPPT's current regulatory approach for new and existing chemicals. While the program believes that we'll gain experience with risk assessment and mitigation of nano materials and gain insight on the test data needed to be developed.

One of the activities discussed in the white paper was the need to conduct some case studies on nano materials. Currently, there are two chemicals that are being looked at as candidates. One is this titanium dioxide and the other is carbon nanotubes. The goal would be to identify research needs, to gain experience and then to identify needs for conducting risk assessments for nano materials. I don't think these have been absolutely chosen. Those are the two that have come to light. No one told me not to mention them, so I did.

(Laughter).

MR. HOUSENGER: They're looking at a spring timeframe for these case studies to be completed.

So, finally, we get to where it's OPP on nanotechnology. How does OPP plan to regulate nanopesticides? FIFRA requires a finding of no unreasonable adverse effects, regardless of whether something is defined as nanotechnology or not. That is all pesticide products are held to the same standard and we must consider both active ingredients and inert ingredients.

Do we have any currently registered nanopesticides? I know that there's been a lot of talk. Some products have been identified, but we're not currently aware of any. Some companies have claimed that nanopesticides -- that they have nanopesticides and we have been informed by others that they think their competitors' products are nanos. However, when we checked on these, we found that they did not fit the definition of nanotechnology.

We have had discussions with some registrants about future submissions of nanopesticides. So, we know at some point in the future we will be receiving them,

but none have been submitted so far.

OPP faces some of the same challenges as other programs in assessing the potential risks posed by nano materials. How do we adequately assess the health and safety of nanoscale pesticides? Are current testing requirements adequate? How do we identify that a pesticide's active ingredient or inert ingredient is nanosized? And maybe the biggest challenge is being able to make good sound science decisions so we don't hold up whatever benefits nanopesticides could bring.

Like I said before, Jim asked Betty and I to co-chair a work group charged with developing a regulatory framework for nanopesticides. We've just recently formed that work group. It has representatives from most divisions, as well as OGC. The work group will respond to applications as they are received and help inform policies and testing requirements for nanopesticides. Next slide.

This is a group of our -- or a list of our group with all the expertise listed. You can see it's a fairly large group. Virtually every division is represented. I think there's a few people from the group that may want

to stand up just so you can see their face. You know who you are. It's not as good of a turnout as we had hoped for, but --

(Laughter).

MR. HOUSENGER: I'm sure the other ones are working on nano issues.

Next slide, please.

So, this slide lists the areas that the work group is exploring to help us in our charge. One important aspect will be training and education because we realize that we have a lot to learn in this area.

The work group goals include learning from others, including offices within EPA, other agencies and other countries. We want to ensure that when we do receive our first application for a nanopesticide, that we are as prepared as we can be. There is many potential benefits from nano materials, but as with anything new, there's a lot of concern about the unknown. We need to ensure the public that we are making the right decisions and clearly explain why. We also need to provide clear guidance to pesticide registrants of any additional data that may be needed and why as early in the process as

possible.

A couple things that industry can do to help us out, engage early in the process; share whatever plans you have on nanotechnology far in advance of the submission; and if you think you do have nanotechnology in your products already, identify them, certainly identify them before they come in.

I think the public can also help us by sharing their information and concerns on nanotechnology and providing comment and input to what we put out for comment and public review.

So, in summary, we will be proactive in communicating and identifying our needs as we progress. We'll work with others in identifying a health protective and efficient way of evaluating nanopesticides, and we hope to develop a clear, transparent and scientifically sound regulatory framework. That's it for my presentation.

MR. JONES: Thank you. Okay, Gary?

MR. LIBMAN: Has there been any thought to maybe incorporating things that actually have been registered already as nanotechnology? I'm even thinking of

something like the BTs, the (inaudible) the active ingredient is not the microorganism, but it's actually the endotoxins that is produced. So, it's actually at the nano level, if you will.

UNIDENTIFIED FEMALE: I guess the question would be, does it meet the definition, the three-part definition of a nanotechnology?

MR. HOUSENGER: Would it, would it?

UNIDENTIFIED FEMALE: Probably not.

MR. HOUSENGER: Probably not. That's not deliberately engineered.

MR. JONES: And I think what's probably more important is that it behaves the same way as the material from which it's derived, which is one of the real keys here. If it doesn't behave the same way, then it argues for additional testing. If it behaves the same way as the material from which it's derived, there may not be as much need for additional testing around it. That's one of the real key elements to nanotechnology from a regulatory perspective we're concerned.

Caroline?

CAROLINE: What you just said makes me very

curious because isn't the delivery mechanism a very key feature of this that we'd be worried about in terms of unintentional releases? Hello, Jack? I'm talking to you, buddy.

(Laughter).

MR. HOUSENGER: I mean, certainly exposure is a big component of this and I -- and we're concerned about that. I think the real question is if it's the same material, it's just nanosized, is what we already have -- is the data that we have adequate to assess the toxicity or whatever with this. I don't think we know enough yet about that to comment on it.

CAROLINE: That would be a key question, right?

MR. HOUSENGER: Yeah, yeah.

CAROLINE: The unintentional release issue would be a key part of this, right?

MR. HOUSENGER: Um-hum.

CAROLINE: So, we do see parallels here with biotechnology, do we not? So, the same set of characteristics might be of concern.

MR. JONES: Well, the --

CAROLINE: Because we keep having these releases

with biotech, not every day, but periodically.

MR. JONES: There may well be products of nanotechnology that have the same ability to reproduce in the environment, which is the feature of the unintentional release of biotechnology that I think people get focused on. So far the things we've seen -- which we certainly don't feel like we've seen all the potential applications by any means -- don't involve that element of being able to reproduce it again in the environment. It doesn't mean that unintentional releases wouldn't be of concern, but that aspect of unintentional release so far is something we've seen.

Jennifer?

MS. SASS: Well, first of all, thanks for the presentation, Jack, and also thanks to EPA for putting this on the agenda and thanks to the team who came, because I am the one that kept pushing to get it on the agenda and I do think it's a really important issue.

I thought the presentation was really good. I want to bring up some of the things that I guess I do in my presentations when I do nano tox presentations all around the country. First of all, on your slide 12, all

your numbers are right, of course, but just to clarify, there's been a lot of actual taking a real close look at where that environmental health and safety issue spending is going, and almost all of it is going on environmental applications, uses, R&D. And, actually, according to the Woodrow Wilson Center for International Scholars who did a very rigorous review with the agencies as well, only $11 million is actually going on targeted health and safety testing.

So, that means that we have over a billion dollars going towards research and development and about $11 million spread across the agency that's actually trying to keep up with that research and development in terms of doing the health and safety testing (inaudible) these things are being used in a lot of commercial applications already.

On slide 14, which is on the white paper, I was on that expert advisory committee. That was an expert scientific review of the white paper and I don't see it on the list and maybe it didn't get into your final version, but I want to point out that every single expert on that committee was in agreement in recommending that

the federal agencies use their statutory authorities to request data and also test samples so that they can run tests on them. Both of those were difficult to acquire.

So, while I'm extremely sympathetic to the lack of data in this area, that expert panel pointed out that you do have statutory authorities that can be used to gather that data. You don't have to sit and wait for voluntary programs.

(Inaudible). Oh, on 18 --

MR. JONES: On that point, we recognize we certainly have statutory authority.

MS. SASS: Right.

MR. JONES: And we will likely exercise -- I think what we're struggling with is, you know, I don't want to necessarily require a test on a nano material that actually doesn't tell me anything. It may be that there needs to be a different test. So, one of the issues we're going to have is sort of backed up from do we use the authority? Yeah, we're going to use it. The question is, we ought to use it appropriately and make sure we're asking for the right information for the right compound.

MS. SASS: The right samples, yeah. And -- well, you know this, but you also have to consider the purity of the sample and the commercial formulation. I mean, this is a complicated issue. I'm very sympathetic about how complicated this is, which is why I wanted this on our agenda for PPDC so that we could begin to follow this issue early, because it is so complicated and it's so important.

On Slide 18, I like your definition of unique properties and deliberately engineered or deliberately engineered. Is that why nano silver -- the biocide nano silver wasn't considered a nano material is because it doesn't have unique toxicological properties from silver because silver is also a biocide? Is that why nano silver was determined not to be a nano product?

MR. HOUSENGER: I think -- you mean in the washing machine?

MS. SASS: (Inaudible) washing machines and food storage and now Japan is putting it all over their mall door handles and bus handles and it's apparently in condoms now. I mean, it's like -- yeah, I know you don't regulate that, but that's a pretty wide exposure.

So, whatever you're thinking about it, I'm thinking about it in a lot of things from a public health perspective, so as a biocide in food storage containers and clothing.

MR. HOUSENGER: Yeah, I mean, silver's used a lot as a biocide. Whether it's nanotechnology is going to be dependent on the three-part definition again. We haven't received any applications for nanosized silver so far. So, it might be, it might not be. I'm not sure yet.

MS. SASS: Well, I just searched the web and actually Sharper Image did have a very clear definition of the nanosilver that they were putting into their food storage containment units that they're selling. It's like this Tupperware product they sell, but now it's off the web. So -- and like a month ago it was on the web. So, I'm guessing that you called them and asked them if it was nano.

MR. HOUSENGER: I did not call the Sharper Image.

MS. SASS: All right, I'm using my way-backs to go find that. I'll get back to you.

MR. JONES: Jennifer, I will say that we are saying people use the term, but then when you look into the term, it doesn't meet the definition.

MS. SASS: I know, I know. And vice versa, too, yeah. No, the labeling and public information problem is huge. This is why I think we need regulations.

On 19 and 20, it's sort of the same issue. The voluntary program, which I was also part of the NPPTAC subcommittee that developed that paper and reviewed it. It is a good program, I think. I think the framework is good for gathering -- for developing sort of a corporate stewardship to develop and submit voluntary data, voluntary health and safety testing data to the agency. But there is nothing in that paper except, to be honest, for what got put into the appendix because I insisted on keeping it in the agenda, so it got annexed, where the EPA has told us what action they're going to take upon that data.

So, although these voluntary tools are good tools for data gathering, they put no onus on the EPA to actually take action on that data no matter what it says. So, that's a real concern for me. And I don't -- while

I'm supportive of the data-gathering effort, I don't think it should be confused with the regulatory effort. I do think we need to think about regulation and the reason why is it it's already out there.

MR. JONES: For everyone else's benefit, that relates to our sister office, OPPT, which is the Office of Pollution Prevention and Toxics, that's going to be running a voluntary program.

MS. SASS: Right.

MR. JONES: I think Jack mentioned in the pesticide world where we have to make an affirmative safety finding before licensing a product, it's not going to be a voluntary program. If you have a nanopesticide, you have to come to us and get it licensed, which is a mandatory requirement.

MS. SASS: And the data gathering can also be mandatory and you have statutory authority to do that right now.

Page 24, this is the one on your challenges, these are challenges and these are really big challenges, and, you know, I'm going to throw my weight behind getting you as much funding and resources as you need to

meet those challenges with your sister agencies. But the last one, making decisions based on sound science, you don't have time because these products are already out there. So, I want you to think carefully about what you're going to do in the absence of a full body of data because that's the situation you're going to be confronted with. And I'm promoting precautionary action in the face of lack of data because that's the situation you're really going to be in in real life.

I don't want to sit where we're sitting now, you know, with the rest of the pesticides and with lead and mercury and asbestos having this conversation after we've already put lead in our gas tanks, for example. We have the opportunity now not to allow those exposures to happen until we have data.

On 26, this is your list of your work group and I want to really commend you on putting it together. I think this is a really full work group and especially on including industrial hygienists and inhalation toxicologists. This is going to be so important. I think most of what we do know about the hazards of nano comes from what we know about fine air particulates and

ultra fine air pollution and also metal fumes, epidemiology from occupational studies, and the finer the particle, the more damaging it is, the more toxic it is. So, I'm glad you included industrial hygienists and I would encourage you, and I'm sure you are, to keep worker exposures at the forefront.

That's it. Thank you.

MR. JONES: Thanks. Okay, Kristie Stoick and then Ray, then Jose. Is that Pat? Is yours up? Okay.

MS. STOICK: Hi, thanks for your presentation. You talk about there's going to be opportunities for the public to provide comment and input to the work group. Can you talk about that a little bit more? What are those opportunities going to be? Do you have an idea yet or not?

MR. HOUSENGER: Well, I mean, to be honest, our work group has met twice so far. We're just starting to get our feet wet in terms of understanding some of the issues that we're going to have to be developing. But, I mean, I could envision a policy paper that lays out how we're handling certain things. We're going to be developing our own little white papers. I'm not sure

what the public access to those will be. I mean, some of it is educating ourselves to get up to speed to be able to anticipate some of these issues.

So, I think my point was if we do go out with something for the public, please (inaudible) in it. If we don't and you have concerns, let us know.

MS. STOICK: Okay, thank you.

MR. JONES: Ray.

MR. McALLISTER: You've clearly said that you have not identified any nano materials either currently registered or in the pipeline. But Jennifer's telling us products are out there. Those two statements appear to be in conflict.

MR. HOUSENGER: Jennifer's telling you that some claim to be out there and --

MS. SASS: I'm speaking beyond pesticides, more than pesticides.

MR. JONES: Definitely if there are nanopesticide products out there, we're not aware of them and we need to become aware of them. So far, when we have become aware of them, it turns out they really aren't, and then it's a claims issue as opposed to it

really is nano material. But that doesn't mean we have full knowledge around this. To the extent that anyone has such knowledge, if you bring it to us, we'll follow up.

MR. McALLISTER: Is there any evaluation being done of products to determine if there's a nano material that may not be claimed? How would you do that?

MR. HOUSENGER: Well, I think that's one of the challenges that we have. That's one of the --

MR. McALLISTER: Yeah, in our looking into this so far, we're not aware of any nano products for pesticides, just as you've said, that have either currently registered or are on the horizon. There are some micro technologies using pesticide formulations, but that's a long distance in actual scale from the nano materials.

MR. JONES: Jose and then Pat and Jimmy.

DR. AMADOR: My question is related to the same, there's no nanopesticides registered in the U.S. How about internationally? Is there anything registered internationally as to nanopesticides?

MR. HOUSENGER: I don't know the answer to that

question. I don't know if anybody else here does or not.

MR. McALLISTER: The U.S. has the benefit of the latest pesticide technology.

DR. AMADOR: I didn't hear you, Ray.

MR. McALLISTER: The U.S. has the benefit of the latest pesticide technology.

MR. JONES: Pat.

MR. QUINN: I'm just trying to get a sense for how you think this is going to evolve. Do you think that you're going to learn enough through the interagency discussions so that you'll be able to make selections about test methods that you might use when such a material arrives at your doorstep? I mean, are you aware of test methods that might be out there that you consider now?

MR. HOUSENGER: I mean, this is one thing that our work group is exploring, what research has been done, what test methods are there, what's the likelihood that those test methods will work for us, are there any bridging data that we could do to see, you know, early on if these things behave the same or not, you know, human, animal. I wish I had the answers to those, but I --

MR. JONES: Ideally, that's how it would work, Pat. But my experience is that because we have an affirmative requirement to license -- you have to be licensed in this program, which would be true if it were a drug, too, but other than that in the United States, that's not required before you can be on the market. And when that is the context you're operating in, even if we're not out front, we become out front because there will be -- if some applications are sitting here, there will be a general expectation broadly that we figure out how to evaluate that application.

MR. QUINN: Right.

MR. JONES: So, although the ideal is that we'll be able to learn from our colleagues around the government about how to test, when we have an application sitting in front of us, it's not going to be acceptable to Congress, to the submitter and to others that we wait for 10 or 15 years to figure out how to evaluate the safety of it, and it's not going to be acceptable to us that we make a decision without understanding the safety of it. So, that will sort of, I think, be what forces the action if the interagency process is not giving us

those tools.

MR. QUINN: Right. But, I mean, I can also foresee a path where something does arrive at your doorstep, it meets the definition, test methods have not been identified, you guys feel an obligation to go ahead and select a correct test method, that could be an extremely lengthy process, you know, with all the implications that that has. I mean, while we obviously need to be concerned about the tox side here, my understanding is that many of micronized technologies offer very significant environmental benefits potentially, and so, I'm just trying to figure out how you're looking at that trade-off and whether the goal is really to kind of get prepared or to have a case put in front of you (inaudible).

MR. JONES: You know, ideally, we would be ready when that first application shows up. Do we know how to test it, we know what the requirements should be, and will that deal be achieved, you know, that's what we're working towards. But safety is going to come first and we're going to want to make sure we understand that it's safe before we put it on the market. Frankly, I think

that that's in everybody's interests, as much in the industry's interests as it is in the public interest community. The last thing you need is for us to put things on the market that you're then responsible with the liability of --

MR. QUINN: We don't want to go down the biotech road again.

(Laughter).

MR. JONES: We had Rick and Jimmy and Caroline and Jennifer.

MR. COLBERT: I hope this is an easy one. Just curious, does nanotechnology -- do you anticipate it's going to pose any jurisdictional issues for FIFRA? How these things are made or how they behave or how they act, whether the pesticide is inert or they just don't quite fit some categories because they're so different or is it all sort of (inaudible) fit very easily?

MR. HOUSENGER: I think it will get back to the claim. If they're claiming that they kill pests, then it's our jurisdiction. I don't think nanotechnology is any different from some of the other pesticides that are on the market in terms of jurisdictional issues.

DR. ROBERTS: After I put my card up, some of your discussion may have answered some of my questions. For somebody who doesn't know much of anything at all about nanotechnology, I'm glad that you're putting the work group together. I'm glad to see the presentation today.

In light of one of the things that Jennifer said earlier, I'm a little concerned that over a billion dollars is used in developing uses of this and only $11 million is designated to health and safety issues. I wonder if there's plans in the EPA budget to work more of the dollars into health and safety issues.

UNIDENTIFIED FEMALE: Can I give an observation about how the money has been allocated over the last couple, few years? If you look at federal expenditures going back to 2003 -- well, 2004, 2005, 2006, what you will see is that each agency's budget, as it specifically focuses on nanotechnology, has increased. In other words, the agency has been given more money than they've asked for. That includes EPA.

So, in terms of whether or not more dollars will be available, I think there's certainly a recognition

that there needs to be a substantial expenditure in the area of nanotechnology. I think one of these things that the agencies are grappling with is we have to be able to move a program forward fast enough to be able to use those monies in a way that are going to answer the questions at hand.

So, that's one of the things I think that we've seen is that the money is being made available. It may not be in a proportion that some think might be appropriate, but certainly agencies have been getting more money than they've requested.

MR. JONES: And we would be happy to pass that perspective along. We are not the ones involved in making those decisions, but we can figure out how to pass that observation perspective along. Appreciate it.

Caroline, Jennifer.

CAROLINE: Well, I think the point about not going down the biotech road is obviously in all of our minds here today because we have done it (inaudible) all of us. I think the international perspective is really important, too, because that's a great divide for biotech. I thought that Jose's question was really

important. So, it would be really very important to bring this issue in front of the international groups that EPA works with.

MR. JONES: Thanks, appreciate that, and we agree with that. There's actually an OECB meeting next week which we and our colleagues at OPPT will be at which is going to have a nanotech agenda item on it and we'll make sure we're learning as much as we can from our colleagues around the world.

Jennifer?

MS. SASS: It's a budget question. It's not a question really. But you guys need more money and you should ask us to get more money. The Department of Defense is actually getting 27 percent of the nano budget, the NNI federal budget for '07, and the Department of Energy, if I'm correct, is getting about 23 or 24. So, basically, the Department of Defense and Department of Energy together are getting about half of the budget and, actually, EPA is getting less than 1 percent. I think it's getting .75 percent of that budget. If you consider that EPA is the only agency that's going to be doing the kind of state and transport

out into the environment, that kind of testing, at least it's the most qualified to do that, and that's what's primarily allotted in the white paper in its research agenda that it's recommending.

I don't think that's adequate because all of the other agencies are going to be looking at how to get this out, and EPA, I don't think, is going to be able to keep up with what the potential impacts are once it gets out. And if PPDC can help to increase that budget and steer it towards that really important research, I think that you should use us.

MR. JONES: Well, everyone in jobs like mine like to say or don't like to say, but say we're not -- one, I support the President's budget; secondly, that it is actually a violation of federal law to ask a federal official to ask someone to lobby on our behalf for money or anything else. So, I would never do that. But thank you for your comment.

(Laughter).

MR. JONES: Matthew, last word.

DR. KEIFER: Yes, I'm fascinated by the fact that at the same time EPA is taking this on as a topic,

NIOSH is beginning to understand and doing the research and supporting some of the research with their very paltry budget, I might add, about how these things might affect workers. And unlike pesticides which clearly were there before EPA was created, and a lot of worker exposures were there before EPA, NIOSH and OSHA were created, this is coming right online while we can do the research about the health effects of workers and we can get out there and not just understand their effect on workers, but the one thing about environmental and occupational health is, we always understand that worker exposure means population exposure, but in a microcosm and at a higher level.

I mean, I have to say we do use workers -- the health effects on workers to understand the health effects on population because we know they're usually exposed to the higher levels.

So, I'd encourage EPA to work with NIOSH, work with OSHA as they develop regulations concerning exposures to nanotechnology and support ATSVR (phonetic) in the process of exploring and getting together a team on the forefront of research in terms of its health

effects. These people are doing that work now. I think even NIHS is supporting some activity in nanotechnology research.

So, I'd just encourage you to try and form partnerships with these organizations who will be able to share a lot of information.

MR. JONES: I appreciate those insights. All right, we're going to wrap this session up. I'm glad we had an opportunity to begin to share with you our initial thinkings around this. I'm quite certain this is a topic that we'll spend time with each other in the future on. So, an early look at nanotechnology in the pesticides context.

Okay, we have my colleague from the Office of Science Coordination and Policy, Cliff Gabriel, who many of you I think know, but some may not, who is going to give us an update on the Endocrine Disruptors Screening Program, which is a program that many of you are probably somewhat familiar with, but it's going from a development stage into, in the coming year, an implementation stage. So, we thought it was an opportune time to have Cliff come and talk to the PPDC. Thanks, Cliff.

MR. GABRIEL: Thanks, Jim. It's a pleasure to be here. I met with this group I guess a little over a year ago and gave you an update. I understand that there's been considerable turnover, so I think what I'll do is sort of walk you through the Endocrine Disruptor Screening Program 101 and then spend some time towards the end focusing on the progress we've made since we last met.

So, the program, for those of you that don't know, derives its authority from the FQPA. Specifically, these were modifications to the Federal Food, Drug and Cosmetic Act that required the agency to develop a screening program using validated assays and I stress validated assays -- you'll see that's very important as we get further along in this presentation -- to identify pesticides that may have estrogenic effects in humans.

The statute also gave the administrator broader authority to look at other endocrine effects and also to deal with effects in species other than humans, for example, you know, wildlife species.

The same year, the Safe Drinking Water Act was amended to provide the agency with discretionary

authority to look at chemicals found in sources of drinking water if there's a determination that there's a substantial portion of the public that's exposed to those chemicals.

So, taking our lead from the statute, you know, we established the Endocrine Disruptor Screening Program in 1999, and this program was influenced greatly by the Endocrine Disruptors Screening and Testing Advisory Committee, and also by public comment and through advice from our Scientific Advisory Panel, and also from our Scientific Advisory Board.

In particular, the EDSTAC provided the agency with a lot of recommendations that really laid the groundwork for what this program was to look like. In particular, they focused on needing to look at not only estrogenic effects, but also androgens and thyroid effects, to broaden the program past humans to ecological effects. They also recommended a broad universe of chemicals be looked at, not only pesticide chemicals, but again other chemicals that -- where you may have significant exposures.

And, importantly, they recommended a two-tiered

approach with tier one consisting of in vivo and in vitro screens. Basically, what this tier would do would indicate the possibility that a chemical could interact with the endocrine system. And then depending on the outcome of that battery of screens to go into more detailed tier two testing, which would provide the agency with the data for hazard assessment and for risk assessment in general.

The program is divided up into three principal components. The first component is assay validation. When the program was established in -- or when the statute was passed in 1996, there really were no validated assays for the agency to draw on to construct either the tier one battery or the more detailed tier two tests. So, we've had to work very carefully with our partners in OECD, with the interagency groups, like the interagency coordinates a committee for the validation of alternative methods, ICCVAM, with our Office of Research and Development, basically going through the very exacting procedures for making sure that the assays that we're utilizing in this program are, in fact, validated.

You can see on this slide some of the steps that

are involved in terms of doing the detailed review paper. Essentially, this is a literature search pulling together all of the data on a given assay. Looking at issues of relevance, optimizing the protocol. You know, a lot of these assays have been used in research settings, you know, for many, many years and there was the assumption by many that the validation process would be fairly straightforward given the long history of use. It didn't turn out that way, unfortunately. And the agency, again working with our partners, really has done quite a lot of work in optimizing the protocols and, again, making sure that these assays are, you know, transferrable across laboratories and are producing the types of reliable data which would enable the agency then to rely on them for regulatory purposes.

This slide is new to you. There's been significant progress in the validation process for many of the tier one assays. What I have here on this slide are our best estimates as of yesterday in terms of when the various assays in the tier one screen would be through peer review, which would be the last stage of the validation process. And you can see that, you know,

certainly an important step is the third from the last where you have the peer review of the battery. And, again, we hope to have the battery peer reviewed by the end of next year.

But, again, I mean, these dates all hinge on how successful we are in the peer review process. So, there could be some setbacks, maybe not. But, again, I'm optimistic that we'll be able to move forward with the validation by the end of next year.

And moving on to tier two, these have further to go. We've certainly considered the Mammalian 2-generation assay. That's part of the current battery of tests that's being validated and suitable for the program. We're still in the development stage in some cases, optimization stage certainly, for these other assays, the Avian, Amphibian, Fish and Mysid assays.

Our expectation is that these should be complete in the '09-'10 time frame, which I think will probably work out pretty well given the fact that the data from the tier one screening should be arriving on our doorstep about then. So, it should provide for pretty smooth transitioning to the tier two assessments.

The second part of the EDSP is the priority setting process. As you remember, I said that the EDSTAC recommended that this program cover as many chemicals as possible, I think. The estimate was something on the order of 87,000 chemicals. Well, clearly, you know, that would be quite a job, to say the least. So, the recommendations that we got from the Scientific Advisory Panel and the Scientific Advisory Board was to take a first bite of this apple. Basically, develop a list of say 50 to 100 chemicals to start this program off.

And what we've done in September of last year, we published the final approach for how those chemicals were going to be selected. It's important to note that this list will not be a list of chemicals that we think are endocrine disruptors. This is a list of chemicals that was developed based on human exposure. What we've done is we've looked at pesticide actives and high production volumes, inerts within pesticides products, and looking at various databases that have exposure pathways. So, for the pesticide active ingredients, we have the four pathways to include food, water, residential and occupational exposures. For the

pesticide inerts, we have essentially the biomonitoring data, the NHANES data, things like that, and the fish data, water and air.

So, there are multiple databases that were consulted for each of these pathways. And essentially this is tallying up, you know, which chemicals land in more pathways. The more pathways these chemicals are found in, then the higher priority that it be, you know, making the first cut for the first 50 to 100 chemicals.

And just roughly, you can see here that we have about 1,100 active ingredients. We have more than 600 on one or more pathway lists. We have about 100 of these active ingredients on three or four pathway lists. And it's a similar sort of analysis for the inerts. We have about 650 inerts with fewer than 100 on one or more pathways, with about 15 on three or four pathways.

There are some chemicals that we've excluded from this list, specifically those chemicals that were used as positive controls in the development of the individual assay, also chemicals where there's a low potential to cause endocrine effects, and we have strong acid (inaudible), you know, polymers, things like that.

We also felt that the program wasn't quite ready to deal with chemical mixtures yet, but that's something that will certainly be coming, and also chemicals that are no longer produced or used in the U.S.

In terms of next steps with the chemical selection process, essentially we will be publishing in the spring, probably late spring, I hope, a draft list of chemicals seeking comments from the public, and then publishing the final list in time for the tier one screening, again, hopefully by the end of '07.

For the last part of this, to make it all work, is the various procedures that are going to be required to actually implement the testing. By procedures, I'm referring to things like appeals, data confidentiality issues, data compensation issues. The statutes mentioned all of these, but didn't provide the agency with a lot of new statutory authority to do much about them. So, to a certain extent, we've had to rely on existing programs, existing procedures, and we're still in the process of sorting a lot of those out.

But, you know, clearly we're in the process of putting an ICR together. We have to have that in place

before we can start testing. And, also, we will be using the FFDCA Section 408(p) authority. That's the authority that's provided in the SBCA.

And, again, our hope is that all these documents -- well, certainly, all these documents will be available for public comment and they will be finalized by the end of '07 or early '08. So, again, this is in keeping with our desire to implement the tier one screening as soon as possible.

You can tell that there are a lot of pieces here that have to come together in a very short period of time. There's a lot of work involved in making this happen. A good deal of uncertainty, especially as it relates to the peer review process, making sure that these assays are, in fact, adequately validated. So, it's going to be an intensive year for my staff working on this. But I am optimistic that we'll be able to achieve this time line. But it will be an interesting year, to say the least.

The last slide is just a pictorial of the time line that, you know, lays out some of the things that I was talking about. The first bar across you have the

initial list for the first 50 to 100 chemicals being published early in '07, finalized by the end of that year. Similarly, with the development of the procedural framework, a similar type of time line. Probably the publishing of the draft procedures and ICR will be somewhat later than the publication of the draft list, but it will be along the same lines. Again, finalized by the end of next year.

And then the validation for the final peer review of the tier one screening will happen towards the end of next year as well. So, that's where we are. The staff's been very busy trying to make it happen. It was and is a major undertaking for us and for the agency. There is certainly increased interest in this program, particularly coming from the Hill. The press articles and work on (inaudible) fish in the Potomac (inaudible) where it certainly has increased the visibility of this program. We've had oversight hearings by the House Government Reform Committee, and I expect that as we get closer and closer to the end of next year, the interest will only increase.

So, I'm happy to answer any questions you might

have.

MR. JONES: Thanks, Cliff. Caroline?

CAROLINE: Cliff, I want to congratulate you for putting together this thing. This is a program, you know, and this thing has been sitting on zero for I don't know how long. So, you've done a tremendous job pulling this whole thing together and I just want to commend you for that.

I was just tracking right along with you and nodding my head until we got to the slide about priority setting. And I know this was an issue with the EDSTAC and, you know, you've got a resource issue and I'm on board on all of that. But convince me that using the four pathways is the way to go here because there must be a lot of chemicals that -- or a good number of chemicals that fit that criteria that you don't have any reason to think are endocrine disruptors.

I know there was a lot of politics around the lists, the various lists that got published, I get all that. But isn't there some additional way to screen these things so we can really get at the ones we think are endocrine disruptors?

MR. GABRIEL: Well, certainly, you could look at some effects data. I mean, the sense of the group at the time was that there weren't sufficient effects data to use them in a way that really informed the development of an initial list along the lines of what we did and that the most straightforward way would be to do it, you know, based on exposure.

You know, one of the things that we're looking at doing is after we, you know, get the experience with the first 50 to 100, is then partnering with our sister offices within the agency and, you know, look at what their testing requirements are, whether it's for Office of Water related programs, whether it's in OPPT or the Toxics Program, and try to make sure that, you know, the tools that we've developed here are used in a way that accelerate and is complementary to their regulatory needs, and I'm sure at that point that there will be the type of analysis that you're talking about.

CAROLINE: So, you think from using these criteria you have, these exposure criteria, that you'll be able to develop this indicator that will narrow it down? I mean, my only -- in an ideal world, you'll want

to test everything and I think that's basically what the EDSTAC did. But your resource --

MR. GABRIEL: Right, exactly. So, we have to do this in a way that makes the most sense. The most sense from a resource perspective and the most sense from a regulatory perspective.

CAROLINE: Okay, tell me again which -- how many chemicals do you see in each one of these categories?

MR. GABRIEL: In each one of?

CAROLINE: These two categories you've got here, the four pathways.

MR. GABRIEL: I believe there were around 100 active and -- that was in all -- three or four pathways and about 15 inerts in three or four pathways, which actually -- I mean, that was done -- I don't think the SAB or the SAP had that information when they recommended, you know, screening 50 to 100, but it turned out pretty close.

CAROLINE: How much money is that going to cost? You know, I looked at the time line up there. The time line is greatly accelerated from where we were. But what is it going to cost to look at 100 actives?

MR. GABRIEL: You know, we're in the process of filling that out right now; in particular, you know, getting into the ICR, information collection request process. So, I don't have good numbers to -- you know, to give you at the moment.

CAROLINE: The reason I asked that is I just want to get an idea of how realistic it's going to be with your timetable.

MR. GABRIEL: Well, this will be done through a testing order. So, this will be a shared expense with industry. There's certainly a resource issue when it comes to the agency handling an analysis of the data once it comes in. But the actual testing of these chemicals will be borne by industry.

CAROLINE: Okay. Well, if we could, maybe at the next meeting, get a further assessment on the cost and --

MR. GABRIEL: I'd be happy to do that.

CAROLINE: Okay, thank you.

MR. JONES: John and then Christie and then Caroline Cox and then Ray.

DR. SCHELL: Cliff, I want to second what

Caroline said. You're doing a great job. This is a lot of work. Not to make things more complicated, but on the slide with the validation update and tier one assays, is there a process or an approach that you can add assays to it as technology changes, like pneumonic and photonomic (phonetic) (inaudible) like that?

MR. GABRIEL: Yeah, certainly, you know, science doesn't stand still, and as new assays are developed, new assays are validated, I'm sure there will be substitutions, there will be modifications. We're trying to especially move away from some of the in vivo tests, you know, if we could move to more in vitro tests once we have a better understanding of all the various modes of action that we have to screen for. So, yeah, I mean, I think that, you know, we would anticipate further developments and refining of all these methods. I think we'll know an awful lot more, too, after we get done looking at the first 50 to 100 or so.

DR. SCHELL: Have you given any thought to how you would modify this, Cliff, to the extent it's changing all the time?

MR. GABRIEL: Yeah, yeah, yeah. I mean, I would

imagine the way we would do it would be, you know, through interactions with the Scientific Advisory Panel, the Scientific Advisory Board, you know, bringing recommendations to them, making sure that the assays, whether tier one or modifications to the tier one battery that we are, in fact, capturing all of the -- whether it's (inaudible) points of concern or modes of action that the regulatory programs might have an interest in.

DR. SCHELL: Thank you.

MR. JONES: Thanks, John. Christie.

MS. STOICK: Thank you. I have a question on the same slide actually about the tier one battery or the tier one assays. I'm a little confused as to how --

MR. GABRIEL: They're not all going to be ready at the right time.

MS. STOICK: Well, no. How the battery -- is that meant to imply the battery of all tier one assays?

MR. GABRIEL: Yes. Well, all tier one assays that are currently ready to do. I mean, EDSTAC developed a battery or the recommended assays, it included a fair amount of redundancy. So, we believe that we'll have a sufficient number of assays validated to provide the

necessary coverage for the three hormone systems that we're interested in. So, it will be the estrogenic effects, androgenic effects and thyroid effects.

MS. STOICK: But so before the last (inaudible).

MR. GABRIEL: Right. In that case, for example, with the estrogen receptor binding assay, that those effects would, in fact, be captured by the uterotrophic (phonetic) assay.

MS. STOICK: I think I have one final question. On the slide, chemicals to be excluded from initial testing, just a clarification. Can you address why chemicals no longer produced or used might be addressed in future rounds of testing?

MR. GABRIEL: Yeah, now that's a good question, and I looked at that and didn't have a chance to ask my staff why that had an asterisk at the end of it. But, yeah, I would imagine that, you know, perhaps there could be products in other countries, for example, you know, a certain residual exposure or -- you know, I could imagine that there would be reasons why you'd want to do that. They might not be real high in your priority list, however.

MS. STOICK: Right. So, that would be few and far between?

MR. GABRIEL: Yeah, I would imagine.

MS. STOICK: Okay, thanks.

MR. JONES: Caroline and Ray.

MS. COX: I wanted to follow up on the other Caroline's questions about the priority setting. One thing that occurs to me, if the selection is supposed to be based on exposure, the pathways are important, but I can certainly imagine a situation where you have a chemical that has maybe just one or two exposure pathways, but the magnitude of those exposures is so great that it would maybe outrank a chemical with more exposure pathways, and I hope that you're going to include that in the priority setting process.

MR. GABRIEL: The one caveat to that is that exposures through the food pathway would have a higher priority. You know, this was not an exercise in looking at absolute exposure to all of these chemicals. We just didn't have, you know, the time or resources or probably data to actually do that. This was really looking at whether or not, you know, a chemical was listed in one of

the databases that hit one of these exposure pathways, again with the caveat that if it was a food exposure, that that would carry more weight than some of the other exposure pathways.

MS. COX: And my second comment has to do with the registration review and hoping that we can develop some of this endocrine disruption data in time to use it in the registration review. So, I hope that that would feed into the priority setting process so we don't end up with a situation where the registration review was completed a year before the endocrine disruption screening was completed.

MR. GABRIEL: Jim and I are talking a lot about this.

MR. JONES: That's actually the plan.

MR. GABRIEL: Right.

MR. JONES: Other than the first group of 50 to 100, after their testing is done, which doesn't necessarily synchronize with registration review; although there's a subset of those chemicals that are in the first four years of registration review, it's ultimately going to be implemented through registration

review.

MR. GABRIEL: For the pesticides.

MR. JONES: For the pesticides. For the non-pesticides --

MR. GABRIEL: There will be other (inaudible).

MR. JONES: (Inaudible). Ray?

MR. McALLISTER: With the list of tests, it looked like about a dozen there, I didn't count for certain, but with those tests becoming available or completing their validation cycle over a period of time, how are you going to schedule them? What's the scheduled testing? That, combined with the identification of priority lists, does a chemical wait until all the tests are available before there's any test or does each chemical do every test?

MR. GABRIEL: No. With the tier one tests, those would be done at the battery. So, when the order is -- this first 50 to 100 is issued, you know, the requirement will be that the chemical will be tested through -- you know, with all the tests and the battery. Unless they were used as a positive control in the development of that assay, then they would be (inaudible)

from that test.

So, you know, I think given the fact that there's going to be resource issues not only with the agency, but also with testing labs, companies we can work with, you know, there will be ample time given to make sure that the testing actually gets done and that the testing time line is reasonable.

MR. McALLISTER: What about the time line for the testing labs to get the necessary experience to do these (inaudible)?

MR. GABRIEL: That's my point.

MR. McALLISTER: Okay.

MR. GABRIEL: This is the first time out for some of these assays. So, we're anticipating that there's going to be a lag phase, if you will, in getting labs up to speed, you know, making sure that processes are clear in terms of the agency receiving the data. I mean, this will be the first time through. So, you know, I'm sure there will be some hiccups, but we'll certainly try to be as reasonable as we can be.

MR. JONES: All right, well, thanks very much, Cliff, for coming in and joining us here this morning. I

appreciate it.

Our last item this morning on the agenda, or this afternoon -- I guess it's the first one of the afternoon, last one of the meeting -- is a brief follow-up to an item that this group has talked about before, and that relates to alternative non-animal testing. And Tina Levine, who's the Director of the Health Effects Division in OPP, and Pat Quinn, a member of the PPDC, are going to take us through this topic.

MR. QUINN: Okay, for those of you who are worried that what Tine and I were going to do was show you a lot of eyeballs and slides on depth of injury, we're not going to do that today, even though some of you have been through that in the past and we don't intend to do that. This is not a formal work group of the PPDC, but it is an informal initiative that grew out of a fairly widespread interest on the part of antimicrobial, as well as agricultural registrants, animal welfare groups, environmental groups several years go.

I guess I want to say at the outset that it has not progressed -- this initiative has not progressed as quickly as we would have liked. It, in fact, is more

complicated to put together paired animal and non-animal data of the kind that is persuasive to the interagency group that reviews such things, which is called ICCVAM, which includes participation by FDA and CPSC and the Federal Trade Commission. So, we have spent more time generating data than we anticipated, not new animal data, but non-animal data.

I guess I also want to say at the outset that there are nine companies participating and they are all in the antimicrobial sector, Jim Wallace's company, S.C. Johnson has been a real leader in the effort, as well as Proctor and Gamble, and I think it's important to understand that the motivations here are not cost, they're not timeliness, they're not certainty. Each one of these companies, I think, recognizes that it will be more costly to run the non-animal assays, that they may very well end up with judgments on the part of EPA reviewers, and I was happy to see Tim McMahon and Jonathan Chen in the room from AD because they are our clients on this. It may very well be the case that they get more conservative toxicity category decisions as a result.

So, each one of these companies, I think, is to be commended for what I call their corporate ethic on these issues.

And, finally, I think what our objective here today is, is just to share with you some progress that's been made on the initiative because we are now probably about three months away from submitting what's called a background review document to ICCVAM for its consideration.

So, why don't we go -- I don't know where we are here.

MS. LEVINE: I don't know where we are, either.

MR. QUINN: So, what's important to understand, I think, about this is that the goal is for ICCVAM to approve a set of assays that would be used for eye and dermal irritation to be alternatives to the Draize tests which are now in place and have been in existence for 60 years. A good deal of progress has been made on ex vivo and in vitro assays that allow for judgments to be made of the kind that we're talking about here.

And this is the other important thing to understand. This is not a typical broad validation

exercise involving all products, all chemicals, all sectors. This is an attempt to do a pilot so that we can go ahead and see if we can identify assays that work for a narrow class of products, namely antimicrobial cleaning products where there are an unusually robust database, and for a very specific regulatory purpose, namely to allow EPA reviewers to make decisions about category toxicity decisions. That's all we're talking about.

It may be self-evident, but what we're trying to do as an overview here is look at the in vitro information that we have, and I think this is really where we found we have more data to generate. We've had to go ahead and run some of the assays at the in vitro institute out in Gaithersburg, Maryland, so that we have a substantial amount of paired animal and non-animal data available. As I said before, the objective here is to make available these alternatives for EPA category labeling decisions.

Tina?

MS. LEVINE: So, basically, this slide, I think, pretty much says what you just said. What we're doing is we're gathering the extant data on eye and skin

irritation, both from animal and non-animal tests, and then we're filling in some of the gaps at least on the in vitro side, and we're trying to develop a way to compare the in vitro data with data from the Draize tests and also from the low volume eye tests, and develop a background review document that will be reviewed by ICCVAM.

And there are -- I think there are eight or nine -- these are the eight companies that -- I think they were presented at the last ICCVAM meeting -- that have submitted data and are assisting us in developing the information we need to prepare this background paper.

For the eye irritation studies, there are three alternative tests that are being looked at. The Cytosensor assay and the EpiOcular assay are both assays that tend to be good for distinguishing labeling in the mild to moderate range, and the Bovine Cornea Opacity and Permeability assay, BCOP, is better for those agents that have more severe eye irritation effects.

On the dermal side, there's an in vitro study, EpiDerm, and then there are also data on human skin patch tests.

MR. QUINN: I'd just say since human studies have been such a lightning rod issue and Jim has had the pleasure of sitting through now several HSRB meetings with a very independent and active outside board of advisors on these matters, the human testing would be used in this case for confirmatory purposes, if necessary. We're actually working -- I am -- pretty closely with John Carley (phonetic) and Bill Jordan who've headed up a lot of the agency's efforts and it's quite likely the HSRB will look at some dermal irritation tests of the kind that we might use here at the January and spring meetings of the HSRB.

So, what progress have we made? We've gotten to a point where we've got data that's been blinded, confidentiality has been assured. We've got about 330 animal studies, 280 with full information and 500 in vitro studies, about 160 of those are paired with animal data. As Tine described, we've found that you can't select just one assay for this group of materials, for the eye irritation side. You really need to have a couple that look at products, end use formulations, at the more mild end of the spectrum, and then use the BCOP

assay, the bovine ocular assay for testing of more severe or corrosive materials.

We've, as I said, been spending quite a bit of time filling the gaps with testing, but the BRD is now, I would say, 70 to 80 percent prepared. Let's go to the next slide.

We just briefed -- Bill Stokes is the head of ICCVAM, the interagency testing validation entity, and we went down to North Carolina and briefed Bill about two months ago, and then just recently here in the past couple of weeks, Glen Sowers (phonetic) from Proctor and Gamble and Roger Curran (phonetic) from the In Vitro Institute briefed the Ocular and Dermal Testing Working Group out at NIH in a briefing that a number of people here attended.

I do want to acknowledge Tina's leadership on this and she was there and made very valuable contributions to the discussion.

John Redden (phonetic), I also want to acknowledge for some of his colleagues in the room. He's been an important player in all of this.

And so, what we're looking at we think now is

submitting a background review document in the spring, hopefully be back to you guys in May to report on how ICCVAM has responded to the proposed testing regime, and the objective here is to have something teed up for you guys to consider and then for EPA to consider as alternative science policy or an interim science policy on the alternative tests by the end of next year.

MS. LEVINE: I have a couple of more slides. I just wanted to -- I'm pinchhitting for (inaudible) who was also a member of the Ocular and Dermal Technical Working Group. When she saw that there was a discussion of alternative methods on the agenda, she asked me to bring something to your attention, and I think there are a couple of handouts in your materials.

In the 2006 Appropriations Bill, there was some language put in asking the ICCVAM to develop a five-year plan that addresses research, development, translation and validation of new and revised non-animal and other alternative assays to be integrated into federal testing programs. The specific language is in your handouts. There is a process that involves public participation, and I think that's why we wanted to draw it to your

attention.

OSCP, that's Cliff Gabriel's organization, is going to organize the EPA priorities. NIEHS will organize all of the federal agencies' priorities. And as I said, the process to develop a five-year plan includes opportunities for public comment on the criteria for selection and the draft priority list. I think a time line for how this plan is going to be developed is also in your handouts. Since there was public participation, we wanted to get it to your attention as early as possible. Thank you.

MR. JONES: Thanks. For those of you who are newer to this committee, this issue was brought to the PPDC several years ago by a narrow group of the PPDC, the consumer products representatives here as well as the animal rights representative here or your predecessor. Although the broader group didn't want to actively participate in it, the broader PPDC wanted to be kept apprised as this moved forward, and we were very serious at EPA about non-animal test methods. And although the consumer products element of it wasn't that interesting to everybody, I think everyone had some sense that they

wanted to keep apprised because future efforts could be of real interest whether you're from the other parts of the industry or the public interest community. So, we committed to doing that and that's why we came back and do come back periodically to give you an update on where this effort is.

Are there any questions or comments? Christie, did you have a --

MS. STOICK: Yeah, I just -- I want to just quickly introduce myself to the -- I know I've met a few of you. I am Troy Seidle's replacement, Christie Stoick. Feel free to come to me with anything. I was a little late yesterday running between meetings, so I apologize. I just wanted to really express my thanks to Patrick and Tina and EPA for this initiative because for the animal welfare communities, the Draize test in particular is a little bit of a lightning rod and we're really happy to see at least this portion move through and have something happen on it. So, thanks.

MR. JONES: Thank you. Any other observations, comments, questions?

(No response.)

MR. JONES: All right, Pat and Tina, thanks very much.

I believe we have one public commenter. Bernalynn McGauffy (phonetic). I saw Bernalynn earlier.

(No response.)

MR. JONES: Okay, all right. Okay, in terms of follow-up, I don't think I necessarily have the solutions to the issue we saw coming up yesterday, and I can expect it playing out again in some of our other work groups and that's around the performance measures. The issue -- very generic issue actually. I don't think it's at all just related to that, which is that we're relying more on work groups, although we're getting pretty robust participation. Some of the work groups have over half of the PPDC membership on them. Obviously, not everybody is in every work group and how we -- what we can do to avoid having the people who didn't participate have to recreate it in the full committee, then you've sort of defeated the whole purpose of the work group and we'd never have enough time to have that kind of deliberation, while at the same time making sure that they have enough knowledge of what we have done to meaningfully participate when we

bring work group recommendations to the full committee.

So, Lori, if you have any thoughts on that, I'd be happy to get your perspective.

MS. BERGER: Well, yeah, I just wanted to -- first, it's been a very good meeting. I really appreciate the breadth of information here. But this work group issue, I wanted to underline a comment that Bob Rosenberg made yesterday about if we could maybe review the process of the work group so that when -- you know, the work group -- I thought the Performance Standards Group did a really good job yesterday in summarizing their points and then it was almost like their efforts were somewhat derailed in the larger work group. I think for those of us spending time in work groups, it's kind of discouraging because you kind of feel like you get to a point where -- closure is not the right word, but a certain level of understanding or presentations to the larger group -- and I'm sure they must have felt kind of discouraged that now they're starting over at square one.

So, I think because there's so many work groups going on now on some extremely complex topics, you know,

worker protection and spray drift, it would be really a good time to kind of review with everyone the process and where we can agree to disagree and kind of let it move to the next level.

MR. JONES: That's (inaudible) why don't I do that. Every one of you is going to ultimately want to have the same right preserved if something comes forward that you're like, I cannot sign on to that. So, I think it's important that we solve it because a solution will solve everyone.

Work groups -- FACA committees can have subgroups that work in a more focused way on a topic. However, recommendations to EPA or to any government agency using a FACA need to be brought to the full committee. There's a process that is brought to bear to make sure we have adequate representation on the full committee and you're appointed to the committee, unlike the work group which is much less formal. So, only the FACA committee, you, can actually make a recommendation.

So, what has been worked out over time with the FACAs is that the work group brings its product to the full committee for the full committee to decide whether

or not it wants to endorse it or not. Again, if any of you saw something on any topic that came from a work group and you were asked to endorse and you felt you couldn't do that based on who you were representing or your own personal views, you can say I can't endorse that.

Now, we can just sort of capture that and say, you know, this part of our FACA recommended it, these parts didn't. But I think it's usually worth one more effort to see if it's just about getting everyone's perspective to be captured in a recommendation. I think you do that one extra try and then you say, okay, well, this part of our FACA could endorse it and this part couldn't and that information goes back to EPA.

So, that's sort of how we've worked our work groups. I think that one of the process issues that we'll want to build in is a product of a work group getting distributed to -- not only distributed to all of the members, but with an opportunity -- which we did in the case of the performance standards, but we then didn't say, and if you have any issues with this -- oh, by the way, we're going to ask you if you can recommend this

paper to the EPA as advice at our meeting. So, if there's anything in here that you're uncomfortable with, please speak now so that we can try to bring this to closure at that meeting. That's probably a step we'll want to build into all of our work groups. It's a review loop as opposed to here's the document for consideration.

I mean, that's one idea we could use to -- again, the other thing is that in the work group environment, you don't have to have consensus. You can just talk about this group thinks this and these group of people think that and the third group are thinking this. We weren't able to all come up with a single. Or you could choose to instead try to compromise to get something that everybody can sign on to. Either of those approaches are fine.

So, that's the process and, again, I think that what I tried to protect in that situation is something I'd want to protect for anybody who said I can't sign on to that. I would like to get to a place, though, where everyone's had an opportunity before this meeting to say, I have a problem with this, not just an opportunity, because everyone can join every work group, but we'll

never want to achieve that. It would get too clunky. There will have to be some interim step where people can look at it before it comes here and express their issues.

Carol? Amy? Sorry, Amy.

AMY: Yeah, actually, I was going to suggest the business of trying to bring an interim level one up where you are getting close to -- so that the committee itself knows that this is -- it has to go through a further step and it has to come back to the entire group and there will be times for input from the entire group. I think that's very important, so I'm glad that you left that open. It may be frustrating to those of us on work groups, but the reasons for people not sitting on work groups are because either they don't have the time or they don't feel they have the expertise, and then when the reports come to them, they realize that there are implications that they had not thought of that they actually had some expertise in, and it can be very important for you to capture that. So, I think that would be a huge -- if you can build that into each of the work groups, that will be very helpful.

And, also, if there are things that you know

you're going to want a vote on, it would be helpful to not only send it to the members of the full PPDC a couple of weeks before the meeting, but to tell them that we are going to be voting on this at this time so that they'll know that they need to read it ahead of time.

MR. JONES: Those are some good ideas. Cindy? I'm sorry, Carol. You never want to give up your space in line. No, go ahead, Carol.

(Laughter).

MS. RAMSAY: I think that's the best alternative. However, if we end up with a situation where that preparedness wasn't allowed and it really -- you know, the work group met the day before and they signed off on the document and you just end up in that situation, I don't know if this would be a viable alternative to where you discuss it like we did the other day in the PPDC and then if you have how many people cannot buy off on this, maybe you have six people that don't, is there a way that those six can provide comments to a smaller group and send out that revised document to the full PPDC strictly just by email and say, can you now live with this amended document, and if you could just

get that approval by email. I don't know if that would fit your criteria or procedure.

MR. JONES: Yeah, that's another idea that we should explore. Actually, we may be able to even explore that in the context of the performance standards paper.

MS. RAMSAY: Correct.

MR. JONES: Cindy?

MS. BAKER: I think my comments are similar to what both Amy and Carol said, but I think, also, one possible alternative is to say that, you know, the recommendation that comes from this group could very likely say here are eight points that we have consensus on and here are three that this group feels very strongly about that the rest didn't, so that you have that and so that we can move beyond that.

But I also think the point that Bob made yesterday is one that we shouldn't forget, which is that those of us who volunteer for those work groups have an obligation to go back to our constituents and get feedback and bring that in, so that even if not everybody can participate, you know, if it's Ray participating, that Ray and I and Beth talk about what the registrant

from the ag-chem side might view on something like that. So, I think if we try to do our homework along those lines a little bit, I think that will help, too.

And I think a little bit in Sherry's defense, I think her email when she sent that paper out, she said, you know, it's coming to the group and we can't do anything unless the group approves it. So, I think she tried to do it. I think some of the ways that you explained it and that Amy talked about would make it clearer for everybody. Read this and be ready to voice your opinion. But I think she did try to lay that out for people.

MR. JONES: Right, thanks, appreciate that. I think that one of the -- your idea that you'd say, here's where there was consensus and here's where there wasn't is definitely sort of a next tier -- you know, if we give it one more short, you can't get that, that would be the place to go. I think that when I know that we've had broad enough participation, one of the things I may do in the meeting is if someone is objecting to a piece of it, I may ask someone who also represents that same part of the stakeholder community to -- well, why don't you

answer that question because you were in the meeting and have people -- but I would like for there to be that coordination amongst you all, but I certainly can't mandate that that -- if you're sort of representing the same general type of -- part of the stakeholder community that you are working together, although obviously that would expedite things and I think make the process more efficient. I think it's a good idea.

Frank and then Caroline.

MR. GASPARINI: What we faced here is very similar to working for a trade association and having to bring position papers to a board for approval. It's almost the exact same process. And we used to do that, write a position paper, bring it to the board, when our board was smaller, they would approve it. The same as faced here. As this group gets bigger -- our board's gotten bigger and the last few years, if we bring a position paper, just as you suggested, without pre-vetting it with them, they rewrite it and go through the whole process again.

So, just as you've suggested, we've gone to a two or three-step process that works very well. One of

the things we've done -- you all use a very -- you pretty much use the same format. I've been on a couple of groups that Anne has led and I've been sitting partly on the worker protection one. You all use a similar practice. We've tried to boil it down even more to a one-pager. Your presentation to the board might be 10 or 20 slides, but we try to get it down to a one-pager.

I've been using the Wharton-Case (phonetic) method, problem, statement, a teeny bit of background, list half a dozen or maybe even a dozen, a laundry list of possible alternatives that not everybody's going to agree with, in fact, you know many people won't agree with, and then you come down to your recommendation or recommendations. And if we don't have consensus, there might be two or three recommendations for the board to then choose from. This is where the committees came out. There are three alternative recommendations. We like this one, but they're all three suggested, we may not have consensus, and then the board has to decide which -- what this group would then do.

So, that works out pretty well for us. But it is a longer process than it used to be.

MR. JONES: Thanks, Frank. Caroline?

CAROLINE: I just want to commend you for the discussions we had today. I thought they were just great. I think that we're really getting into some good substantive issues and in a timely way, so we have time to react to them, think about them and talk about them. That's really great.

I would urge the group, however, as we talk more about the complexities of our process, to remember that this is just advice. You know, we're not voting on anything on the Hill, thank God. Thank God they're not either right now.

(Laughter).

CAROLINE: So, I think that -- you know, I mean, it's good to perfect our processes and I think work groups are a great thing and I think it's great for everybody to get their input in. You know, I wouldn't want to see anybody feeling like they were excluded at the end of the day. But I do think we ought to remember it's just advice and they're going to take the advice they think really works and they're not going to take advice that they don't think works no matter whose

opinion it is.

MR. JONES: That's right, Caroline. I appreciate both of your comments. It's advice and we really want advice or we wouldn't be doing this. At the end of the day, though, we're going to move forward whether we've got a formal recommendation from this group or not. I'd rather have recommendations. Again, as much consensus or as little as there is, I'd rather have that formalized recommendation than not. But we're not going to not do things. We're not going to move forward in this program because this group's unable to proffer an official recommendation.

Amy?

AMY: Just one more comment in relation to Carol Ramsay's comment about trying to do things, when necessary, by email and have comments submitted by email that we could all read. I would counsel about thinking hard about doing that because if we start doing that, it makes even more of a time commitment for everybody here, and I doubt that 40-some people are going to put in the time commitment that they really need to do to give good comment back.

The other thing is I really appreciate hearing the comments that my colleagues and my peers make and it changes what I might think and it changes how I might vote on a particular issue, too.

MR. JONES: That's a good point. Gary?

MR. LIBMAN: I agree with everyone who said that -- I think both days were excellent. This particular PPDC series was excellent, I thought. I'm just curious from your perspective. Give us some feedback on a PPDC perspective. When you say that you're doing something and you have the backing of PPDC, does that have an impact? Do people -- does it matter what our advice is?

MR. JONES: It definitely matters. I think that the two most -- well, there's three very recent experiences around that where it mattered a lot in terms of what we were doing. The registration review rule would never have happened in the way -- with the substance that it has, nor would it have made it through the process, the interagency process as expeditiously as it did had we not gone through this process. And that was both for process reasons, because we had -- process reasons being that we had stakeholder (inaudible), but it

was also because of the substantive reasons of what people -- the advice that we got. And so, I think that that is sort of the gold standard of how we'd like to operate.

Arguably, a procedural rule is going to be easier to do than a rule like the worker protection or the certification and training rule, but I think that's why we're trying to do it that way as well.

When we were going through the agency process around -- on the strategic plan, as Sherry said, that everywhere up the chain, people did not want to hear about that there may be these other societal benefits above and beyond public health and environmental protection, and in a licensing program, although you're always ensuring public health and environmental protection, sometimes the action, in and of itself, is supporting some other social benefit. A me-too (phonetic), for example. A me-too is, by definition, neutral to public health and environmental protection. It's the same thing as something already registered. But when you license a me-too, you ultimately lower the price of the product, which drives another benefit. And had it

not been for the work group saying this is an important part of what you people do over there, I don't think we would have been successful in convincing OMB that it was an important element of our strategic plan.

The worker protection certification and training, the initial advice we got from the subcommittee was like you're taking on way more than we can possibly digest in the schedule that you've given us. So, we've done a couple of things. One is we're going to take a little bit longer, not much longer, but we're also trying to focus in on what we're trying to do. So, I mean, I think just in the last year and a half there have been a couple of very important examples of how advice we were given has affected how we've moved forward both in substance as well as in strategy and timing. So, I find the exercise to be quite useful for myself as a decision maker in the pesticides program, and that's just off the top of my head.

Any other -- yes, Matthew?

DR. KEIFER: I just want to express my appreciation for being invited.

MR. JONES: We're glad to have you. We're glad

to have all of you. Yes, Bob?

MR. ROSENBERG: I think I've been turned off. It's 1:00 and I'm not suggesting we have this conversation now, but at some meetings in the past -- I'm not going to make us be late. At some meetings in the past, we've done some agenda setting or agenda building for future meetings, and I don't know, again, that it's a good time to do that now, but in the course of the discussions that occurred over the last few days were just a couple of things I thought might be worth putting on the list. And you know what, I know if I say what they are, then everyone else has got theirs and then we'll be here until 2:00, so I'm not going to say what they are. But what I was going to suggest -- well, no, if you want, I'll be glad to.

(Laughter).

MR. ROSENBERG: What I was going to suggest was could we have some opportunity -- I'm sure everybody has similar thoughts or things they heard that triggered other things in their mind. Maybe sometime over the course of the next month or so where the members of the committee could have some opportunity to maybe suggest

some topics that they think might be useful.

MR. JONES: Yeah, we'll definitely do that. Why don't I just sort of now segue into kind of some follow-up because the agenda is becoming, and it has been for the three years I've been here, at least half-dominated by our work groups. If you got work groups going on, they're coming back and reporting. But then that does leave the other half or third or whatever is left over.

So, why don't I just start with the specific follow-up? On the Performance Measures Work Group, we're going to have one more effort to see if we can bring that to closure, and that may be -- we'll have a meeting here, but I expect many people will participate by teleconference, so that's perfectly fine and we're going to make sure some specific individuals who hadn't been on that work group who said, you know, I really think I need to make a statement, will be specifically brought into that.

On spray drift, it looks like there's one more meeting and that group is going to be prepared to bring a report back to the PPDC, and again, we'll be talking to Anne and Jim Hanlon about what kind of mechanism can we

use to make sure those of you who were not on that work group are aware of that early enough to have some feedback before it comes here. So, we'll have dialogue here, but I want to make sure that you've had some chance to have some awareness.

Worker protection and the certification and training rules actually have a long list of things they're going to be doing with their work group between now and our next meeting involving revisions of the papers that you all have seen that will hopefully allow that group to come back with some set of recommendations, whatever they may be, around areas where there is agreement or not agreement.

And then we are going to initiate a registration review work group that's going to be very -- it's going to be case studies working on specific -- the first couple of chemicals out the gate in registration review, looking at sort of the preliminary choices we're making about, well, we think we need this assessment or we don't think we need an assessment here. We're thinking that this data may be necessary and we made these judgments based on this vast body of information.

If you're interested in that, I know a number of you have already expressed an interest and Margie's got those names. If you are interested, please send Margie Fehrenbach a note, who all of you know, and we'll, between now and the next meeting, pull that together. That group will probably have a first meeting in the February, March, probably not much later than April time frame.

So, I definitely see all four of those coming back at the next meeting, and depending on what mechanisms we use, I'm not sure how much additional stuff -- for example, I have this feeling that we could spend a fair amount of time on the spray drift report and the worker protection certification and training, and because they're so important to us, I'm inclined to give them as much time as they may need at this meeting to see if we cannot have to go back to another work group meeting.

So, with that being said, we'll solicit some ideas about other topics that you may like to have at that next meeting. We are thinking of an April/May time frame. I'm more inclined to May because I want to get some product out of the two -- some of these work groups.

I know Bill Diamond feels he needs 'til May to get something really concrete on the worker protection certification and training front. Anne may feel the same way on the spray drift. I'm not sure. She may be ready by April or March. So, my gut tells me that May will be the next meeting.

And Margie next week will email out to all of you proposed dates. We are very -- we try to avoid dates that create multiple conflicts for multiple people of you. I know this week was also a methyl bromide alternative conference and I know one of our members was able to make it despite that conflict. But one, because I think Dan actually runs that meeting, wasn't able to get back. But it's not ever possible to avoid all conflicts, but we'll try to get some sense from you as to whether we're creating conflicts that hits multiple of you.

Okay, so I think we are -- I'm sorry, Carol, did you have one -- Amy definitely gets to sit down there next time.

MS. RAMSAY: It's just dates, the sooner we can get them on the calendar, the faster we cannot have them

be blocked off by something else.

MR. JONES: Absolutely. We'll try to do that.

UNIDENTIFIED FEMALE: Just one suggestion because we had such great discussion today and we always have really good discussion here and there's never enough time. One possibility may be for allowing us a little extra time would be for the program update, particularly like the registration information, could be just a handout that we could get ahead rather than an actual presentation, and then if we have questions --

MR. JONES: That's a good point.

UNIDENTIFIED FEMALE: -- do we want to ask them.

MR. JONES: That's a very good point. All right, well, thank you all for all of your time over the last three days, I think some of you have been here working with us. I really appreciate it. Safe travels. Have a good Veteran's Day.

(The meeting was concluded.)