Transcript of Meeting of

Pesticide Program Dialogue Committee

Conference Center

2777 Crystal Drive

1 Potomac Yard South

Arlington, VA

July 10-11, 2013

ATTENDANCE LIST

Steven Bradbury, Ph.D	Chair, Director, Office of Pesticide Programs Office of Chemical Safety and Pollution Prevention
Margie Fehrenbach	Designated Federal Officer Office of Pesticide Programs
Jim Jones	Acting Assistant Administrator Office of Chemical Safety and Pollution Prevention
Sarah Bittleman	EPA Agricultural Counselor
Marty Monell	Deputy Director Office of Pesticide Programs
Richard Keigwin	Director, Pesticide Re-evaluation Division Office of Pesticide Programs and EPA
Helen Golde	Deputy Director, Office of Protected Resources, NMFS
Robert McNally	Director, Biopesticides & Pollution Prevention

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Jennifer McLain, Ph.D	Deputy Director, Office of Pesticide Programs Antimicrobials Division
Mary Manibusan	Director, Exposure Assessment Coordination & Policy Division Office of Science Coordination and Policy
Lois Rossi	Director, Office of Pesticide Programs, EPA, Registration Division
Jerry Baron	Executive Director, IR-4 Princeton, NJ
Steven Coy	National Honey Bee Advisory Board American Honey Producers Association

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Bret Breton	California Department of Pesticide Regulations

P R O C E E D I N G S

DAY ONE - JULY 10, 2013

MR. BRADBURY: Good afternoon, everyone. If -- everybody could catch their seats, get their seat, we'll get started.

MS. FEHRENBACH: Would everybody please take your seats.

MR. JONES: Thank you.

MR. BRADBURY: Thanks, everyone. This is Steve Bradbury speaking, for those on the -- on the phone, Director of the Office of Pesticide Programs at EPA. I want to welcome all of you for joining us for the PPDC meeting, the public that's listening in and in the room here at Potomac Yard, as well as all the members of the -- of the panel.

As you know from the agenda and some of the work you've all been doing in work group meetings, earlier today we've got a full agenda and a lot of important issues to work through, so thanks in advance for all the hard work the members of the panel have been -- been putting in over the last six months and certainly this morning.

Before we get started into the meat of our agenda, I want to share some opening comments and welcoming comments. And we have two very important

guests at today's meeting and we're really honored to have -- have them here, Jim Jones, who's the acting Assistant Administrator for the Office of Chemical Safety and Pollution Prevention, and Sarah Bittleman, who's the Agriculture Advisor to the administrator -- administrator, also joining us today. Now I'll turn it over to Jim and Sarah for some opening comments.

MR. JONES: Thank you, Steve --

MR. BRADBURY: Um-hum.

MR. JONES: -- and Sarah. Let me add my welcome to everyone for coming here today. I know we have a number of new members to this important advisory committee. And to those of you who are new to the Pesticide Program Dialogue Committee, a special welcome to this effort.

For those of you who -- who don't know me, I've got a pretty long history with this program. I had Steve's job some time ago now, and so some of the faces are -- are more -- there are more new faces to me than -- than there had been maybe five years ago, so if I don't know you hopefully sometime over the -- the coming months and years I will get to know more of you.

I have long thought that this was one of the most effective committees that the -- the federal government or the agency runs as it relates to getting

stakeholder feedback about the direction of a particular program, in this case it's the pesticide's program obviously. The -- the input that we get from each of you in -- not only in this -- in this meeting itself, but in the meetings that you participate in, in the various subcommittees that you participate in, it is very important and useful information for this organization as we chart our course path, our -- our path forward on a number of very difficult and complex issues.

I think one of the things that we learned a little earlier in this dialogue committee was that getting together a couple of times a year, given the density of the topics, wasn't giving the topics justice and that they were so complicated it required a little more energy and effort. And I know many of you have -- have devoted many, many hours working through many of the issues that are on today's agenda to help us better understand the perspective of vast and diverse stakeholders that are -- that are impacted by the decisions that this -- that this organization makes, so thank you for that.

I also often say that participatory government is such an important part of what -- what it is about to be in America, but I also understand how hard and how costly it is to participate, because the -- the issues

are so complex often. And again, thank you for the time and energy that each of you give to helping us do a better job through your participation.

I did want to just touch on a couple of the issues that I know are on the agenda just to -- to -- so you understand the -- the -- the level of -- of priority and importance they are to me in -- in my role as the assistant -- acting assistant administrator under which the pesticide program falls. Not to say that everything else on this agenda isn't important, it is important, but there are -- there are a couple of topics that are -- are of particular importance to -- to me, some specific to this program, some have actually a little broader scope within -- within my organization.

Pollinator health, a huge priority to the administrator -- the acting administrator. I expect that when we have a new administrator hopefully in a week or two, it's going to be a huge priority for her as well. And it was a huge priority to -- to the former administrator, and it is a very big priority of mine and I know of Steves. It is something that we are very -- working very hard on and we are struggling with many of you about how to get our arms around the issues affecting pollinator health in the United States in the role that pesticides play in that, and so I -- I'm very

appreciative that the PPDC spent as much time as it does and actually has been for a number of years.

It is not as if this organization just figured out last week, last month, last year that there were important issues. I think it was over five years ago that the PPDC began working on pollinator health issues, so thank you for that, it's -- it's of critical importance to the country and to -- to -- certainly to this -- to this organization and I know to many of you.

The Endangered Species Act is something that has -- we have struggled with mightily for many years, an area where I think we are beginning to get a little bit of traction. Glad to see our colleagues from the services, as well as USDA are here who -- they have routinely been members of this committee, but the -- the issues associated with USDA I know are of critical importance to them as well, so, again, you guys are focusing on an area of great import to this organization, EPA, as well as also chemical safety and pollution prevention.

Computational toxicology, which I -- I just wanted to give a -- a little bit of a -- a shout out to all of you who have been working on that. Thanks to Steve for his leadership in this arena, which I -- I believe will -- in the future the people who succeed the

likes of us in these jobs will be very grateful that we spent as much time, energy, and effort trying to figure out how to take advantage of some of the new and emerging science around computational toxicology.

What I -- what I say to -- to my team is that we -- we want to take this as far as the science is going to allow us to, and that -- that -- that distance seems to be changing all the time. Fortunately it seems to be -- be getting further out, in that I think it will take us farther than we thought even a year ago. But we will only take it as far as the science allows us to, and that's something that -- that we all firmly are committed to here.

And we -- we understand the importance of doing it not in -- in a room in Crystal City by ourselves, but doing it out in the open. The only way to do that is with -- with stakeholders, and so I'm -- for those of you who have been able to participate in -- in that exercise of huge importance, that stakeholders understand what it is that we're doing and what it is that we're not doing, and ultimately we're going to need to have enough buy-in from the stakeholder community if we are really going to fully avail ourselves of this emerging technology.

The -- the -- the end of the day the objective is that we can be making better decisions that are better

for human health and the environment and that we're able to do it more cheaply and more quickly. And I think if we're able to achieve that, there -- there shouldn't be too much people are not happy about with respect to the -- the use of that science.

And lastly, and I -- I assume you guys will spend a little bit of time on this, we are in an incredibly difficult budget situation. For those of you who around the table who are with state organizations, you've got something up on -- on that and that you've deal with incredibly difficult budget situations where you've seen reductions in the range anywhere from 10, to 30, 40 percent. Unclear we're going to see reductions in the high end of that range, but it is very clear to me just -- and -- and this is with no -- nothing other than I'm -- I'm watching the process.

I have no inside information, I am watching a process that is -- anybody can be watching, I expect many of you are. It doesn't seem likely that -- that congress is going to be giving us more money in the future, I would be shocked if we got the same amount of money in the future. They figured out a way around the -- the -- the PRIA threshold that we had last year, and I figured -- you only have to figure it out once and you can keep doing it.

We are -- we are in a budget constraint environment and we are going to need to figure out how to get the job done here, which is a critical job for -- for the people of this country. We're going to have to figure out how to do that with -- with fewer resources going forward, so I just -- hard to imagine that's not somewhat in the -- in the back of the mind of most of the people who are participating as actively as you are in your government, but -- but useful just to make sure that that was on the table.

So, again, you know, thanks very much for all of the work that you have done and the work that you're -- you're planning on doing, it is hugely important to us in -- in how -- us how we figure out how we're going to -- to go forward. And -- and in deference to -- to Steve, I've -- I've made it a long practice to come, say hello, and to leave, because this is the advice that -- that Steve is getting in -- for his program, he keeps me very well apprised of what he's doing.

But as someone who sat in that chair before, I know how important it is to be able to get, without your boss sitting there looking over your shoulder, the kind of advice that you're all getting, so I -- I make it a practice always to come and to -- to welcome all of you. But I will be leaving you all to your good work in just a

-- in just a few minutes, so I -- I wanted to -- and you know that that's -- and generally my practice is to sort of give Steve the space to get his work done. There.

MS. BITTLEMAN: Thanks, Jim. So I'm Sarah Bittleman, I'm the ag counselor to the -- to the administrator. And -- and I've turned my phone off now so I -- I won't be interrupted, just Jim, so I apologize about that. I just wanted to take a few moments to say hello to everyone here and to let you know how appreciated your work is. I'm sure you hear that from other folks, but I wanted you to hear it from me.

I'm relatively new in this position, only been it for about four or five months, before that I spent a bunch of years at USDA working for the Secretary Vilsack. As the ag counselor to the administrator, I get to interact with all of the program offices at EPA. And let me assure you that the program offices that you guys are dealing with through this FACA are some of the best that we have, the work that you're doing is really important, the input that you give is taken seriously.

I want to thank everybody for the time and effort that they -- that they put into being truly participatory in this process. A lot of the issues that you will cover that Jim touched on are issues that I actually am engaged in at various levels, that I was

engaged in actually at USDA, and that I'm still engaged in at EPA. I am all about adding value to your process, so as you guys move forward with these conversations it is helpful to all of us at EPA to get your -- to get your sage input on them.

I also, for -- for -- I just really wanted to -- to just say hello to everybody and to let you know that my door is open to everybody at all times to discuss agriculture and how it relates to EPA. I'm -- I'm just over -- just across the river on the second floor of the -- of the building and am very -- I meet with a lot of stakeholders in agriculture and a lot of stakeholders in the chemical industry, but I'm open to having conversations about these subjects at any time. They're really important, they're -- they're far-reaching, the work that you do -- do here will have an effect for a long time.

So, like I said, I just really wanted to express my appreciation for all of the work that you're doing and I know that -- that Steven and his offices all appreciate it as well. That's it.

MR. BRADBURY: I thank both Sarah and Jim for -- for joining us to -- to kick off the meeting. I thought what might be good, Jim, reflecting on some faces you've seen and some are new, and for Sarah some of these faces

will be new, why don't we introduce ourselves and -- and go around the -- go around the room, that should work out well, I think, for Sarah and Jim's schedule, and maybe a couple of seconds on the organization you're associated with.

As we go around the room, Valentin Sanchez from the Oregon Law Center should be on the phone, so he's participating. And then Wayne Buhler from North Carolina State's on vacation, but he told us if he gets a connection in the Smokey Mountains he'll try to call in as well. So I'll sort of introduce -- let those folks -- let you all know those folks are trying their best to -- to stay connected with us during the next couple of days. So why don't we start with Marty.

MS. MONELL: Marty Monell.

MR. BRADBURY: Did you not hear me?

MR. ARMSTEAD: I'm John Armstead, EPA Region III, we're the lead region for this program office.

MR. BRADBURY: And one -- hey, Jacob, just one thing.

MR. VUKICH: Yes?

MR. BRADBURY: If you're -- if you're sitting in for somebody, you're an alternate, if you could just make that clear when you introduce yourself. Thanks.

MR. VUKICH: I'm Jake Vukich with DuPont Crop

Protection.

MR. TAYLOR: I'm Donnie Taylor with the Ag Retailers Association.

MR. TAMAYO: Dave Tamayo, California Stormwater Quality Association.

MR. SMITH: Steve Smith, SC Johnson.

MS. RUIZ: Virginia Ruiz, Farmworker Justice.

MR. SCHERTZ: Scott Schertz, Schertz Aerial Service and the NAAA, National Agricultural Aviation Association.

MR. ROBERTS: I'm Jimmy Roberts, I'm a pediatrician with the Medical University of South Carolina.

MS. PATTISON: Hello, I'm Fawn Pattison, Toxic Free North Carolina.

MR. WHALON: Mark Whalon, Michigan State University.

MR. WHITTINGTON: Andy Whittington, Mississippi Farm Bureau Federation, replacing Ken Nye from the Michigan Farm Bureau Federation.

MS. HURLEY: Janet Hurley, Texas A&M AgriLife Extension, replacing Dawn Gouge as her proxy.

MR. DELANEY: Tom Delaney, Professional Landcare Network, The National Lawn and Landscape Association.

MS. CLEVELAND: Cheryl Cleveland, BASF.

MR. BARON: Jerry Baron, IR-4 Project.

MS. BISHOP: Hi, I'm Pat Bishop with the People for the Ethical Treatment of Animals and I'm replacing Kristie Sullivan from PCRM.

MR. COY: Steven Coy, I'm a commercial bee keeper and I represent the American Honey Producers Association.

MS. LUDWIG: Gabriele Ludwig with the Almond Board of California.

MR. ROWE: Brian Rowe with the Michigan Department of Agriculture, standing in for Marylou Verder-Carlos representing ABCO.

MS. STARMANN: I'm Allison Starmann with the American Chemistry Council on behalf of our panel.

MR. GJEVRE: Eric Gjevre, Tribal Pesticide Program Council.

MS. RAE: Liz Rae with Sipcam, I'm here representing Biopesticide Industry Alliance.

MS. FERENC: Sue Ferenc for the Council Producers and Distributors of Agrotechnology.

MR. HANKS: Douglas Hanks with National Potato Counsel from Idaho.

MS. HARRIOTT: Nichelle Harriott with Beyond Pesticides.

MR. KEIFER: Matthew Keifer from the National

Farm Medicine Center.

MS. LAW: Beth Law, Consumer -- Beth Law with Consumer Specialty Products Association, also known as CSPA.

MR. GREEN: Tom Green, IPM Institute, sitting in for Marc Lame, Indiana University.

MS. PALMER: I'm Cynthia Palmer, American Bird Conservancy.

MR. MCALLISTER: Ray McAllister with CropLife America.

MR. WILLETT: Mike Willett, Northwest Horticultural Council and the Minor Crop Farmer Alliance.

MS. WU: Mae Wu with NRDC, Natural Resources Defense Council.

MR. GORDON: Scott Gordon from the Armed Forces Pest Management Board sitting in for the director, Captain Mark Beavers.

MR. CALVERT: Geoff Calvert, I'm a physician with the Centers for Disease Control and Prevention.

MR. SOUZA: I'm Paul Souza with the U.S. Fish and Wildlife Service.

MS. KUNICKIS: I'm Sheryl Kunickis, I'm the Director of the Office of Pest Management Policy at USDA.

MR. BRADBURY: So thanks again, Sarah and Jim. And -- and welcome everyone on the panel, as well as

participants for public listening in here at Potomac Yards and on the phone. For folks on the phone, just make sure your phone is muted. Sometimes over the years we've heard some interesting conversations on the -- on the phone and sometimes they're kind of fun to listen to, but generally speaking it's -- it's best to keep that phone muted. If you are interested in -- in public -- participating in the public-comment period, we can certainly do that by phone. And by getting the word in, we can -- we can certainly make that happen.

So I'd like to just spend maybe a -- a few minutes, just sort of an overview of -- of the committee and what it's all about, given that this year we have some new members on -- on the panel, and then maybe just spend a few minutes going through the agenda and just hitting some of the -- some of the highlights that are -- that are coming up.

Both Jim and Sarah have indicated the -- the input from -- from stakeholders is really important to the business of the agency. In the pesticide program and across the agency, I can't think of too many simple problems that have simple solutions. But those problems are solvable and there are solutions to be gained and to move forward environmental protection, human-health protection, and the other components of what we have to

take on, but reaching those decisions and having sustainable decisions are built upon input and bringing forth different perspectives and viewpoints to the -- to the kind of solutions that need to be brought to bear.

And this federal advisory committee is, I think, a very good example of how people from all sorts of different backgrounds, and perspectives, and -- and ideas come together and have historically been able to help us figure things out. And a federal advisory committee is just that, a body by which we can have some structure, an appropriate process to get that information in and to have dialogue, to have discussions so that we can explore different approaches, different -- different ways of trying to -- to -- to get things done, so it's -- it's critical to -- to the work that we do in the pesticide program.

We have another federal advisory committee, the Scientific Advisory Panel, which helps us think through the scientific tools we use in the -- in our risk assessments and form our risk management decisions. But as we move into policy issues, and sort of the risk-management perspectives, and the interface of the science with how we move forward, like in the toxicology 21 century arena, this FACA is critical to helping to bring it all together to help think through our solution.

And by having a -- a FACA like the PPDC, it's a way to make sure we're trying as best we can to get everybody's input. And everybody's input is valuable, everybody's input's valuable. And what makes it valuable to you as the public and us as the government trying to serve everyone, is by having that robust discussion and making sure all the ideas are coming forth. Ideas that aren't expressed, are ideas that could be untapped knowledge and untapped insight, and so having this kind of conversation is critical.

So I think alone all these problems are pretty darn challenging, and I -- at least I know I can't even begin to solve some of them by myself or with my colleagues. So working with all of you, I think we have a long history of working through issues and coming up with practical solutions. And again, it's hard, you know, and so we try to reach consensus. And if we do, that's really good, that's cool. And sometimes we won't, that's okay too.

What's really important for the agency is understanding what the various issues are, what are the different options, what are the strengths and limitations of different approaches, because eventually the -- the buck does stop with us and we have to make decisions and we have to move forward, and we have to move forward as

best we can with the intelligence and the insight that you all -- you all bring to bear.

And so for some of you who have been on the panel for a while you realize sometimes we reach a certain point and a certain topic, and we go, this is good, realize you didn't each consensus on everything, but this gave us a lot of good information. We understand the insights and the -- and issues behind the different proposals, and that helped us move forward. Sometimes we do reach consensus on certain components, and that's excellent, that's great too. We'll think about it, and then try to figure out how we move forward with -- with our approach.

So for those of you that are new, you start to kind of pick up sort of how the dynamics work. One of the things that's -- that's become, I think, sort of the modus operandi -- it is the modus operandi for the -- for this group, is all the work that happens in between our two meetings per year. We have five different work groups, and these work groups get created over time based on issues that are challenging and have some -- some life to them, they're -- they're not the kind of problems you probably solve overnight and they've got some staying power.

And so we use the work groups to help really

work through issues to -- to come up with options, and then to report back to the main committee twice a year with recommendations, if -- if things are ripe enough, so then all of the panel can then weigh in on recommendations or options that the different work groups are -- are putting forward. We've found over the years that that's the most effective way to ensure that we're making decisions, that we're making progress.

It's really hard with a group of about 50 people to -- to get into the details of some of the topics we need -- we need to talk about, so -- but there's -- saying at the opening I really want to thank everybody who's been on the PPDC for quite some time and all the effort you've been putting in various work groups. New members, you'll start to get a -- decide which groups you want to be involved in and -- and that's great.

And another aspect of the process is that people that aren't standing members on the PPDC can be members of -- of work groups. And Margie Fehrenbach, our DFO, makes sure everything's done right, but it's -- it's very doable. And, for example, the pollinator protection work group I think -- I know it has more people than sit on the PPDC. I think it's up to, like, 75 people right now on the pollinator protection work group, and that's great. Rick Keigwin and Don Brady I think sometimes get

grayer hair trying to figure out how to advantage all 75 folks, but that's okay because it means we're getting a lot of people engaged and a lot of people talking and working through solutions.

So, again, thanks for joining the committee, if you're just joining, and thanks for all of you who have been on for -- for a number of years. What I would like to do now is just spend a little time and just kind of touch on -- on the upcoming -- upcoming events for the next couple of days, and -- and then we'll get -- we'll get on with it.

The -- the first session is going to be chaired by Marty Monell. Marty's a -- one of the deputy office directors for the pesticide program, and among her many facets of her portfolio is helping us through the budget and aspects of budget implementation and forecasting, forecasting becoming quite an art and science lately.

Marty, among other things, also oversees the implementation of PRIA, which is the Pesticide Registration Improvement Act, and that's the act that provides some funds from the registrants that with appropriate funds helps make some of the business of -- of OPP get done and the basis of a -- of a coalition of -- of all of you that are instrumental in -- in -- in the PRIA process. So Marty will spend some time giving --

giving us all an update on -- on some of those issues, which I know are typically topics of interest and as Jim's highlighted it a challenging area lately.

After that, Rick Keigwin, and Paul Souza, and Sheryl Kunickis, and Helen Golde from National Marine Fishery Service will give an update on where were in -- in implementation of the Endangered Species Act, touch on the recently-published National Academy of Sciences' report on how to move the science forward, and -- and some other aspects of -- of the work we're undertaking as part of the federal family in -- in moving forward and getting a -- a sense of some of the coming events playing out with the NAS report.

After the break, Bob McNally will chair a session with -- with input from -- from the IPM work group to give you an update on some of the activities going on with the work group, as well as some updates from within EPA in terms of how we're structuring and managing our efforts in the school IPM area. Many of you know Bob, and know Bob from his most recent pass as the director of field in External Affairs' Division.

And within the last couple of weeks, Bob has now become the director of the Biopesticides and Pollution Prevent Division, and that's because Keith Matthews decided to maintain his law profession and -- and

continue his law profession in -- in private practice in -- in the D.C. area. So we wish Keith all the best and hope we don't see him on that side of the table in terms of legal -- legal issues, but we wish him well, and looking forward to Bob taking on this -- this new responsibility. We'll be in the process of -- of filling that position, and right now Jay Ellenberger, who many of you know, the Associate Division Director, will be the acting division director for this field in External Affairs' Division.

The last session today will be chaired by Rick Keigwin and Betsy Behl, who's division director in -- in the Office of Water. And Rick and Betsy will give you an update on a joint effort between our offices in -- in ways that we're trying to make it very easy for people to get information -- toxicology information about pesticides that are sometimes found in water supplies, and we'll give you an update on where we are in getting that information out and some of the approaches we're using to get that information disseminated so it's easy to -- to get at, then we'll have a public-comment period at the end of the afternoon.

And starting tomorrow morning, we'll -- we'll pick it up with Jennifer McLain, who is chairing our -- our TOX-21 work group. As you know, she used to co-chair

it with Vicki Dellarco, who is the senior science advisor to the pesticide program. And Vicki has retired over the last -- end of June was her -- her last week, so we also wish Vicki the best as she goes forward, tells me she's still going to stay involved in science. As you all know, she was an internationally-recognized expert in risk assessment and human toxicology, and I'm sure she'll still be busy and we'll probably see her name showing up in other activities that many of us interface with, so we wish her the best.

And Jennifer is working with lots of colleagues in the program and will continue to move forward with the TOX-21 effort. So tomorrow we'll hear a report out of the workshop we had yesterday, as well as an update on some other activities that have been ongoing in that -- in that group.

Following that session, Mary Manibusan, who's over in the Office of Science Coordination and Policy and heads up the endocrine disruptor screening program, will provide an update on where the program is in terms of scientific peer review they've been playing out this year, as well as some other the other aspects of the program implementation.

Marty Monell will then lead a session that she -- with the work group she chairs on comparative safety

statements, and Marty indicated you guys had a really great -- those on the work group had a really great meeting this morning, so I'm looking forward to hearing -- hearing the efforts that might have been playing out in that group.

Then we'll have a session that will deal with the pollinator protection work group, and I'm hoping to hear some recommendations from that work group in moving forward in several areas. That work group is very large and it has several subcomponents, including a group looking at labeling, a group looking at best management practices, a group looking at communication and training, and a group that's looking at enforcement issues. And we'll be hearing outputs from all the subcommittees and, as I understand, getting some recommendations of steps going forward.

Sheryl Kunickis will -- will join Rick and Lois Rossi in chairing that session, and -- and we're -- we're going to kick that session off with Sheryl providing an overview of USDA's activities in -- in pollinator health. USDA is the component of the federal government that has overall leadership and responsibility for -- for moving the federal government forward in -- in pollinator protection, so it's got to be good for Sheryl to give you an update on the activities across the federal

government, and then we can zoom in on -- on the efforts that we're undertaking through the PPDC.

After that session, Lois Rossi will chair the -- the presentation from the work group dealing with public-health pesticides, and -- and she's associated with public health, and we'll get an update from that group. And they'll be sprinkled in, these various work groups, various recommendations for moving forward, as well as some updates of long-going activities.

We'll then spend a little time at the end of the session tomorrow reviewing some of the action items or the homework that we'll have come out from the reports from the various work groups and try to crystalize some of the activities that will be happening in between now and the next meeting within the work groups; we'll also see if thee's some specific topics that we'd -- we'd want to address that may not naturally flow out of the specific work groups and get those up on the agenda; and we'll also take a look at calendars and pick a time likely in November -- a week in November, so we could start checking ahead when we'll have the next meeting, the fall meeting. We need to try to schedule those early, so we can reserve the room and -- and take care of all of the other logistics it takes to put a -- put a room together.

So before I turn it over to Marty and move on to the first session, I -- I want to take two seconds and thank Margie Fehrenbach, who's the designated federal official. And there's Margie, if some of you haven't met her. Margie has put in enormous hours in getting ready for this meeting and the process it takes to go through and seat new members of -- of the committee. It's been an unbelievably challenging effort, but she's fantastic. I don't think there's a better person in the entire agency from a number of perspectives than Margie, and we can't thank her enough for effort. So thanks, Margie. All right. And thanks --

MR. JONES: Have a good day.

MR. BRADBURY: -- Jim and Sarah.

MR. JONES: Two days.

MR. BRADBURY: Yeah.

MS. BITTLEMAN: Yeah.

MR. BRADBURY: So with that, I'll turn it over to Marty and we'll take on our first session of the afternoon.

MS. MONELL: Okay. Thanks, Steve. What I handed out, this is called, "Other duties as assigned," is a -- a budget summary, a couple of sheets. And I didn't want to get into a great deal of -- of detail, because federal government budgeting is really

complicated and you can -- you can make numbers say a lot of things, so I just wanted to show you the facts at a very high level and show the -- the first page actually depicts three years a pesticide program budget.

And the way -- the way the pesticide program budget is -- is articulated by the agency is it includes things such as the regions, the work that the regions do to support the pesticide program, the STAG grants that go to the state supporting the pesticide program, the AA's office for the support that it provides to -- to the pesticide program, as well as the amounts that are actually given to the program office to run the operation.

So you'll see that from '11 to '12 we -- we endured a $9 million cut -- less than $9 million cut, and then in '13 we endured another about $7 million cut, so that's very significant cuts over the past two years. For '13, as Jim noted, congress also eliminated the minimum appropriation required under PRIA so that at least we're still able to collect the fee, but the -- the amount of appropriated dollars is significantly less than what the PRIA coalition envisioned when they passed PRIA.

So how do we absorb all of these cuts? In 2012 we consolidated contracts, we reduced all of our discretionary work, took a -- a pretty-significant cut,

IPM in schools, for instance. The grant program that we initiated in 2011 didn't actually get funded and out the door until 2012, so we were not able to do any grants with '12 money. The -- we -- we had to greatly reduce the amount of money that we -- we give to the National Pesticide Incident Center -- Information Center, NPIC, at Oregon State. We -- we really devoted a lot of time to figure out how to do our work more efficiently, yet not compromise the integrity of the science and the risk management work.

We -- the -- the contract support we -- as I mentioned earlier, we -- we collapsed a lot of the contracts and -- and focused it into one or two, but a lot of the work that had previously been done by contractors was now being done by staff here at EPA. And then we -- we reduced greatly the amount of hiring we did, due to -- due to retirements or -- or folks moving on, we did a very limited amount of backfill hiring in 2012.

Now we come to 2013 where the cut is even more significant, because it's on top of the '12 and it includes the -- the sequesterable amount that congress imposed in March. And by the time we got the amount in early April, it was -- it was -- it was very significant. We've been operating under a continuing resolution, which

was at the higher level of 2012, so we had to absorb that much more of a cut in a shorter period of time.

Virtually no hiring has -- has gone forward, obviously we had to endure, as an agency, furloughs. And because overall the agency cut due to sequestration was so large, that we couldn't -- the agency could not meet in -- it's payroll in many areas where they didn't have the discretion to use non-payroll money to cover payroll needs, so there -- there was virtually no hiring, we had this -- these furloughs that have been phased in.

So the first phase was from the end of April through the end of June, that was 32 hours, one day of which was designed, that was the Friday before Memorial Day. And -- and then after a short period of reassessment, and moving, shifting some funds around, we are facing 23 more hours to be taken between the 4th of July holiday, that Friday was the mandatory furlough day, and the end of the fiscal year, the day before Labor Day also being another mandatory furlough day for us.

So all in all, it's 55 hours total furlough as a result of sequestration. It could have been a lot worse, you -- those of you from states know how bad it could have been. We fortunately didn't have to lay people off, so that's the bright side. But the not-so-bright side is that we weren't able to -- by and large, the work that we

do in the pesticide regulatory process is staff driven, it's -- it's a federal program. It's -- it is -- the -- the kinds of reviews and decisions that we make, we can't have contractors doing the work, we can't have anybody else doing the work, other than those that are authorized by our statute, so grants have virtually been eliminated.

We were able to scrape together a few funds, so that we will have a -- a 2013 IPM in schools grant program. Not -- certainly not what we have done in the past, but enough to keep the progress moving forward. A larger portion of PRIA funds will now have to be utilized for maintaining our registration program, so by that I mean historically the -- the fees that we have collected have covered between 25, 30 percent of the cost of running our program, we're anticipating it will be closer to 40 percent this year. And obviously every year that we see further deceases, we'll be relying more and more on fees to run the program.

If the minimum appropriation is not addressed, as it was for 2013, and we're not able to collect fees, well, we'll -- we'll be in a real pickle. But I'm assuming, as Jim said, if congress did it once and they figured out how -- how to reduce the appropriation and also allow us to collect the fees, it's entirely likely that they will do it again, but, again, we don't read the

tea leaves.

The -- I talked about the furloughs. Some of the additional impact will be the product re-registration that we've been on a -- on a schedule to complete, 20,000 products over a period of time. And we're -- we really had a goal of completing that whole process by the end of 2014, that will be slowed down somewhat. Our -- our emphasis will be on those products, the labels that really need mitigation on them sooner rather than later, and that will be our focus going forward.

The -- we've had a minimal investment in IT. As many of you are aware, we -- our tracking system, if you will, is called, "OPEN," and it is literally held together with Band Aids, and Super Glue, and duct tape. It is -- it is -- it's a legacy system, it's -- it's antiquated, and -- and very difficult to operate, and -- anyway, so -- but it is all that we have, basically.

And then we've -- we've developed another system over the years called, "PRISM," which helps us with our -- the tracking of the registration review work, endangered-species work, some of the -- the DCIs associated with -- with the registration review work. And then this Documentum, which is the is library that contains all the studies and all of the other information -- massive amounts of information that we collect as a

program, so there's basic maintenance and operation of those three large components.

So we -- that's just a given, we have to support that to -- to keep functioning, we all recognize that that is not the desired state to be. That we really want real-time information available to those that need it, both internal to the program and external, you know, for transparency purposes, so we did invest. We invested a quarter-of-a-million dollars in 2012 in an -- what we call an alternatives' analysis.

In other words, we hired an expert to come in, take a look at our system, take a look at our business process, such as we were able to articulate it at the time, and -- and come up with some suggestions for us to move forward, so that whenever we are able to invest the money in systems that we'll be poised to move. And -- and if we're able, we'll take some incremental steps towards that ultimate vision as we go forward, but it really is -- is -- we've -- we've decided it's foolhardy to just keep Band Aiding what we have, we have to look to the future and do what we can to plan for something a little bit more appropriate for our needs.

Now, if you want to look at the fee charts, those are the next two pages, they basically take the same three years and project. For the FIFRA fees we have

a set amount that we're authorized to collect under -- under PRIA, and that -- what we do is we calculate and -- and we have one person who has an algorithm that is -- he's able to figure out what the per-product fee needs to be in order to calculate this amount of money, taking into account the business -- small and large business caps, the ultra-small business caps, and so forth and so on. And so we're pretty close, we are -- we're about at $27 million now collections for maintenance fees for this year.

I will tell you that OMB determined last summer that these fee accounts are susceptible to sequestration, so they've taken five percent of our $27.8 million and banked it for us due to sequestration. It doesn't go to the treasury, like the rest of the sequestered dollars, it will eventually come back to the pesticide program once the sequestration has been lifted, if and when that happens.

On the PRIA side you'll see that -- you'll see what our collections were actually in '11 and '12. And '12 was -- was high over the last seven years of PRIA, and I think that that, in large part, reflects the uncertainty related to PRIA-3. We -- as you know it was up for reauthorization last fall and had to be reauthorized by October 1st, so a lot of folks got their

applications in beforehand so that they would at least get the time frames in the event that PRIA-3 did not pass, so that's -- I think that explains the anomaly in the -- 2012.

Thus far in 2013, $12 million again, OMB has taken five percent of that off the top. We never get anything directly, by the way. Although it all eventually sifts down to us, it goes into the agency, and then it goes OMB, and then it comes back to the agency, and then it comes down to us, so it -- your dollar spent eventually gets to us, but it goes a circuitous route.

We -- we have quarterly meetings with the PRIA coalition to sort of keep them apprised of how things are going under both the -- the PRIA, the registration actions as well as the registration review and set asides. So we had 1,112 applications for the first six months of this -- this fiscal year, that's very high, we've never received that many. We suspect it's in due -- due in large part to the gold-seal letters now being a PRIA-fee category. Likewise, the amount of decisions that were completed in those six months, higher than in the past, but probably reflect the gold-seal-letter completion.

Due-date extensions, we're at about 23 percent overall, that's -- that's on the low side. I would have

predicted it would be much higher, given the furloughs and -- and budget constraints. I suspect what's going to happen though is that that reflected things that were in the pipeline that we're able to complete on time or renegotiate, you know, with -- by agreement. Eventually we will get to the point where that rate increases, how much we don't know, but that -- the -- the numbers just don't -- the numbers, in terms of resources, just don't support our ability to maintain the current workload.

Worker protection set asides, applicator training, and partnership grants, those are set asides out of a -- the PRIA amounts, the registration fees that we collect. Worker protection activities, fully funded already. The certification and training set asides, $500,000 that the PRIA coalition set aside with the intent that we would maintain our arrangement with the extension services through USDA to continue to provide applicator training.

USDA informed us that they no longer wanted to be part of that arrangement, and that was fine. We -- we got the effected stakeholders together with a plan, and so NASAC, the National Association of State Ag Commissioner, is that right? Close enough, stepped up and -- and they are going to administer the -- the -- the program to -- to the extension services, so that the

training will continue onward and we -- it will be funded, just not -- not through the USDA mechanism.

If you recall, if you've been on this committee for a while, you -- you will recall that we -- we had problems with the USDA, their very arcane budgeting and financing operation. In any event, that -- that was the arrangement, that's the arrangement now. So the money is -- is out there and will be received by extension services, so there shouldn't be any -- we shouldn't skip a beat in terms of the training program.

And then finally the partnership grants set aside we used this year to fund the INPEC, the -- the Information Collection Service that we provide, the incident reporting service. And then FIFRA fees new this year, we have it set aside out of maintenance fees, and that's $800,000 for the five years of PRIA-3. And those are specifically devoted to IT initiative that -- that serve our interests, but also the interests of the PRIA coalition.

So one -- one is the -- the tracking of registration action, so that's sort of UPS-type system I think is envisioned, so you could go online and check on the status of your application at any given moment. Right now this year we'll be issuing e-mails to people that give us e-mails in -- with their applications, we'll

be issuing e-mails at each of these certain points in the -- in the life of an application for a pesticide action.

And then we have the tracking for conditional registrations, this will be to -- to ultimately enable a web-based application where you would be able to go in and see the conditional registrations that have been approved by the agency, what the conditions were that were imposed, when those conditions were due to be satisfied, if they were satisfied, if they were changed to decisions, and then this would be a database that could be manipulated to pull reports and so forth. For starters, it's going to be a spreadsheet that we'll put -- put on the -- on the web, simply because we -- we -- we haven't had the -- the -- the people resources to put together the final web -- web approach that we want to us.

Electronic CSF, this is something that we're working on in partnership with Canada, our PMRA up there, and this will enable a registrant to submit a CSF to us or state submit a CSF to us electronically, and it can be -- it can be sent to either PMRA, or us, or both, and it will be one format, one form, and applicable to both countries.

Electronic labeling, this includes not only the ability for you to send us a label electronically via a

media source and us to review it via a media source, it also includes work on structured labeling. This isn't web-based labeling, this is a structured-labeling kind of template that we could use to capture most of the information that is necessary on a label so that it just reduces the -- the number of errors and improves our ability to read and -- and compare the labels.

And then finally we have a set aside to enhance our endangered species' database. This is -- this is an effort that we began a few years, putting the knowledge that we gained from the services and as well as our own literature searches and so forth, putting it into one database that will ultimately be accessible and not -- we -- we don't have to reinvent the wheel every time the same species, or the same location, or the same chemical comes up, we'll be able to use information that we have previously garnered for -- for multiple purposes, so we're -- that is an active work and constantly being upgraded and updated.

And there seems to be some interest at the OMB level to -- to try to do something with all of the interested agencies to develop one large database that will be accessible to all federal partners in these efforts, so more to come on that, but we are moving forward with everything. And I guess maybe I'll take a

few questions, do you have any?

MR. BRADBURY: And just for new folks, well, how we manage that is I get to be the arbitrator of who gets to talk. Put up -- if you, like Jacob did, put up your -- your name tag and then I'll try to keep track of the order as best we can. And then you all know I also watch the clock, so -- and I trust all of you to not repeat things, if possible. And -- and we have always, over the years, worked it out pretty well, so we stay on task and -- and on topic. So, Jacob?

MR. VUKICH: Thanks, Marty, two quick questions. Do you have a feel for what the fiscal year 2014 maintenance fee is going to be, and number two, on the PRIA fee collection, you've got a year to date, I'm just wondering if there's -- does the average track kind of monthly or are there peaks and valleys, and as such if you could project fore year end?

MS. MONELL: Well, it's -- it's very difficult. This year coming up in October 1st is going to be a five-percent bump-up in the fees across the board, so it's entirely likely that September we'll see a lot more applications. Now, whether that translates to a million dollars or $50,000, it's impossible to predict, but that usually happens before we have a bump-up. Other than that, the summary's usually pretty quiet, so I don't

expect to, as I say, collect a lot more in PRIA fees.

MR. VUKICH: How -- how about maintenance fees for 2014?

MS. MONELL: Maintenance fees, I can't tell you what the per-product fee is going to be at this point, we -- we have to wait until we get to the -- sort of the end, if you will. We're in the process now, and hopefully none of you in this room are in that situation, of issuing letters of cancellation because of nonpayment. We've given -- those that have not yet paid their dues, their fees, we've given them a couple of opportunities to reconsider or to remind them of their obligations, and then ultimately we have a legal responsibility to cancel them for nonpayment.

Once we have that finalized, then we'll be able to predict how many products -- well, a number will be put into his algorithms as to the -- the number of products he anticipates will need to be addressed and then he'll figure out what -- the per-product. It won't be a -- a large difference from what is in place right now.

MR. VUKICH: Okay.

MR. BRADBURY: Eric?

MR. GJEVRE: Just quickly, and I can go offline with it too for the question, but you mentioned legacy

systems, you mentioned IT, and I'm just wondering if there's -- if there is any -- if you could expound on the -- the IT, particularly with regard to enforcement database for EPA.

MS. MONELL: Well, the enforcement database is maintained by AWECA, the EPA's enforcement, AA ship, if you will. That said, we -- we share a database with them on section-seven tracking, that's facility information that companies have to provide to both us and to -- to AWECA, so we share a database around that. But I think what you're really trying to get at is a database that is maintained by AWECA.

MR. BRADBURY: And offline we can explore --

MS. MONELL: Yes.

MR. BRADBURY: -- a little bit more of what you're looking for and -- and I'll get you the information. Anybody else? Oh, Cheryl/Sheryl, sorry.

MS. CLEVELAND/KUNICKIS: So originally the PRIA system, as it came out, was really a win, win in a lot of ways. And if you look around the globe, I see that PRIA system with that predictable set of time lines as a real advantage for U.S. agriculture and -- and -- and the whole system, it's -- it's -- it's -- it's important. So understanding that there's budget constraints and now there's shifting of funds, what can be done to preserve

the original intent to have that predictable, fairly-fast time-line fee for service that -- that was set in place to date, what -- and what do you see maybe the coalition doing, what is the work group doing, or what -- what is the solution to this -- this maybe potential bleed of that original intent?

MS. MONELL: Well, actually, the -- we -- we gave a very similar budget presentation to the coalition a month ago, and that was their question, what can we do? And -- and, you know, the -- the congress passed PRIA, and in large part it was because it was supported by a coalition of such divergent interest it almost couldn't help itself. And congress also recognized the need for the U.S. budget to -- to, at least temporarily, eliminate that provision of PRIA that provides for the minimum appropriation.

I would say that, you know, me, Marty Monell, Deputy Director, OPP, in charge of pre-implementation, get your packages in as good a shape as you can, that's what you can do to help the pesticide program, so that we don't have to spend time on -- and we won't be able to spend time, quite frankly, we'll be rejecting things left and right if they're not put together well. If we don't have the data, we can't -- we can't review it and we're not going to ask you for it a second time.

Things that are -- that are less risky and don't require us to make a lot of adjustments for the risk and -- and you all can negotiate after the fact with -- around risk, obviously we won't make those time frames. We -- we just won't be able to, because we won't have the resources to spend on trying to make things work. So less risky, packages that are put together well, those are the kinds of things that will be our high priority.

I will tell you I -- you know, as I -- as I noted, we're only in the 23-percent renegotiation rate. We're at about a 98 percent completion on time, that's -- that includes renegotiations, but that's -- that's still very good, our goal has always been 99 percent. So to be at 98 percent is -- we're very proud of that. But, you know, you -- this is on the backs of our staff, and we can only ask so much of them, and I -- I fear that those numbers will go down.

But nonetheless, we also recognize our responsibility and -- to maintain the intent of PRIA in terms of predictability for growers and -- and registrants and -- and -- and our own obligation to do it and with, you know, good science and -- and effective risk-management decisions, so it's a balancing act that we're going to do. The more you can do to -- to help with our work by making the package complete, I guess, is

-- is what we would ask.

MR. BRADBURY: We'll just -- we'll close out this session. And just to -- to re-emphasize Marty's point and -- and Jim's before, without meeting the minimum appropriation, that -- that does put a -- that changes things in terms of the resources that we have available.

Having said that, I -- there's a way, as long as the fees keep coming in, to maintain predictability. Some of the predictability may be that the percent decisions on time may go down, but it will still be predictable. If -- if the fees can no longer be collected, as Marty indicated and Jim indicated, then -- then it's a new ball game, because then the resource base is dramatically different. And then what the process would be, I -- none of us can speculate now, so -- and then the other point is we don't petition congress for funds, so that's the business of others.

Okay. So why don't we move on to the next session, which is update and a lot of new information on our efforts with implementation of the Endangered Species Act. And all the -- our colleagues across the federal government that have been working with us very hard over the years will all share in -- in presenting it, so Rick from Pesticide Program, Helen from National

Marine Fishery Service, Sheryl from USDA, and Paul from U.S. Fish and Wildlife Service. So turn over to Rick, I think, that will kick us off.

MR. KEIGWIN: Yeah, I'll kick us off. And I think it's really great that it could be the four agencies that are involved in implementing the Endangered Species Act considerations as part of pesticides to be co-presenting, because certainly over the last few years it's very much been across-the-federal-family team effort. And as you hear more on the -- where we are, particularly with the implementation of the recommendations from the National Academy of Sciences, I think we've all gotten to know each other really well, and have spent lots of time together, and -- and so we'll -- we'll share with you where we're at.

Unfortunately we didn't have time to sort of coordinate, so I thought what we could do for the four of us is I would cover the -- the focus-meeting piece, the stakeholder-engagement piece, and then the latter half is very similar to a presentation we did recently. So maybe Paul and Helen, if you -- if you remember which parts you did in that one, we can go from there and I think we'll be okay.

And I would be remiss to not mention the fifth member of our little group, Don Brady, who is on

vacation, but I know he wishes he were here to be part of this. Really, he does. So as I said -- is there someone who has the --

UNIDENTIFIED FEMALE: This one?

MR. KEIGWIN: -- clicker? Right. Yeah. Oh, no, I'll just take it. Okay. So, as I mentioned, we're going to cover two topics today. And I'm sure there will be lots of questions, so we'll leave lots of time. The first area that we're going to cover is to update you all on where we are with our revised process that we're applying to registration review for increasing stakeholder engagement in the registration-review process, particularly as it relates to EFA, and then the second topic that we'll cover is our efforts today across the federal family to implement the recommendations from the National Academy of Sciences.

So the first area you all are probably aware that in the summer of 2012 EPA, NIMS, Fish and Wildlife Service, and USDA jointly developed a proposal for increasing the opportunities for stakeholder engagement in registration review. And the idea here was to ensure that as we're going throughout our re-evaluation process and as we moved into the consultation process, that we had the best available information on the intended pesticide use, what uses registrants were supporting as

part of re-evaluation, and how these products were being used in the field either by growers or in the non-agricultural sector in -- so the application setting both residential landscape types of uses.

We got considerable comment on that proposal, but overall pretty much everyone in agreement that these were the right things to do. And so with -- with very modest tweaks to the proposal that we issued in the summer of 2012, we issued the final program in March of this year. One of the biggest changes to this program was that we instituted something in the very early stage of registration review called a focus meeting, this was a concept that we had utilized during re-registration, at that time we called it a smart meeting. Don't me what smart stood for, it was not an acronym. But -- but the intent remained the same, which was to get the best information about what was no the label, we've -- and what should be on the label.

We've tweaked this a little bit here for registration review, because what we're doing is a -- a few things. Our federal partners are invited to participate in those meetings, we've had some great success, particularly where there's been an overlap with an -- on a chemical with an ongoing consultation. Sometimes we can not only address some of the issue that

we're having as part of scoping out the registration review, but it also helps the services as they're doing their evaluation in the development of a draft biological opinion to get some questions answered that really help meaningfully in helping them complete their analysis.

To date we've had about 40 of these meeting, by and large we think they've been pretty -- they've been pretty good meetings. We've only had one or two that were sort of the -- the sales type of shows. What we're really trying to do is dig deep into what does the registrant want to support, what are the stewardship efforts behind a product. We've done an analysis of where there are gaps in information on the labels, you know, if something says -- doesn't say how many times per year it's supposed to be used and we have to make an assumption, we share that assumption.

And oftentimes we're finding out, not too surprisingly from the registrants, no, we didn't intend for that to be used once a week, 52 weeks a year, we went -- meant it to be used once a season. That's very critical information, because that's a -- that's a key perimeter in -- in driving the risk assessment.

We've even had some instances already pre -- sort of the risk assessment part of registration review where registrants have said, "Now we understand where

you're going with that based upon the uncertainty analysis that you're presenting, we don't really support all of the use patterns that are on the label," or, "We'll clarify this so that it's only used in the in-furrow application," or -- or, "We'll put greater specificity on the number of application rates and what the retreatment minimals are." Those -- that's really key information for us to have, so that as we're doing our risk assessment and as everyone is responding to our risk assessments, we're all working from a common set understanding of how the product is used, how it's intended to be used, and we think it minimizes sort of the back and forth between all of us and is a better utilization of our resources.

Now, even though this chart says that the focus meeting is only intended to be at sort of this early scoping stage of the process, in fact, we've been experimenting with doing them at various stages of the process. So because some of the registration review cases are further along, sometimes we're doing them as we're entering into the preliminary risk assessments, sometimes we're doing them as we're in a public-comment period on the preliminary risk assessment.

As we've mentioned here before, those are typically meetings between us and the registrants. But

if others want to come in and discuss the chemical with us, happy to have those meetings. We are docketing minutes from any of those meetings that take place, so to the extent to which people want to find out what happened, minutes for each of those focus meetings will appear in the registration review docket for that chemical.

One of the other changes that we made to the registration review process with this revised stakeholder-engagement program is we shifted where in the overall re-evaluation process we thought we would seek consultation with the services if we felt that consultation was necessary. Initially when we started registration review, we had envisioned initiating consultation at the preliminary risk-assessment stage.

I think one of the things that we all found out is that’s a bit too early in the process, it’s not -- it’s not really at the point where we’ve defined what the federal action is. And so consistent with how the services interact with other parts of the federal government on federal activities, we thought shifting the consultation process to a later point that is really more of the point where we’re saying, here is where we -- what we think is eligible for continued registration is more appropriate, and it’s more -- it’s more in the model of

how most consultations are done with the services under ESA.

And so I think over the next year we'll be getting to that point with a number of registration review actions, about 15, or 16, or so cases have gone out for preliminary -- comments on the preliminary risk assessment this year, so you'll start to see those start to move to the revised risk-assessment proposed decision phase in the coming year. And so that's likely where if we felt that we needed to initiate consultation, that's where we would do it. Again, the focus meeting is really to focus on the information needs for us in the risk assessment, and we really think it's an opportunity to -- to reduce the uncertainties in our analysis so that we can make more-effective assessment and risk management decisions.

So let me stop there, and we can shift to the report from the academy. I think -- Paul, if I'm remembering the last briefing we did, I think this is where you sort of kicked in, but --

MR. SOUZA: Sure.

MR. KEIGWIN: Okay.

MR. SOUZA: Sure, I'd just love to introduce myself to this group as well. I'm also going to be a part of this group going forward, and very much look

forward to the conversation.

I started my current job in our headquarters about two years ago, and I must admit I did not know a whole lot about pesticide consultations at that time. But since then I've dived into the deep end with our staff and we've been working on this a tremendous amount, we'll talk about some of that coming up here.

I can tell you without question this is one of our highest priorities regarding our consultation program, we recognize that we have a tremendous workload associated with the registrations moving forward. We know that we've seen litigation over the years that have -- that litigation has changed the dynamic, so to speak, of the need to complete these consultations. And I think all of the federal family is working really closely now to work through this and figure out a path forward, and we'll talk about some of that now.

Some of you may have seen the national Academy of Sciences' report that came out just a few months ago. If you haven't, I really encourage you to read it. It's a, I think, very helpful document to us, it represented an effort that our agency's funded to have independent scientists give us their best advice for how we might move beyond some of the scientific challenges that we've faced, quite frankly, for decades regarding pesticides

and consultation under the Endangered Species Act.

I think the report provides us a really strong basis for moving forward, I also think that there are lots of questions that we still have to answer in more detail. Some of the recommendations are clear and I think can be implemented quickly, others are going to take more time, but I do believe I speak for everybody when I say we're committed to the long haul to figuring out how to implement them all to the extent that we can.

We've met a series of times over the months that have occurred since that report was finalized, both at kind of senior leadership team level and also a staff working group level, we tried to figure out how to make sense of this report. There are major sections that outline the issues that really have been the basis for our challenges over time, things like sublethal effects, how we deal with indirect effects more broadly, to really dive into the details of the recommendations, figure out what we think we could do in the short term and what we think would take more time to implement.

The goals that we've outlined, I think all of us would love to be in a position where we could develop a single and unified approach where the scientific methods that are being used to assess the impacts on species are clearly defined and clearly agreed upon by all agencies.

And again, I think the report takes us a step in that direction, but we do have some more work to do.

One of the pieces that is really important is the engagement piece as well that Rick talked about. What we have found throughout our experience with consultation, is consultation is most effective when there's early discussions with registrants, with user groups when the best science is brought to the table on impacts to the species and you don't have a situation where a consultation that's provided under the duress of a timeline is changing some expectations that have been long set over years. So the public engagement piece really is a process piece, but one that is, I think, going to be integral in us figuring out how to implement this report's recommendations best.

I think another point that I'll add about this is just the need for continuing evolution. We're not going to be able on a dime to address all of the outstanding questions, but there are things that we can do and having a process that will allow us in partnership as we get more experience under our belt to adapt, and change, and improve, and reach that goal that we have of the unified approach, the transparency in a process that has early engagement as the key. How about you, I'll pass the baton to you, Helen.

MS. GOLDE: Okay.

MR. SOUZA: Does that make sense?

MS. GOLDE: Sure.

MR. SOUZA: Just like Rick said, that's where we left it last time, right?

MS. GOLDE: Yeah, why don't you flip to the next slide. So just -- just to introduce myself, my name's Helen Golde, I'm the Deputy Director of the Office of Protected Resources in NOAA Fishery Service. For the last year I've been the -- I was, until very -- until about a month ago I was the acting director. Jim Lakey was the director before me and he was a member of this group prior to Paul representing the services, so I was acting after Jim retired.

We just brought on a new director, Donna Weeding (phonetic.) She's getting up to speed on a number of things, but she and I have agreed that since I dove in deeply into this -- into this stuff as acting director, I am going to keep this as -- as part of my portfolio and which I am actually very pleased about. I think we, as Paul mentioned, Paul, Rick, and -- and Sheryl, and I, and Dawn have all developed a very good working relationship and I think it's important for us all to think about how we move forward collectively on this.

So on that note, I'll turn to where we are here.

So as Paul mentioned, we are -- have been thinking about how to use this report to move forward, and one of the -- one of the things we realized is that we didn't want to -- no one agency wanted to be able to hold -- wanted to hold up this report and say, we won or -- or we lost. That there's a lot of recommendations in there, and that what we all need to think about is how do we collectively take those recommendations and move forward. So we recognize that there is probably going to be changes in how all of us do business at least relative to one another, how we think about some of our assessments.

And as Paul also mentioned, we are going to implement this in a -- in sort of a phased approach. There are some things that we think we can implement right away, there's recommendations, for example, about engaging the public more. And as Rick already mentioned, that's -- that's something that we were already moving forward on, so that's sort of an -- an easy check to do and -- and that's -- that's sort of mentioned in these last couple bullets on this slide about the -- the stakeholder paper.

In moving forward iteratively, I think we realize that if we were to start at the very beginning of the process it would be a number -- if -- if we just said, oh, let's start with the -- the next few that are

entering the -- the re-registration process and -- and start implementing changes in how we do business there, we wouldn't need changes for a fair number of years.

So that in looking at sort of the whole schedule and how the registration process works, we want to implement actions, implement changes with various actions at the stage they're at, so we don't want to move backwards. We realize that it's -- it's probably really difficult, and given everybody's workload, to say, oh, let's redo work that we've already done making some changes, so we want to move forward from this point forward with whatever -- at whatever phase different actions are in.

I think we can go to the next slide, if you have the -- the clicker there. So on that note we identified, you know, as I said, things that can be done immediately, things that -- sort of interim approaches of things that are going to take longer. We are going to have another internal meeting in the beginning of August to really dive more deep into some of these recommendations and look at how we can work out interim approaches in moving forward, and we think this is going to be sort of an iterative thing.

We'll say, okay, here's how we want to collectively do these types of analyses, now let's try it

in a few -- in a few registrations and a few consultations and see how well that works. And if we need to tweak things, we'll tweak things, but -- so as Paul said, we can't sort of shift on a dime, but we are going to phase this in at various phases in the process and using an iterative approach to develop our best way forward.

I think the one other point on this slide that I really want to point out is the last bullet, and that is we all have, all of us, a huge workload already. In NOAA Fisheries we have a number of consultations that we have completed, one of which has now been remanded by the courts that we're going to need to rework.

We have some others on our docket that we have settlement agreement for timelines to complete, so we can't -- we have to work new consultations, changes into that existing workload, and so that's one of the things we've all been talking about is how do we not -- how do we move forward and make appropriate changes at the appropriate time and not derail the workload that we already have, so it's going to be a challenge for all of us and we appreciate your patience with us as we -- as we do that.

And I think that we need to show the last slide here, Paul, and then maybe tell me what I forgot and we

can open it up to questions. So we will be putting out an interim, tentative plan about how we're going to respond to this report -- report, which will summarize a lot of what we've -- we've said here, sort of what -- what is our process for integrating and implementing changes recommended by a report.

And then as we develop these more-concrete scientific approaches to how to address things like more-concrete ways to do -- to deal with mixtures, say, then we will put those out for the public to respond to so that folks can see the kinds of approaches we're planning on taking. So now what did I forget?

MR. SOUZA: Sheryl was going to sort of help sum us up and talk about USDA's role.

MS. KUNICKIS: Yes, as -- as most of you probably know, USDA really doesn't have a role in -- in -- in this process, but it is our agricultural community that is impacted by the decision, so let me just talk about what's already happening, even though the report just came out in late April.

My staff at the Office of Pest Management Policies is very engaged with -- in consultation on -- in the focus groups, those are -- like Rick said, have already started, we've been invited for -- in a number of meetings to participate in. My staff has -- EPA staff

knows the names of all of the staff that they can reach out to for assistance, we've had the services come over to our offices and spend time with our staff, depending on whether it's an herbicide, or an insecticide, whatever, to talk about, to find out and ask questions how are these pesticides used, tell us about this, and that, and explain what happens, and why does a farmer do this, so it's being -- it's really turned out to be a really terrific process so far, we feel like we're able to provide value to them early on.

And then in turn we find out what information is important to -- to inform this process, which has allowed us to reach out to our grower groups, IPM centers, others that we know have expertise or can provide information to find out how -- how -- how the -- how pesticides are being used for, or specific pesticides, so we feel very comfortable with what's happening. I will tell you, compared to a few years ago, this is very different and this is very good.

This -- I can tell you the senior leadership of the four agencies are very committed to seeing this forward, and I can assure you that the staff-level folks are very committed to making sure that we get this right from the beginning, so we appreciate the partnership that we have here. And I know it sounds kumbaya, but frankly

that's pretty much what's happening now.

MR. SOUSA: So, Steve, with that, that's our report and we can take questions.

MR. BRADBURY: Opening it up for questions. Mark?

MR. WHALON: I just wanted to ask Helen if she'd do a -- maybe a couple of examples of what you mean by implemented or -- or shared scientific approaches, what -- what are you up to there, and also down further in that same slide you -- you talk about shared scientific approaches again and illustrate that with -- or outline that with a two-year outside time frame. I'm -- I'm not sure what you mean by implemented shared scientific approaches.

MS. GOLDE: Sure. So, sorry if I wasn't clear on that. So if you read the report, you'll find things a lot of places where it will -- it says generally and then more in specifics that the agency should agree on an analysis framework and a way to do analysis. So the way things have been happening sort of up until now is EPA has been doing an analysis based on -- on, you know, the models we have traditionally used, I guess I'll say, on what the likely impacts of the use of the -- of the pesticides would be on -- in this case listed tomonans (phonetic,) because those are the -- those are the

species we've been working on.

And then we at NOAA Fisheries have taken that and done another analysis in a different way, and I don't -- I think that you could -- you know, you could make a case that one or the other is a better one to do, but what we all recognize is that it's not really a great use of all our -- they're sparse and getting sparser resources to do an analysis twice and disagree on the best way to do analysis, and that that opens all of us up for all sorts of legal challenges, not to mention it's just, you know, as I said, not a great use of resources.

So in what -- sort of where we would like to end up eventually, and I think two years is sort of our -- our outside time frame for this, is that there is one analysis that's done and the services pick up that analysis from EPA and say, yeah, we're going to sort of -- we're going to look at this, we'll do a sort of check to make sure that we -- we don't think that there is some, you know, error -- inadvertent error or whatever that was made there, but we -- but we've all agreed already that this is the right analysis to do, and we'll take that, and then we can do our final jeopardy analysis using that same analysis on the -- on the impact of the pesticides, so that's sort of the -- that's the -- the -- in general what I'm talking about.

So if you look at the report, there is recommendations about how to -- how to -- to talk about and -- and -- and analyze mixtures, there is recommendations on -- on how to deal with uncertainty, there's -- there's -- so those sorts of things. So we -- now it's relatively easy for us in the last couple months in assessing the report to look at those and come together and say, yeah, we all agree that we need to figure out a way to deal with uncertainty and so we agree with this recommendation, but the details of how to do that is -- is sort of a whole different level of discussion, so that's where -- what we're starting to work on in the next few months.

And moving forward is what are those -- what are -- what is the devil in the details on how you do that assessment, and how you deal with the mixtures, how you deal with uncertainty, there's -- there's a -- you know, a -- a list of those things, and so that's what we're calling our scientific approaches to -- to addressing those types of issues.

MR. WHALON: Thanks, that's helpful.

MR. BRADBURY: Nichelle and then Ray.

MS. HARRIOTT: I guess as to expound on what Dr. Whalon was asking, could you give us more of a glimpse into the steps that the consultation takes, for example,

EPA initiates a registration review, there is data culling at this point, what type of data, is there any specific type of data that is specifically requested for these types of consultations, are there specific issues that is analyzed -- that are analyzed, is there any type of -- of environmental monitoring data, use patterns, things like that?

MS. GOLDE: I'll take a first stab at this, and then I'll let Paul weigh in with -- with anything he wants to add. So our -- the Endangered Species Act requires that every federal agency ensure that their actions not jeopardize the continued existence of those species that are listed either as threatened or endangered on the Endangered Species Act.

So, first of all, those are the species we're looking at, those species that are listed on the Endangered Species list. So the way I -- I tend to think of consultation is it's the services working with the action agency, in this case EPA, to help them meet their obligations of ensuring that they don't jeopardize, so they're, you know, sort of in a -- one way people look at that is the services can't say, here's our new theory. The services say, here's our federal action, they -- or, sorry, the action agency, the EPA, here's our federal action, hand it over to the services. The services do an

analysis and say, yes, we think you have insured that you won't jeopardize these species or, no, we think that you are likely -- you may jeopardize these species.

Now, I think one of -- in our continuing to work more cooperative moving forward in incentives, what Rick talked about, about looking at actual use patters, that helps us to work collaboratively and say, well, let's not just hand over a label and say, well, here's what the label says. You know, you, services, determine whether this jeopardizes the species that you are responsible for.

Instead, as we work more cooperatively and say, well, if you made this shift, can we work with the registrants to say, this is the kind of thing we're worried about. We're worried about, for instance, aerial application, because it's -- you know, when winds are higher than X, because it's likely to -- to blow, you know, into a stream where we have listed salmon, for example.

So we are required to use best-available scientific information, that's the standard within the Endangered Species Act. So that's -- you know, people -- some people may interpret that differently than others, but basically we -- we like to get as much information as we possibly can that's there and out there. Because it's

best available, there's not a requirement under the Endangered Species Act to do new studies or develop information that isn't already available, so we do our assessment based on information that is available.

Now, I know that in the registration process there may be some requirements for you all to do some additional studies, and we have started talking about if there's particular information there that would be helpful to the services in doing their analysis we could certainly try to build that in if it wasn't, you know, huge extra things. So I'll -- I'll leave it there and let -- Paul?

MR. SOUZA: Just briefly, and I'll echo a lot of what Helen said, just try to say it in a different way. We do consultations every day for all kinds of different things. The Department of Transportation wants to build a road, we do a consultation on it if it may effect listed species. When the Corps of Engineers wants to build a dam, we do a consultation on that to determine whether it's going to effect listed species. In our experience, it's always been the same, consultations are most effective when we have early engagement. When there has been, in some cases, years of investment by a permit applicant in a federal agency about a specific project, and then in the -- maybe not 11th hour, the 10th hour

there's a proposal that's brought before us and there's a -- so much buy-in to that proposal it's difficult to change, that's when oftentimes we can see challenges.

When, however, we can sit down through a focus meeting process with registrants and have a stakeholder engagement process that brings other views to the table, have a direct conversation about how is the pesticide really going to be used by the user community, have a conversation about whether the application of that pesticide could be changed perhaps to avoid a specific finite area at a certain time in the nesting season perhaps, reach that agreement, then EPA would proceed to a biological evaluation that basically had addressed most of the concerns and it makes the process much more smooth.

So it really in my view is a classic case of embedding the consultation process within the FIFRA process. In the other federal agency nomenclature we'll often fold it within the NEPA process, the National Environmental Policy Act process, but FIFRA is essentially the mechanism that we think consultation needs to be folded into from beginning to end.

MR. BRADBURY: Okay. Ray and then Steven.

MR. MCALLISTER: In terms of complexity and scientific challenge, as well as the impact on and

importance to agriculture, I believe that the task or set of tasks represented by the NAS report is on a par, if not exceeding that, of the Food Quality Protection Act, which was dumped in your lap 17 years ago with no phase-in period. At that time the agency chose the path of involving all stakeholders in not only commenting on policies, but integral involvement in developing those polices. Is this an approach you're considering taking for ESA in implementation, or are we going to get the policies to comment on after they're pretty much written?

MR. KEIGWIN: What we've all committed to is we think it's really important that we get agreement across the federal family. We also think that there is great value in public involvement and engagement on those -- those draft approaches. So as -- as Helen was mentioning, the current plan is to develop these sort of uncertain timelines, but as they're being developed to make them available to the public for comment, and -- and, you know, we will make revisions to them based upon those comments. Yeah, go ahead, Helen.

MS. GOLDE: I -- I -- I just want to add that while the NAS report is new, certainly the requirements under the Endangered Species Act are not. And there is a lot of case law and a lot of history in all of the work that we do, and so I think that's one of the things that

informs a lot of our -- our discussions, and so I think I -- while I totally agree with Rick and we do think there's a lot of value of what comes in from -- from you all, there's also some perimeters that we need to work within that are pretty well set for us by the law, regulation, and a lot of case law from years of lawsuits from the -- under the Endangered Species Act.

So we do want to make sure that what we put forward to you all is within those perimeters, and I think that's one of the reasons why I -- at least for me personally, I think it's more efficient in -- in many ways for us to sort of -- to -- to come up with our best thinking first, and then -- and then put it out to you all for -- for comment.

MR. SOUZA: I just had a couple of points about that as well. To go back to our next steps, it's our sincere intention that within the end of this summer we'll be in a position to have a short white paper that describes the path forward for implementation, the things we can do now, the plan for developing interim approaches, the plan for the adaptive management through experience over time. We're also hopeful that in the fall we're going to have some draft interim approaches that we can share, and our current thinking is that is a -- a good time to have something meaningful for people to

respond to.

The other point I'll make is the public engagement process that Rick described, it has now a situation where draft biological opinions would be provided for public comment. So not only would there be a transparency and -- and ability to provide comment as we try to take the next step for the policy development, but it's -- it's -- actual manifestation through individual registration and consultations will have that opportunity as well.

MR. BRADBURY: Steve and then Dave.

MR. SMITH/COY: This process -- all right, I'm new to the PPDC, but I'm not new to the pollinator work group, and this process seems to be very productive, more so than what I've been engaged with the last 10, 12 months, I think. Have there been any recommendations made for existing labels, or are we -- are you not that far along?

MR. SOUZA: Well, this is really at more of the assessment stage and how we go about doing the biological evaluations of the potential risks associated with the product. And then as we work through consultations, we are envisioning -- and even the biological opinions that we've received to-date are -- help us get at, under the Endangered Species Act, reasonable and prudent measures

and reasonable and prudent alternatives which can lend themselves to the development, in some cases, of label language to help address risks to endangered species.

So at some point in this process during the consultation, the consultation that would result in the biological opinion, there would likely be, and it could vary case-by-case, but ultimately some label language that would go on specific to the potential risk to endangered and threatened species associated with that specific chemical.

MR. SMITH/COY: So you --

MR. SOUZA: It's not envisioned to be generic across chemicals --

MR. SMITH/COY: -- right.

MR. SOUZA: -- as we've been talking about through the pollinator work group?

MR. SMITH/COY: Right, but have you -- have you made -- you're not to the point yet where you have actually made specific recommendations on specific things?

MR. SOUZA: No, that's --

MR. SMITH/COY: Because I see some --

MR. SOUZA: -- right.

MR. SMITH/COY: -- I see parallels with what -- what we're working on there and what you're working on

here, and --

MR. SOUZA: Um-hum.

MR. SMITH/COY: -- and is there some way we can improve the process on the -- on the work group -- pollinator work group sides?

MR. BRADBURY: Steve Bradbury speaking. I enjoyed your -- your -- and I respect your comment that we've made good progress, and all these folks and all their colleagues working with them have made great progress, and it's been about a 15-year slog to get to where we are today, not because people aren't trying really hard, don't get me wrong.

So -- but your observation is well taken, in that I think what you're seeing across the federal family and all the folks that we're working with is starting to think through the science and how does the science interface with FIFRA, and ESA, and how do you start to create steps and processes that we can leave the last 15 years behind us and start focusing on pesticide registration decisions that are compliant with endangered species, so we're protecting the species as we need to protect them in ensuring products that are important for agricultural production and other uses are properly -- properly used.

So one of the things I think may be helpful as

we sort of absorb the -- the lessons learned, are some things like what the pollinator group's working on and will be playing out in endangered species, how do you write a label in such a way that it's easily understood so that people that want to do the right thing can easily do the right thing.

And there will probably be some discussions around how do you build in space and time in terms of how you use a product, because the risk picture isn't always the same at every moment in every place, and how to create that flexibility. So I think across a lot of different themes that we take on, we'll probably get some lessons learned like from pollinators to endangered species and some other -- some other examples. But maybe at one level, part of the take-home message is -- and it's hard, is lots of people have lots of different opinions on how to get there, but figuring out where the common ground and going, well, we might not be able to solve all of this all at once, but we can start to solve parts of it this way.

And I think the team's laying out some of the NAF's recommendations are challenging, some of them are more low-hanging fruit. And so I think the team's decided, let's not miss the low-hanging fruit, because we can start making things happen, making improvements, and

then we'll go to the mid and then the -- the high-level fruit, and that may be a lesson that we can take into our pollinator actions, so maybe lessons learned in terms of some process things.

MR. SMITH/COY: Yeah. Well, it seems like the -- the -- we can take some of what you all have done and -- and implement it into our process and speed us along.

MR. BRADBURY: Let me see. Dave, Mark, and then Michael.

MR. TAMAYO: When are the -- the minutes of the focus meetings available, on what sort of time frame?

MR. KEIGWIN: They're generally available within about 60 days of the meeting.

MR. TAMAYO: Yeah.

MR. KEIGWIN: And they go on the docket.

MR. TAMAYO: All right.

MR. KEIGWIN: Go back and forth.

MR. TAMAYO: Yes. Now, those are -- the results of those meetings are going to -- are going to help shape, you know, the -- the types of things that you're considering doing, right?

MR. KEIGWIN: Right.

MR. TAMAYO: Because then you're going to be talking about, okay, well, we are using -- going to support this use and maybe not --

MR. KEIGWIN: Um-hum.

MR. TAMAYO: -- this use. Can -- can you get those minutes up any quicker than that, because, I -- I mean --

MR. KEIGWIN: You know --

MR. TAMAYO: -- that seems --

MR. KEIGWIN: -- that's the outside bar.

MR. TAMAYO: Okay.

MR. KEIGWIN: You know, given where we are in registration review, you know, our -- our chemical-review managers are juggling lots of cases --

MR. TAMAYO: Yeah.

MR. KEIGWIN: -- all at the same time between working through problem formulations with our science staff, to getting BCIs out, to getting -- managing public-comment periods, so if we can do them faster, we will, but it's just sort of a -- a time availability.

MR. TAMAYO: And -- and then you -- you mentioned that there's -- there's -- you would make opportunity for other stakeholders to weigh in sort of on a --

MR. KEIGWIN: Um-hum.

MR. TAMAYO: -- similar fashion --

MR. KEIGWIN: Sure.

MR. TAMAYO: -- and at an early stage, and

that's why I'm concerned about the timing of the focus meetings in case those work inform --

MR. KEIGWIN: Um-hum.

MR. TAMAYO: -- the types of comments that somebody else might want to -- to provide. So what is the process for, you know, I guess, establishing those opportunities, what -- what does one need to do to -- to get that and -- and --

MR. KEIGWIN: Um-hum.

MR. TAMAYO: -- how would you coordinate, you know, variety --

MR. KEIGWIN: So the requests --

MR. TAMAYO: -- of stakeholders?

MR. KEIGWIN: -- are made through the chemical-review manager.

MR. TAMAYO: Um-hum.

MR. KEIGWIN: You can find out who the chemical-review manager is through the chemical-search function on the EPA website for an established docket. We also have published on -- on the registration-review website the four-year prospective schedules for when chemicals enter the process and the approximate timelines that it will enter the process, so that would be the best starting point is to sort of see where that is.

But as I was also mentioning, even if a chemical

has already started the process, if you -- if anyone wants to come in and discuss a particular chemical or set of actions with us, you know, contact the chemical-review manager and we'll get that meeting scheduled.

MR. TAMAYO: Okay. Thanks.

MR. BRADBURY: Yeah. And the other point date is as -- as a chemical is going from moving along and it goes out for preliminary work plan, there's a public comment period in -- in there too. So just as a team is talking about incrementally kicking things in, there's a -- formal common periods where you -- you can sort of see what the outcome of maybe a focus meeting, and some use patterns changing, you can call us ahead of time. So you probably all want to be taking a look at the schedules in -- in sort of optimizing how you want to invest your time, and then we'll be as flexible as we can to make -- to make a go.

Okay. Mark, since you already had one bite at the apple, why don't we do Mike, and then Allison, and then we can come back to you.

MR. WHALON: I always like to have the last word.

MR. BRADBURY: I'll decide.

MR. WILLETT: Thanks, Mark, I appreciate that, your kindness for yielding. I just have a question.

There was a reference to biological opinions just in the brief discussion and in -- in relationship to the policies, and of course we're all looking forward to seeing what those things are going to be, but I would assume that this process, what the aim is, is to reduce or eliminate the need to write biological opinions, wouldn't -- wouldn't that be the goal and wouldn't you expect to see a -- and plus for us to read 900 pages of biological opinions?

MS. GOLDE: So -- so I certainly think that a goal would be to have them be a little shorter. So the way -- the way that -- the way it works is if -- if the determination is that the action -- the federal action, in this case the registration, may adversely affect the species, you have to write a biological opinion.

Now, I think we can -- I would certainly say there -- you know, it's always great if we can work up front through informal consultation to make a not-likely-to-adversely-affect determination, in which case we wouldn't have to write a biological opinion, I don't anticipate that will always be the case.

I think it's also fair to say that we would have a -- a secondary goal, if we have a biological opinion, to work closely with EPA to do everything we can to -- to have a no-jeopardy opinion. Again, we can't guarantee

that up front, we have to see where the analysis leads us, but the more we work cooperatively and we -- more we have, as Paul talked about, the early engagement from the registrants as to really look at the real use and changes that can be made that are helpful to the species, but don't undermine the -- you know, the -- the need for the -- the use in a way that makes it not -- not efficacious. I somehow lost my self in that sentence, sorry, but it will be great.

So, sure, if we can -- if we can make not-likely-to-adversely-affect determinations, then we won't have to write biological opinions. And if we do have to write biological opinions, we'll work to try to make -- to -- to get to know jeopardy if we can.

MR. SOUZA: And I'll simply add briefly that I believe all of our vision with the shared scientific methods is that when we reach that point, recognizing we still got some work to do, that the biological evaluations, the risk assessments that we're getting from EPA, will essentially have all the parts and pieces of a biological opinion. So our review becomes a detailed review of that work to ensure it's accurate, but as Helen said earlier on, not with an additional series of reviews that could take time and energy.

So in the end if it's a biological opinion,

because the species may be adversely affected, that comes from our agencies, but it's our hope, and we've seen this in some other cases with other agencies, that the bees that EPA provides will essentially be 99 percent there.

MR. BRADBURY: Allison and then Mark.

MS. STARMANN: I -- I think that this is easy, and I apologize if I missed it, there's been a lot of talk about timing, but in the work that the federal agencies are -- are doing to try to come up with the -- the process, are you all working to dovetail that with the PRIA timelines where there are PRIA actions involved?

MR. BRADBURY: We've discussed that a number of years and the 15-year challenge. The way we want to approach it at this point is the re-evaluation program registration review, and use that as our first engine, if you will, to get compliance. These tend to be the older products and many of them, through the fits and starts over the years, we've got to start on some of the science that goes into the effects.

Determination is now being upgraded where -- where we pick up with the NAS report, so right now we're focusing on dovetailing into the registration review program, get some -- get some progress there, then we can -- we can start to take a -- a look across. I mean, ultimately we want to make sure every decision we do is

compliant with the Endangered Species Act, practical issues to work through, so the re-evaluation program being how to get started. Mark?

MR. WHALON: Thanks, Steve. I applaud this joint movement, and the evidence of -- of its -- of its progress, and hope not to jump too far ahead, but I wanted to ask about the mapping implementation process and where it -- where that's at these days, and whether we are going to be dealing with risk communication in an arena surrounding ag, or whatever, where the -- where the -- where the likely chemical would be applied.

MR. KEIGWIN: So you hit upon one of the specific areas in -- in the report about availability of monitoring data, how do you utilize existing monitoring data. I think Marty also spoke her comments earlier about the efforts to try to pull together in -- in a shared place for all agencies to use information about habitats and critical areas of habitat species location, species biology, all that type of information, and there is a fairly concerted effort across the federal family to pull that together.

I think we got -- did get some recommendations from the NAS in this regard, and those are probably some of the ones that may take a little bit longer on the timeline that Helen was -- was referring to, but the goal

is to get there.

MR. BRADBURY: One of the charge questions -- that we embedded in -- in one of the charge questions was the issue of best available information, in -- in that regard, georeferenced information, temporally-referenced information. And I think we all are looking to the day when you can be downloading different GIS layers and you can visualize, along with the words, where and how to use a product at a certain point in time, and then actually get that, everything from information quality issues, but I think it's fairly positive and it takes -- as they look across the federal government, and really between USDA, interior EPA, these data layers exist and they sort of lay out some -- some steps that we should consider.

And as Marty indicated, we've been working with OMB. Not just us, but with Department of Defense, Department of Transportation who all have this same need to figure out where all this information is and bring their information in, so we're going to try to elevate that part of the NAS report to an even larger federal government discussion. Because if you're building a dam or you're building a road and the species are where they are, they may also be where soybean fields are, cherry orchards are, and so how do we layer this information together and make sure the federal government isn't

trying to capture the information multiple -- multiple times?

But it will then, Mark, I think, be a part of moving forward as you start to use geospacial information, how do you communicate that, how do you make sure people understand it, how do -- how do words get linked up with maps? I mean, this gets into some of the things we've talked about before where right now growers are downloading satellite information in terms of, you know, what their nitrogen or phosphorous situation is in the soil and it's managing how things are being applied, it could -- it's not inconceivable.

Not tomorrow, but not in probably too many years some of this information could actually be downloaded into application equipment to help implement the label into computers in the -- in the planting equipment. So I think those are some near-term things and some -- some farther-ranging things that we're -- that we're kicking around, and that will definitely have a lot of input from folks as we go forward.

So we're doing pretty good on time. If there is any last question on this topic, the floor is open. All right. Well, let me thank Helen, and Rick, and Paul, and Sheryl, and everybody that works with them to help make this all happen, it's quite a team. So we'll take a 15-

minute break and we'll start again at 3:15 on this clock. Thanks.

(Whereupon, a brief recess was taken.)

MR. BRADBURY: Hey, all, if you can start to grab your -- your chair we'll get going with the afternoon session. Thanks, everyone. Okay. So we'll start our -- our afternoon session. And we've got two sessions for the afternoon, one is an update from the integrated pest management work group, and we'll turn it over to them in a second, and then more of an update briefing on benchmarks with regard to drinking-water sources.

Okay. So we'll start the afternoon -- second half of the afternoon with the report out from the IPM work group. Bob McNally, who I mentioned earlier, is the new division director for the Biopesticides and Pollution Prevention Division, and he's picking up where Keith left off in helping to guide the effort, along with Frank and other colleagues in OPP and across the agency. Bob?

MR. MCNALLY: Yeah. Thanks, Steve. So we have two things we want to do this afternoon. First, Frank Ellis is going to talk about the Center of Expertise in Dallas, Texas, and then we're going to have a report out from the work group from this morning's meeting. So let

me turn it over to Frank, who's also going to introduce the -- Thomas Cook, who's our recently-selected head of the Dallas Center of Expertise.

MR. ELLIS: Thanks. Good afternoon, everybody. We want to spend a -- just a couple minutes giving you a -- a little background on the work group meeting that we held this morning, we had pretty good attendance from our work group. We had some key folks who were traveling and weren't able to make it this morning, but we did have a core -- a good, active core group that was present for the meeting and we had a good discussion.

We kind of steered the group in a little different direction than we've taken in the past, we had a lot of discussion about some of the practical things that we could do as -- as our school IPM program kind of evolves and grows. And that now that we have our center of expertise for school IPM up and fully staffed, some of the things that we could help engage them in, so it was a very productive meeting that we had this morning.

And we wanted to give you all an update on -- on the center and some of the staffing, because we've talked as -- over the past year and a half or so with you all is -- is we've brought the center online. And one of the things we want to do is to take a moment to have Thomas Cook, who's the lead for the center there, introduce

himself and also talk about the staff that we have onboard there. So with that, I'll turn it over to Thomas.

MR. COOK: Thank you, Frank. Good afternoon. As Frank mentioned, there's exciting times in Dallas, Texas right now, so we -- we basically have completed all our staffing in the -- the region-six office. We have a total of four FTEs that are housed in the actual center, again, I'm the lead for that -- the -- the center. We have a young lady named Sherry Glick, who's the -- enormous amount of experience within the agency, she's providing a lot of leadership as well.

We have a gentleman by the name of Brad Miller, who has over 20-years' experience within the IPM arena. He is a recent veteran, he spent many years over in Afghanistan as well as Kuwait performing on-the-ground IPM. And our last individual we have is Marcia Anderson, who is a -- she transferred over from region two to complete our staffing within the center itself.

We -- we're -- we're -- we have exciting tasks that we are looking forward to accomplishing, we have ongoing work that we're performing related -- directly related to the strategic plan regarding IPM, but just to let everyone know we're -- were hitting the ground and we're going to run hard and heavy.

MR. ELLIS: Thanks, Thomas. One of the things that we also spent a fair amount of time this morning was -- was updating the work group on some of our activities related to improving and -- and cultivating relationships with some of -- some of the national groups that have influence over the school's arena.

Some of the work we've done within the agency improving our relationships and building upon them with the other children's health-related programs, both within the Office of Children's Health Protection and the Indoor Air Environment's Division with their tools for schools' program, I think we've made a lot of effort in that arena over the past few months. There's a lot more to be done, but we are -- we're proud of the accomplishments we've made to date and we're looking forward to doing some cross training with those groups and -- and building those relationships over time.

We're doing some key outreach with the help of the staff in the Environmental Stewardship Branch. We were fortunate to have Lori Fragario (phonetic) on detail as an OPP fellow for the past year with our program, and she's been instrumental in helping us reach out to some key national organizations as well, and so thanks, Lori, for that, she's back in the audience today. And also the -- the other staff, as -- as Thomas mentioned, Sherry

Glick and the others in the center, have been very productive in -- in that effort.

So with that I think I'll turn it over to Dave Tamayo, he's going to lead the report out from the work group this morning, along with some of the discussion and recommendation that the work group had. So, Dave?

MR. TAMAYO: Thanks. I -- I'm -- first I wanted to report that I -- I did try to trick some of the other members to doing this report out, but I failed in that regard. So, actually, even though the -- we -- we covered a lot of ground in our discussion, we -- what we really settled on that sort of jelled into a recommendation to EPA that -- that it -- start a -- a pilot project in -- in a couple of states and looking to increase the level of school IPM adoption, and, I mean, the idea is there that -- that EPA would -- would use this pilot project as a way of, one, sort of developing some of the work products that would be necessary to -- to -- to do that successfully.

So some of the information work projects, for instance, information on the quantitative benefits of -- of IPM that would be useful for IPM advocates, consolidating training resources, making sure that -- that training resources were readily accessible and available to -- to folks in those areas, information on

-- on contracting, a lot of information on how to develop IPM within your -- within your school district, that work would be accomplished both by folks from the centers, but also in partnership with -- with people in the regions, the regional IPM coordinators, and then also in -- in -- one of the ideas is that they should be partnering with other federal agencies that are concerned with -- with children's health. And so issues, say, like it -- it could be lead abatement, or it could be mercury, or other types of things that are really complementary to the message of IPM, so there's a number of opportunities for that.

Now, the actual shape of this, what they would actually be doing would be an ongoing -- an ongoing effort that the work group would help advise them on to help shape what that program's going to be, what the resources are going to -- going to look like, what kind of information should be in there. So that's what the work group will be continuing to work with, with staff on, is advising them on -- on what -- what types of information, and what -- what that outreach effort should be, who they should be talking to in the states.

And -- oh, and I also forgot to mention that the -- also in -- in covering issues, not just another aspect of children's health, but also on working with other

folks to address environmental justice issues. And then finally the -- one of the advantages -- or -- and the end result of this, there would be a body of -- of materials that -- some of which are -- are already out there, but maybe they're put out by a -- more of a regional-focus effort or an NGO, and we think that there's some advantages to having materials and information sources that are basically bedded by a broader group of stakeholders, and that would actually be coming from EPA, and then I would think that there's some advantages in doing something on a national basis and trying to influence the direction that states are taking by having materials that -- you know, that are coming from EPA.

And -- and then also the idea is to -- to create things -- or a program and an approach that's exportable to other states. So it wouldn't necessarily be that -- that EPA would continue to be the -- the -- the primary deliverer of this type of effort, but at least an approach would be developed. And then also some of the work products themselves could very easily be just moved from state to state, they're -- they're not necessarily going to be state-specific resources. I think especially in this field in the -- in -- in a focused area like school IPM, a number of these resources, say, like the quantitative benefits of -- of IPM, would be something

that -- that will be useful to basically somebody anywhere in the country.

So -- and so we're looking forward to continuing to schedule these work group meetings and -- and trying to give a little bit better shape and definition of the program, and that's where we're at.

MR. ELLIS: Any other work group members who came in want to comment on any of that, that -- that Dave talked about, or is that pretty much -- pretty much it?

MS. HURLEY: This is Janet Hurley and I have no extra comments, other than that, yes, it's -- I think that you will find a -- a more collective approach of us trying to work more with -- with EPA now that we've got the fully-staffed center of expertise. I will say this, I'm going to put a plug in to everyone that I know that if that work group is open to anybody, since I didn't know this, I'm just going to dive in and say that I'm going to start telling more people about that work group meeting so that we can get more involvement with the people who are doing it, the boots on the ground.

MR. MCNALLY: Well, I might just add that with EPA's support we're completing a survey of school districts nationally, so state-by-state we've been contacting school districts and finding out a level of IPM in each school district, and we also did a -- a

state-level survey where we contacted state leads and asked them to profile school IPM activities in their state.

And since the -- the national coordinated effort started back in 2006 with the development of the pest management strategic plan for IPM, we've seen quite an improvement both at the state level -- we have many more states that had a coordinated program with multiple agencies getting involved in school IPM in the state, we have more funding at the state level than in 2008 when we did our first survey.

We have 240 people now who are part of the national working group, which is comprised of four regional working groups, and then our state-level school district survey data is very interesting. And one of the -- the most striking things about it that we have tremendous variability from state to state by -- in terms of indicators like IPM policies, IPM plans, IPM coordinators in school districts, and we've identified a number of states that are way, way behind the curve in terms of getting school IPMs in place, so that information will help us target our activities more effectively.

And -- and also some interesting correlations in terms of the state-based legislation in school IPM and

IPM performance in the states too, and this tremendous variability from state to state in terms of the regulations that are in place, and we'll be doing some more data analysis to identify what are the -- what are the key factors associated with state-level legislation that really favors high performance in terms of presence of these, the indicators of IPM.

MR. BRADBURY: So I've got some questions. Realizing that the work group's going to be -- oh, Mae, go ahead.

MS. WU: Oh.

MR. BRADBURY: You're more important than me.

MS. WU: So I'm brand new to this, so apologies for asking what may be obvious questions. So, I mean, I heard that this is all school related. Are -- like, are part of the plans going to be that -- I don't know, like the materials that you all are coming up with, I understand that they will be able to go from state to state. Would they also be something that would be applicable to, say, like, public housing places, or, like, ag uses? I mean, it sounds -- it sounds like, like they're quantifying the benefits and that kind of thing might be useful outside of the school arena.

MR. MCNALLY: There was discussion about the applicability of -- of this particular type of IPM to

other institutions, and I think that a -- a hospital's daycare, I'm not sure, maybe multi-family housing, but certainly there's things that -- that sort of -- that sort of would be.

MS. WU: Um-hum.

MR. MCNALLY: So I think the -- the focus right now is just on this. I -- I think some of the work products would be adaptable to -- to other situations like that. Certainly the farther, the less you have in common, so it would be harder to make a case for agriculture.

MS. WU: I mean -- I mean, and I've been envisioning since you were talking about, you know, the farm worker kids, buyer, or whatever may have, and schools would have too, so I'm just trying to think of the broad --

MR. MCNALLY: Yeah.

MS. WU: -- like making it as broadly --

MR. MCNALLY: Yeah, it is. I think the idea is -- (inaudible) -- so I -- I think that's in -- in the little bit longer term, but certainly some of those other institutes are much closer, I think it would be readily transferrable to that.

MS. WU: Okay.

MR. BRADBURY: And -- and just to clarify, the

-- the charge for this group does go beyond the school IPMs, so -- and -- and we've had report outs over the last -- the time I and Dave -- the last couple of three meetings where we talked about, things like what would be metrics for successful IPM programs in ag, or in public health, or -- I mean, I think we talked about health care centers.

And I -- and I think some of the -- would you guys correct my memory, one area of it that we thought, because of initiatives going on within the pesticide program, the school IPM area, try to make sure we could really start to get some movement there and then maybe sort of pick up on some of the other areas down the road, but members from the -- from the work groups should weigh in, in terms of my recollection.

MR. MCNALLY: So on the ag side we -- we invited Bill Coley (phonetic) from University of Massachusetts to participate in the work group, he was involved and there were EPA people as well. Ten years ago or so there was a national IPM evaluation work group, I don't remember exactly what the name was, but essentially they -- they had done a chunk of the work that we had not identified our work group wanting to do, and had developed a series of very-detailed logics models that presented the benefits and metrical metrics for IPM and ag for the work

group, and felt that those really didn't need to be updated, and we -- we pulled out some of the metrics from that list and reported out on that, I think, in November.

MR. BRADBURY: Janet?

MS. HURLEY: And just so you know, as far as homes or multi-family housing, USDA and HUD have already taken on that charge. For those of you that are web savvy, if you go to stoppests.org, that is where all of that information is housed. We've not been quite as cohesive as that effort has been out of the northeast IPM center. However, I believe that that's with the center of expertise and what we're doing on a national school IPM thing, we are trying to make it more cohesive and not make 50 states all different, so that's -- we are working it, just so -- just so you know, because you're probably a young mom too.

MR. MCALLISTER: This is a question for the work group and perhaps for Tom Green. You -- you mentioned that you had someone in to present metrics on IPM adoption and agricultural, and your conclusion was you're good enough. Did it -- did you need to do any more, or is that the conclusion of the work group that ag IPM is already okay, or you were drawing from that experience on how to measure IPM use in other arenas?

MR. GREEN: Well, Dave can correct me if I'm

wrong, but our -- our conclusion wasn't that IPM and ag was -- was doing okay, but just that workable metrics had already been identified and we didn't need to recreate that wheel. We had a good list of metrics that EPA could use to measure adoption and outcome of IPM in agricultural, they took that out of it.

MR. MCALLISTER: I -- I would challenge that, because we do not have the expertise in that group to make a -- a conclusion like that in terms of IPM in agricultural. I think there's a lot of work -- awful lot of work that's been on IPM in agriculture, but we just don't have the people in the room there to make that conclusion.

MR. GREEN: Well, I disagree with you, Ray, and maybe we can just compare notes. Really what we're doing was pulling that existing body of work from that national IPM evaluation group that EPA, and the IPM centers, and the IPM coordinators were -- were charged with assembling 10 years ago. So really it wasn't the -- the group that was creating -- creating a wheel, it was a presentation of this work that had already been done, that the group published at that time, I'd love to have you take a look at that.

MR. BRADBURY: All right. That -- part of the effort, Ray, as I recall, was to -- the group had a

charge to take a look at ag, school, I think health care facilities, I'm probably missing something, and -- and we're -- and federal staff working with the -- the work group is just sort of get a sense of where -- where are -- where are we, the big we, in terms of just metrics to -- to measure implementation of success of IPM in these different sectors.

And I think some of the conclusion that we made as a -- as a whole work group, given limited resources, were to focus and -- and sort of focus on a school IPM area first, because that's where we were pushing resources as part of -- of the pesticide program and a niche where it -- not that we aren't collaborating.

We've heard about working with HUD, now there's -- they're as appropriate in the school systems, but more in a -- in a real EPA domain to -- to be working anywhere, as USDA has a big role in -- in IPM and agriculture, not that we don't work together. So it wasn't so much to -- to -- to do a report card on IPM and ag, it was -- it was trying to figure out where are we in indicators for different sectors and mirroring that up with school IPM being an area of focus for the -- for the group, for EPA at least. Cynthia?

MS. PALMER: I'm from American Bird Conservancy, but I'm taking off my bird hat for a moment and putting

on my mom hat. As a resident of Arlington County, I'm on the -- the county advisory committee to advise the public schools in pesticide use and other environmental issues, and it's tremendous to see here about -- the progress so far in getting an EPA involvement in the IPM issues. And for us it would be really useful to have a clearing house of best practices and examples of IPM and how it's being done around the country, because we are constantly looking at other jurisdictions and trying to find the best past and lessons learned.

MR. BRADBURY: Good. And I think that resinates with -- with some of the efforts the group's taking on. So can I explore a little bit the -- the recommendation, and -- and others can certainly -- and work group members can -- can dive in? So the -- the recommendation is pick a couple of states as pilots and -- and through that -- that effort to presumably see a state go to or approaching 100 percent of the school districts having IPM programs with certain characteristics and -- but those are my words, I don't know if they're that work group's words, so it would be helpful to get feedback on -- on that, you know, what would be the outcome of these two state pilots.

And I did hear the part about coming up, you know, lessons learned, this tended to work well in these

kind of school districts in our state, this didn't work so well, but this works a little differently, here's some of the ways we tracked how we were making progress, that -- that's what I'm hearing, but is it like being able to track a state moving toward the 100-percent implementation?

MR. TAMAYO: Well, we just sort of settled on the concept and agreed that we needed to work out, and that's not really even a detail, but, you know, important aspects of that. So, you know, how would -- would -- how would we choose which place, are we going to pick the worst, are we going to pick ones that, you know, just need a little bit of help? We -- we haven't even worked that out, what -- what the criteria are and -- or even what we mean by success yet, so, I mean, I think we're just -- that's sort of the next steps of -- of working that type of thing out. So I think it was actually successful to get the -- the focus of where we're headed now, so -- so now I know why you were laughing.

MR. BRADBURY: I was pleased.

MR. TAMAYO: Yeah. Okay.

MR. BRADBURY: It might be -- I think it would be helpful though to use the full committee, I appreciate Cynthia's observation. So if we -- let's -- now let's hone in on school IPM and the proposals from the work

group. I think it would be helpful if members from the -- the full committee have some ideas, some attributes that you think the work group should consider, some -- some other attributes of the process, not for us at this meeting to decide for sure, these two states, but nor to necessarily come up with the waiting scheme or whatever, you know, process the work group wants to use, will use, and then report back to us.

But if the -- this will be a good opportunity for the work group to hear from all of you what are some of the attributes we should consider, what -- you know, states that have legislation and that requires school IPM and states that don't, states that have a wide range of -- of land -- I'll use the word, ecosystem -- you know human ecosystems from agricultural to heavy -- heavy, big cities.

There's a whole bunch of -- of different attributes that could be brought to bear, and I think spending a little time, you know, the PPDC committee going, knock yourself out, work group, you've got carte blanche, or if you think there's some -- some attributes you think they should take into account, this would be a good time to give them some -- some feedback, now we'll leave them alone and let them -- let them work it -- work it through.

And if there are work group members that you know from your discussion this morning where you'd like to get some feedback on some of the inputs that you'd like to use, this would be a good time to do that as well. Cheryl/Sheryl?

MS. CLEVELAND/KUNICKIS: So I -- I guess I'm honestly a little confused, because I thought the charge a year ago was for this group to come up with metrics for school IPM. I -- maybe my memory's wrong, but it doesn't sound -- it sounds like now, Steve, you're asking us to brainstorm metrics here, so I'd like actually just a little bit of clarification on -- remain me what the charge of the work group is and also how does it relate to the -- the new office, because I would think some of this is being handled there, and also we got that really great presentation from Mark about a year ago, about how you measure IPM in schools, and so he -- I mean, he had a ton of metrics right there, so I just need a little bit more clarification.

MR. BRADBURY: So my understand, but work group members correct me, is that using the presentation from last -- the last time we met, was that while not completely done, done, the metrics for -- for evaluating how a school IPM program is moving forward is in reasonably good shape, it seemed like the work group had

coalesced. I mean, not 100 percent, but it had coalesced around 90 percent there, 85 percent there.

And so my understanding is a work group started to evolve then from, okay, we've got a pretty good handle on what it looks like as school IPM programs are starting to -- to get steam and starting to move forward, how can the work group assist the agency -- now at the new center of expertise with six cooperative agreements going on around the country, how can the work group help in the -- in coalescing around the different groups that are out there moving forward and -- and get more towards how can we provide advice to the agency in actually helping it happen and giving you feedback as it's really starting to happen?

My sense is that this idea would also be complemented with other things going on either through cooperative agreements that EPA has with the first round of funding, as well as federal first, but this would be a way to try to really target an approach. So it isn't about brainstorming some more about metrics, it's going, okay, we're -- we're -- we're in pretty good shape on what the metrics are, how can we provide some assistance to the agency to start doing it realizing we have different -- different, you know, federal resources or federally-funded resources that can be levered with other

groups that are doing things as -- as well? That's my interpretation of what I heard from the work group report out, but I want to make sure that my summary to help with Cheryl's/Sheryl's question is reasonably accurate.

MR. TAMAYO: Number three on the work group direction is other issues relating to the promotion and use of IPM that the agency brings to the work group. Now, in our discussion today we were talking about the status of the -- of -- of the -- you know, the metrics to assess effectiveness and we talked about the -- you know, there were -- in the -- in the past report out we -- we had reported that we recommended that there be some work done on identifying the quantitative benefits, and then the -- the discussion warped into how do we promote the -- the adoption of school IPM, and that's -- that's the direction that we headed.

You know, the agency was interested in, well, okay, well, we'll -- what are we going to do with this stuff, so that's -- that's what we moved -- moved into, so it's in number three.

MR. BRADBURY: Thanks, Dave. So, again, it -- we've got two options, one is just let the work group run with it, and that's -- that's an option. I am curious though if the -- first, is the full committee okay with -- with sort of taking the idea of -- of metrics and how

to measure benefits, which came out at previous meetings, and using that knowledge, realizing it will probably get tweaked as it -- as it plays out, and having the work group, at least in the school IPM part of the work group, now start to transition toward advice to the agency as we move forward with our ultimate goal in the strategic plan is reaching a day when 100 percent of the school systems in the United States would have school IPM programs and have a certain kinds of characteristics, that is the overall goal of the agency.

And to the extend the work group's thinking, okay, now it seems like consistent with the discussion with Tom, and -- and Frank, and Bob, how can the work group start to help in making that happen with the proposal, why don't you start with a couple of states and -- and -- and start to play it out and see how that experience can then be helpful across the other 48.

So I'm looking at Janet, I'm looking at Tom, I'm looking at Dave, why don't I just make -- what I'm trying to do right now -- do right now is making sure if I'm speaking for OPP and I'm trying to reflect back what I heard, is that accurate, am I accurate in synthesizing what the work group's recommendation is?

MR. TAMAYO: Yes, in my perspective.

MS. HURLEY: Yes.

MR. TAMAYO: And -- and now, you know, EPA has this fully-staffed center and representatives in each region, so you're really ready to go and start taking some of these -- these ideas and moving forward with them, we're very interested in working with you to do that.

MR. BRADBURY: Yeah. Okay. So that was the -- the first -- that's good, that reasonably captured the synthesize of the work group, so the next step is full PPDC. I mean, we don't have to raise hands or something like that, but are you all comfortable with that sort of task for the work group and the work group's, you know, primary focus area as we go forward over the next several months working with the agency to -- to now implement that -- that effort?

And I'll kind of do it, unless somebody's got a violent disagreement with it, that by and large the -- the full committee concurs with that being a task in front of the work group, and I'm opening that up to talk about to the extent it needs to be talked about. Okay. We're good to go.

So that will be the -- the -- I know I'm going through this sort of painfully, but it's really important to make sure through the advice process the work group's provided advice, and I want to check and make sure the

full committee's okay with that advice. I'm concluding that the full committee is in support of the recommendation of the work group. Good. Ray?

MR. MCALLISTER: I guess I'm still a little confused. The -- the group has the metrics now, and -- and the -- the next task is go measure IPM adoption in the schools across the country or --

MR. BRADBURY: No.

MR. MCALLISTER: Okay.

MR. BRADBURY: My understanding is the work said, okay, we've got metrics, we know that -- Tom can correct me, but probably the majority of school districts don't have verifiable IPM programs running right now. Our goal is to get to 100 percent, that's challenging to do. Agency, it looks like you've got your center of expertise up and running, you've got 1.1 million dollars of coop money going, you've got another call for proposals going on, now is the time to take the concepts of the metrics and other techniques that are either under development or have been developed and start to make it real across the country.

We think picking two states would be a good way to have some pilots, some proof of concept to help launch this and to help be a driver along with other things that are going on, and then you may learn how well your

metrics sort of benefits. No, that metric works really well, that metric didn't work so well, but you actually start to exercise the metrics and some of the other techniques that -- that are under development as part of the stepping stone to 50 states having all their school districts with school IPM going on as our big goal.

MR. TAMAYO: And -- and just to add to that, so now that we have -- we had this baseline survey data where we used a number of those metrics in the surveys, and so we'll be able to repeat that survey a couple years down the road and measure how well we're doing.

MR. BRADBURY: So, Ray, does that work, does that help clarify?

MR. MCALLISTER: (Nods head.)

MR. BRADBURY: All right. Good. Now I don't want to pound this to death, but if there are some perspectives folks have about picking two states, two out of 50, there's a -- just the variability across 50 states. And again I realize that picking the two isn't to be representative of all 50, and nobody's saying that, I know, but having said that, there could be attributes that I'm sure the work group wouldn't mind hearing about from the full committee to the extent anybody's got some ideas right off the top of their head for the work group then to take back in terms of certain characteristics of

school districts and states that -- that may be beneficial in terms of the proposals that will come forward ultimately.

And there will be some nuance to this in working with the state authorities and stuff as to how we pick this, so I'm not trying to name two states right now, but just hearing about some of the attributes you all think may be important to consider. Sorry, the glasses. Go ahead.

UNIDENTIFIED FEMALE: That's fine. So if you want to look at North Carolina, we -- as far as we can tell, we have close to 100 percent adoption. We've got -- we did a policy survey, so we know that about close to 100 percent of school have adopted IPM policies. And we've had a good training program with N.C. State, so there's been a lot of training in all those districts. So to look at, I think, a reasonably good success story, that's one example to throw out.

MR. BRADBURY: Cheryl/Sheryl?

MS. CLEVELAND/KUNICKIS: Well, on the TOX-21 sub-work group down into some tracking things, we've dealt with metrics now. Kristie Sullivan's been leading something on metrics for a long time, and the thing we've struggled with is how you track them. So we can come up with metrics all day long, but we're the databases of how

are you going to get the information on. So if I was in charge of picking two states, I'd find a subset of metrics that are easy to extract from those states' systems. I mean, it's very practical, but that's what's I'd do.

UNIDENTIFIED FEMALE: Can I just interject one thing, and this is from someone who had a law in her state that even with a law it doesn't work so well? Just because they adopt a policy, doesn't mean they're doing it in the school campus. And just because the law is on the books, doesn't mean they're doing it in the school campus, and it could be, it all depends. I mean, if it's a small district and it's rural, you know, nobody's going to come out here and see me, who cares. There will be some other things, but this -- I will say this, this gives us encouragement that there are several different work groups going on with IPM.

I am hoping, and I'll just go ahead and interject, Bob McNally, I'm going to probably be approaching you via our steering committee making more synergizing, working together, how do we do this before we go forward. I mean, there's lot of states out there. And there may be a state out there that's going to just jump on this and go, oh, pick us, because we want to go forward, and there's others that are going to go, don't

come near us, because you can't tell us what to do, so understand that.

I mean, there is a lot of diversity out there. While we've had some really good results come out, as a matter of fact, I was kind of shocked at the results that Tom, in the IPM Institute, got for the -- the school IPM survey, but, you know, overall it wasn't bad. But, again, the hardest part, and I know, because I've done the surveys myself, is when you go back and spit -- if you were to cherry-pick schools, you know, randomly go in and just look at stuff, it's a whole different thing. So we've got a -- just so you all know, we do really have our work cut out for us. Dr. Bradbury's making it sound so easy, not so much.

MR. BRADBURY: Brian and then Tom.

MR. ROWE: I just offer to the work group and EPA as well that right now states are negotiating the 2014 grant commitments, and within those grant commitments are electives to work in school IPM programs. So if there's a way to reach out through the regions and offer up an opportunity, timing is right now.

MR. BRADBURY: Good point. Good point, thanks. Tom and then the other Tom.

MR. DELANEY: I'd -- I'd like to see the survey questions and -- and look at the survey information,

because I think you need to use some of that in -- in working with what states you're going to -- to pick, because, I mean, resources in the state, there may be the will and they don't have the budget to do it, so you've got to -- you know, got to look at a lot of perimeters before you end -- end up -- and -- and trying to find out what you want to do with that results, you know, you want to see how far you can move with one or -- you know, I there's -- there's a lot to be involved before you pick a state.

MR. BRADBURY: Tom?

MR. GREEN: So a couple comments to -- to Cheryl's/Sheryl's point. We did that with our survey, we kind of boiled the survey down to what are the key, fairly-readily measurable indicators, and those were what I mentioned before, IPM coordinator, IPM plan, IPM policies.

And then when we actually do work in schools and then recruit schools to participate in what we call coalitions, school districts working to implement IPM, to get to another level of metrics that are harder to measure and the people need support so that we get good data back from them, those are things like a number of the testing plants, and pest management costs, and a number of pesticide applications, and types of pesticide

applications, were they baseboard sprays where you're likely to get exposure, versus state applications, so we can get both levels of data depending on how closely you're working with the -- the school. And then I think, to Tom's point, that that's really important.

So we can -- we can share our survey data more or less privately, but we've committed to those in the states that helped us implement the survey not to publish the results, no pointing fingers at states that aren't doing so well, so we have shared those results with EPA and are sharing those with people who are in a position to make a difference.

And we do have some of those states that are very much down at the bottom of the pile in terms of performance, and the hope is that with EPA engagement and the resources that EPA is bring to bear in terms of -- of people and dollars, that we can put some of that infrastructure in place in those states, because that's the reason why they're at where they're at, and we're not going to make progress unless we can bring that to bear.

And I think with EPA's resources now, that we have the potential to educate state lead agencies and others in a state that's not doing well that they've got an opportunity and should make some investments to get the people in place to get the job done.

MR. BRADBURY: Okay. So I think I've got what I need in terms of next steps. The -- the point about the funding cycles for the state grant is -- is very important, a -- a good point, and we need to try to factor that into the time frames we're operating under. So work groups meet, you know, in between, they don't always wait until the day before the PPDC meeting to get together.

You guys do lots of teleconferencing and things like that, so Bob, and Frank, Tom, I would ask you to -- to reconvene the work group soon, like real soon, and continue this conversation in terms of how to think about attributes for -- for piloting that, we'll try to see how well we can match it into some of the -- the funding cycles that the state grants are playing out. I can't guarantee you we can line that up just perfect, but we might be able to find some -- some win-win situation.

I'm trying to balance sort of how to do this proposal with the full PPDC, and looking at time windows to make things happen, and, frankly, being respectful of this -- whatever states that could seem like good opportunities. There's a respect to the state government and -- and the appropriate levels of the state government to -- to work through this interaction, and I haven't quite figured out how to do that yet. It doesn't mean

it's insurmountable, but there is appropriate steps to take to do that.

So if the -- the work group could -- could meet soon and start talking about some of the attributes, because some of the things I'm thinking is that while we may not -- we may wait until the next full PPDC meeting to talk through what some of the choices would be for the two pilots. Given what's going on with the six cooperative agreements, which -- which are in, I don't know, probably 12 different states when you add it all up, because we've got cooperative agreements with University of Florida, which is dealing with Florida, and parts of Georgia, and parts of Alabama.

We've got cooperative agreements with Ohio State and Indiana, so we've got Ohio and Indiana in play with the cooperative agreement. And there's a cooperative agreement with Colorado State, which is -- which is a partnership between Colorado State, Colorado, and the Salt Lake City school districts. Cooperative agreement with University of Washington, which is a collaboration with Oregon State University, so we've got Washington and Oregon in play.

So we have a number of states in play through the cooperative agreements, we've got activities going on in some of the specific regions with their regional FTE

effort in states that they may be working in, so there could be ways to take some of these ideas and just nudge, nurture, boost what's already going on through the cooperative agreements or through some of the federal efforts with other partners in other parts of the federal government or state government, so there may be ways to start making some things happen that way.

And then when we come back four, five, or six months from now, kind of take that pilot concept and -- and -- and play it out. But some of ideas that are playing out in the work group may be able to start to play out through cooperative agreements or other activities that are ongoing in some other states. I don't know yet, but that's something that we may be able to take advantage of, because I am -- I like the idea about waiting six months before we meet again to actually do it. I don't want to lose good ideas, given what we've already got investments in now. Every day those dollars tick, tick by, and we don't want to -- don't want to waste them. So I'd like Dave to go ahead.

MR. TAMAYO: Well, I encourage you, unless the -- you know, the -- and -- and there doesn't seem as though the -- the full PPDC objects to the concept, and the recommendation is really mainly the concept. And we've offered up that we could continue to give advice on

what the -- the shape of it would be, but I -- I -- I -- I would discourage you from saying, oh, well, we kind of have to wait and bring the -- the implementation stuff back to the PPDC, because it will never get anywhere if you -- if you -- if you -- if we have to -- you have to weigh in on every implementation step, so the -- that would be my suggestion on how to take the advice.

MR. BRADBURY: You picked up my signal, so what -- what I'd like to do is use the advice from the work group and see how we can take advantage of -- of those ideas, the concept of a pilot, the concept of certain attributes, realizing we've got -- we're on the ground. Not we, we, but with our cooperators and all other partners that aren't necessarily part of these coops where there may be ways to just start to help accelerate, or advance, or get feedback from the work group in areas we're already working on.

Having said that, the idea I was thinking about, picking two states and -- is -- is a good idea, but we don't have to wait to get that all figured out for some of your ideas from the work groups to start to get implemented in places we're already on the ground. So I think between Dave and I we've sort of nudged the recommendation a bit, but I don't -- looking around the table seeing -- Tom, go ahead.

MR. GREEN: Isn't it to be somewhat tied to grant money in -- in what's the criteria for you picking those states that's going to get the grant money, and wouldn't you be tying some of that together?

MR. BRADBURY: Well, we already have existing cooperative agreements that were -- as Marty said, were awarded in 2012.

MR. GREEN: Oh.

MR. BRADBURY: Those are the -- those were the universities and partners I just went through, University of Florida, Ohio State --

MR. GREEN: Okay.

MR. BRADBURY: -- and Indiana, Colorado State, and Salt Lake City school districts, State of Wisconsin, Washington --

MR. GREEN: Okay.

MR. BRADBURY: -- and --

MS. MONELL: Oregon.

MR. BRADBURY: -- and Oregon State. So those -- those are already funded with the notion of pushing into specific school districts, if not entire states. So some of the feedback from the work group could help in that partnership, some of the feedback from the work group could help in how we move beyond --

MR. GREEN: Well --

MR. BRADBURY: -- beyond that.

MR. GREEN: Well, are you going to compare those states with results that you got back from your survey, to look at those specific states in your survey?

MR. TAMAYO: Yeah, we'd have that potential to do that. So what we talked about in more detail this -- this morning was that we've got a proven model, to take a state and move it forward, and that's by getting all the players at the table, showing them benefits of IPM, showing them that they're, you know, way down the curve in terms of adoption, recruiting some pilot school districts to do demonstrations, make IPM happen there using experts from outside to support folks in the state, and then building from that using a coalition model where essentially those demonstration school districts then recruit their peers that participate in the coalition that gets together on a regular basis and supports the other districts that build their program.

And then the -- the ultimate is having an FTE in the state, like Texas has in -- in Janet, to keep the ball rolling, and potentially having some legislation as well to support the idea that those working in schools and doing test management need to have ongoing training for doing test management in that environment, both on the buildings and the ground side.

And we've talked about this morning too, for your particular interest, of how often the focus in the IPM programs has been structured. And -- and there's a bigger land of opportunity in the grounds and athletic fields as well where you have a diverse cast of characters that are -- are doing test management, including coaches, including parents, and others.

MR. GREEN: And a good number of our members have contracts in school systems and stuff to do either sports fields or the general area there.

MR. TAMAYO: Yeah. And we did ask that question on our survey, and we have to share that, those results with you.

MR. BRADBURY: Okay. So I've got a pretty good image in my mind. What I'd like Bob to do is -- and which I know he's been jotting things down, he's been known to track my verbal musings and reasonable capture them. So, Bob, if you can pull that together and, as needed, work with some members of the work group and sort of share sort of this discussion and see if the work groups got the reasonable reflection. And we'll use tomorrow, before we wrap up, as we kind of go through and summarize what we've done just to -- to verify what our game plan is, because I realize there's a lot of dimensions to this, which we all know, but this, I think,

gives us some focus of how to take advantage of what we're already doing and think about some opportunities for the future.

And the -- the big message is, we kind of know what the metrics are, we've had some experience in starting a program off, tracking how well it's going, getting to where it goes, needs to go. We've got resources now in the agency, some already invested, some that will be invested with the next round of grants, this is a time for the work group to give us advice on insuring that we're maximizing what we can accomplish in setting the stage for others to start to get into it.

Clearly at the end of the day the -- the measure of success in my mind is not that EPA disappeared in school IPM, but that, in fact, it becomes a sustainable part of just how you operate a school district, because it must makes sense. If you're doing your energy work, if you've got leaky windows or door jams that don't work, you need to fix those to keep the heat on the inside or the coolness on the inside. And when you do that, you'll probably keep an -- an entry for pests, you're cutting that down too, so you've spent a buck and you've got two things done with one buck.

And so part of working through this is to just have a goal, this just gets integrated into the efficient

way a school district runs. So you maximize your dollars for teachers, and books, and -- and learning, and -- and -- and by doing that you've maximized your dollars for energy efficiency and all sorts of other things that -- that are correlated with effective management of -- of pests, that's my spin on it and that's where we need to go, to self-sustaining systems.

So Bob will capture sort of the game plan, we'll make sure we check back in tomorrow before we close down to make sure that that's working okay. And I encourage work group members, and Bob, and Tom, and Frank, if you need to caucus a little bit this evening or in the morning before we start, to -- to do that, I think that would be good.

Okay. So why don't we close down this session and we'll move into the last session for the afternoon, which Rick Keigwin and Betsy Behl are colleagues from OPP at the time and now in the Office of Water, and give you an update on where we are in terms of communicating benchmarks for pesticides in drinking water supply. And again, I want to thank the previous work group for the -- for the lot of effort over the last several months. So Rick and Betsy, I'll turn it over to you.

MR. KEIGWIN: Good afternoon again. For many of you, this is -- will serve as an update that Betsy and I

gave you all a couple of years ago now before OPP and the Office of Water launched this effort. For -- for others of you, this may be new and so the presentation that we'll give tries to encompass everything that we've been doing to date over the last couple of years.

We've been doing this set of presentations now to a diverse group of stakeholders over the past couple of months, and we've generally been getting some very good feedback as we move forward, and we're looking forward to hearing your thoughts on this as well.

So if we go to slide three, the -- the idea for developing these benchmarks initially came about as part of Lisa Jackson's drinking water strategy that was announced in March of 2010, and that strategy had four basic elements that are listed up here on the slide to look at, contaminants as a group, rather than working on each contaminant singularly; to foster development of new drinking water treatment technologies and advance the paradigm in that regard; where the human health benchmark piece very much fits into it, this third element, which is looking for opportunities to utilize multiple EPA statutes to help protect drinking water, so in our case utilizing FFDCA, FIFRA, combined with the Safe Water Drinking Act; and then the fourth piece was focused on partnerships with states to enhance the sharing of

monitoring data from public water systems back to EPA.

In many respects these benchmarks are modeled after the aquatic-life benchmarks that OPP has been developing over the past several years, very much in line with the work that the Office of Water does under the Clean Water Act when they move forward to establish aquatic-life benchmarks. So just like we do now for pesticides where there's not an aquatic-life benchmark, we establish aquatic-life -- I'm -- where there's not an aquatic-life criterion, we establish a benchmark.

Similarly here the intent is to develop a benchmark for pesticides in drinking water when there's not already one in existence, MCL, maximum contaminant level, or a health-advisory level under the Safe Drinking Water Act. And as we were in the process of developing these, I think it's helpful to note that we actually received a request from several state departments of agriculture, because of the success of the aquatic-life benchmarks' program, to try to port that over upon the human health side.

Next slide, please. So what are the -- the benchmarks? There is screening levels -- drinking water or screening level standards for levels of pesticides in drinking water, and they are based upon both acute and chronic toxicity values. These values to date have been

derived by using the data reviews that the Office of Pesticide Programs does as part of our registration or re-evaluation work of -- of the hazard data, coupled with the methodology that the Office of Water uses when they're developing a health-advisory level, and to date all of these benchmarks have been developed only for food-use pesticides. As you all know, food-use pesticides have the most robust toxicological database and they're -- they're easier, if you will, to use in developing these benchmarks.

As I mentioned earlier, we're not establishing a benchmark where there's already an MCL, or an MCLG, or a health-advisory level in place, the Office of Water has already done that work, and they're not enforceable standards. They're not limits, they're really meant to be for informational purposes.

We've heard, for example, from a number of states that -- that they -- when they get a request or they receive some monitoring information, they use these as a reference point to see whether or not they need to do further investigation, but it's not intended to be used as a mechanism for triggering an enforcement case. It's not intended to be used for determining safety, it's really meant to be used as that first step in the process to see if any further evaluation needs to be done based

upon the monitoring information that's been found.

Next slide, please. So as I mentioned, last year we released the first set of these benchmarks, they covered about 352 food-use pesticides and they covered, as I mentioned earlier, both benchmarks for acute and chronic effects. However, at the time we had not focused on carcinogens, per se, overall the response has been very positive. And, in fact, subsequently we linked this information to an effort within the OECD, and these values are also available not only on the EPA website at the -- at the link provided here, but they are also available through the OECD temporal, you can see that.

Well, next slide. When we released these, we committed to providing periodic updates with a goal of once a year, but we've committed to periodic updates at this point. So what we have done for this first update is we have updated all of the benchmarks based upon the current case of OPP's reviews of the hazard data. As a result of that, we've added benchmarks for nine additional newly-registered pesticides and we've updated ours for two of the existing pesticides.

What's particularly new here is that we have added benchmarks based on carcinogenicity for 40 pesticides, these are 40 pesticides that have cancer smoke factors Q-1 stars. There may be other pesticides

that are regulated through a threshold mechanism for cancer, and those would have been captured through the chronic benchmarks that we established last year. And as I mentioned, we're -- throughout this process have been seeking stakeholder input as we move forward.

To give you an idea who we have spoken to, on slide seven, we have met with Sheryl and her staff at USDA, we've met with a U.S. geological service, a number of state organizations that provide input to both the pesticide program, as -- as well as the water programs, we're meeting with you all today, we did a briefing a couple of weeks ago for CropLife America, and then we've also done some briefings for NRDC, as well as some other non-governmental organizations. And our goal was to complete all of this outreach by the end of last month, we took advantage of PPDC being this week, and so I think, as I mentioned earlier, you all are our last group that we're intending to meet with as we move forward.

Slide eight, for those of you in the back that don't have the slides, this -- this is impossible to read and it may even be difficult for those of you who have it on paper, but this is just a representation of what you would find when you came to the webpage. Basically you can search on the chemical, you can search on the Chemical Abstract Service, CAS, number, and then it

provides the -- where we have one, the acute reference dose from the Office Of Pesticide Programs' review, what the resulting human-health benchmark is on an acute or one-day basis, and what the reference population of concern is. And similarly for chronic and then where there is a cancer-slope factor, what the benchmark would be for cancer.

Now, what these values do not include in setting the benchmark is if OPP applied a Food-Quality Protection Act safety factor, is that something that we use in our decision-making process under the Federal Food, Drug, and Cosmetics Act. It is not a consideration that the Office of Water uses when setting a health-advisory level or an MCL under the Safe Drinking Water Act. But for transparency and for assistance, you will see in this chart some footnote for individual chemicals where there may be a safety factor for FFDCA purposes, and so that's noted here as well.

The other thing that's not represented in this table, but is also available, I believe, is that the -- the web version of this also allows you to link into the Office of Pesticide Programs' toxicology review for that chemical so that you not only see the value, but you see the data, and you see the dose response, you see the -- the data-evaluation records that OPP generated in, in

helping the Office of Water in the development of the benchmarks.

So slide nine, just to summarize, we have new non-cancer information for about 11 pesticides for adding benchmarks based upon cancer considerations for 40 of those pesticides, bringing the total number of benchmarks to about 363 chemicals. Our plan, taking into account all the feedback that we received from you all today, as well as the feedback that we've received to date from other stakeholders, is to proceed with briefing-up our respective management with a goal of releasing this update later this summer. So that covers slides nine and ten, and with that we'll take questions.

MR. BRADBURY: Any questions? Mike?

MR. WILLETT: Can you give me an example as to how this is used, how this would be used, or how the benchmarks are used by -- in a -- in a real-world attempt?

MS. BEHL: Yeah, I can give you two examples. We've heard from one state that they've used this kind of information to evaluate their state monitoring data and prioritize monitoring resources. So, for example, if they're monitoring for some compound that's been found only at levels, I'm making this up, orders of magnitude below any of the risk levels, any of the tox thresholds,

but they haven't monitored for some of the other compounds that are used in their state, they may decrease monitoring for that one and go look -- look to meet the -- that's one way I've heard it used.

And another way is, you know, when federal agencies working in -- in collaboration with state agencies produce monitoring and there's -- so there's the release of monitoring data from a state. In -- in order to communicate risk communications with their -- with the public, they've used this kind of information, this is too.

MS. CLEVELAND/KUNICKIS: You -- you know, is that one way for -- for EPA to address something?

MR. BRADBURY: Cheryl/Sheryl and then Mark.

MS. CLEVELAND/KUNICKIS: Okay. The -- the links, I think, are really important to be able to understand where the information came from and we could watch out any time you are to post links, they lag if you don't have a plan to keep them updated.

MR. BRADBURY: Right.

MS. CLEVELAND/KUNICKIS: So I hope there's a good IT plan in place. And the -- the question is when you start posting things for cancer, you could possibly start to get questions when you get -- one time hit that cancer, do -- do -- do the states understand that cancer

is for a lifetime, not a -- a one-time blip, and -- and how much communication has gone into that?

MS. BEHL: I -- I believe they do understand that, but we have two --

MS. CLEVELAND/KUNICKIS: No, I --

MS. BEHL: -- updates --

MS. CLEVELAND/KUNICKIS: -- I get it.

MS. BEHL: -- that accompanied the release and are available on the website --

MS. CLEVELAND/KUNICKIS: Yeah.

MS. BEHL: -- that really -- updates of what you see there now. So if you want to see what I'm talking about, you could click on the link that Rick pointed to and you'll find a general fact sheet that talks about all the benchmarks.

MR. KEIGWIN: No, it's -- it's mostly minor things --

UNIDENTIFIED MALE: Okay.

MS. BEHL: Now you find a extra fact --

MR. KEIGWIN: -- into the rule making, because that's --

MS. BEHL: -- that goes into a lot more detail about --

MR. KEIGWIN: -- yeah.

MS. BEHL: -- how the were calculated and the --

what they're meant to be.

MS. CLEVELAND/KUNICKIS: Okay.

MR. KEIGWIN: Sorry, I got out of control there.

MS. BEHL: And hopefully --

MS. CLEVELAND/KUNICKIS: Yeah, I think that's great.

MS. BEHL: -- and we've done everything we can think of to make that, and they've gone through many rounds of review with pesticide program communications' people and our communications' people to hopefully get them effective.

MR. BRADBURY: Thanks. Folks on the phone, if you could make sure your phone's muted. Mark and then Brian.

MR. WHALON: Thanks. I was just curious about assessing the stakeholder feedback, what -- what you're planning there, and -- and are -- are you actually measuring your risk communication or actual detection levels?

MR. KEIGWIN: I think the stakeholder feedback that we've been focusing on is, one, the value of these and -- and the usability, utility of these, accessibility of the data. I think we want to learn over time how states and others are utilizing this information, because we want to make sure as we're developing this and

devoting resources to it that it -- we can use to serve a purpose, it has -- the stakeholder engagement to date has not focused on sort of the measurement aspect that I think that you're getting at.

MS. BEHL: One thing to add is we did share that general fact with -- the cancer information with all of the groups that we met with, and we got some feedback on sentences I thought were confusing, we got some feedback on the formatting of the table, and we tried to, you know, fix that and some of the titles, so I think we have -- we've heard a lot from stakeholders and we did our very best to try to clarify links, communications, and materials as a result. We didn't hear from anybody anything negative. In fact, we heard a lot of very positives from stakeholders, so there's nothing really that would give us pause, and it's been out there for a year.

MR. BRADBURY: Brian and then Jerry.

MR. ROWE: Two questions. When you talk about 363 pesticides, are you talking active ingredients at that level?

MR. KEIGWIN: Right.

MR. ROWE: Okay. Thanks, I -- I guess I didn't understand that initially. And then secondly, has -- your discussion with USGS, will that have any affect or

change on the standard analysis that they're running for the variety of pesticide they're looking for, are they adding anything to their list as a result of this?

MS. BEHL: No, they're -- they're -- they're -- not that I'm aware of. I think they have their own prioritization process for that, they have in the past. And this is one of the feedbacks that we got from several different groups, they have had something very similar to this called a health-based screening level, HBSL, that they developed for the very thing for -- that we developed this, one of the people asking us to do this originally.

MR. WHALON: Right.

MS. BEHL: And so we've been communicating with them about how to move forward so we don't duplicate that effort and, you know, that's the main -- they are -- they are thrilled that we're doing this so they don't have to keep it up, that's the main feedback we got.

MR. BRADBURY: Jerry?

MR. BARON: There's been a concern expressed to the speciality-crop stakeholders out there that some drinking-water assessments are causing unrealistic contributions to the risk crop and some speciality-crops' uses may be vulnerable in the future. I was wondering if these values were causing that to occur, or am I mixing

apples and oranges here?

MR. KEIGWIN: Yeah, I think that's a little bit of -- I think what you're referring to are the -- the exposure calculation that are developed -- that are derived in developing the -- the aggregate risk numbers to support the tolerance setting. What these are, are -- are really only looking at the -- the tox values, the hazard values from the toxicity information and then running them through a methodology if -- as if the Office of Water were to create a health advisory level, but they're not sort of reinforced by a referenced, again, available modeling or monitoring data.

MS. BEHL: Right, there's no exposure information to estimate risk or drawing conclusions like that. And the other thing I -- Rick said it, but I think it's worth saying twice, is that the values that are in this table are based on the most-recent, peer-reviewed, publicly-available Office of Pesticide Programs with risk assessments --

DONNA: Hello, Donna speaking.

MS. BEHL: -- system for --

DONNA: Hello. Louis, hello.

MS. BEHL: -- it's your phone.

MR. BRADBURY: If -- folks on the phone, you have to mute your line, please. Go ahead, Betsy.

MS. BEHL: Right, so I just wanted to reiterate that, and that -- and that -- there's a hot link to that particular risk assessment we're referring to.

MR. KEIGWIN: Just to close the loop on that Jerry, these values are not what are being used in -- in developing the actual risk assessment to support a new -- establishment of a new tolerance.

MR. BRADBURY: Mae?

MS. WU: Hi, thanks for the briefing that you -- I know we've talked about this before, but also to try to remind myself, can you give me a sense of what -- how much do you have that's not in here yet and maybe what -- what the areas or the challenges are to getting, like, everything that you have into it, like for the pacing, you know, or on the -- it could be faster. I'd be happier with it if they were faster, so I'm just curious what kind of -- in the way of getting more in there quickly.

MR. KEIGWIN: Well, we are -- one of the areas that we're exploring are our ability to develop these for non-food-use pesticides and we're -- we're thinking about that right now. You know, I've -- you know, food-use pesticides have a -- a much fuller toxicity database, and so what types of considerations would we need to take into account something that isn't --

MS. WU: Um-hum.

MR. KEIGWIN: -- a food-use. But we understand that on -- at times non-food-use pesticides could be found in drinking water sources as well, so that's one of the areas that we're working --

MS. WU: Um-hum.

MR. KEIGWIN: -- looking through.

MS. BEHL: Yeah, and we're -- we've -- we've gotten requests to look at degradates with pesticides, it's all really dependent on what data are available.

MS. WU: Um-hum.

MS. BEHL: And if you have ideas about those sort of categories or compounds that, you know, there's data for, and that's some other way of thinking about it, and we haven't thought about it yet. That would be obviously not this year, we're done for this year, but it helps with subsequent years. And I think 363 is a big number.

MS. WU: And is that -- like what percentage of the universe?

MR. KEIGWIN: You know, that's -- I would say for conventional pesticides, that's a very large percentage of -- of the universe that's used. Consider that for a registration review there are about -- across biopesticides, biochemicals, anamicrobials, the

conventions, it's about, I don't know, 1,100 active ingredients, but they're -- these are really cases of active ingredients and there are only about 750, but already that's already half of the pesticides. And I think it's a very large percentage of the conventional pesticides, I don't think --

MS. WU: Um-hum.

MR. KEIGWIN: -- that there are many biochemicals, or biopesticides, or any anamicrobials.

MS. WU: Okay.

MR. BRADBURY: Any other questions, feedback? Okay. All right.

MS. BEHL: All right.

MR. BRADBURY: Betsy, thanks a lot. So we'll -- we've hit our agenda items for the day, so we all get an extra half an hour of our busy day. So I want to thank everybody on the panel, good discussion, and we'll start off tomorrow morning at 9:00. And see you all then at 9:00, so thanks a lot and have a good evening. Oh, yeah, and I didn't do public comment, because Margie told me she didn't have anybody that had public comment, so sorry about that.

(Whereupon, the meeting was adjourned.)

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Connie M. Leonatti, Transcriptionist

Transcript of Meeting of

Pesticide Program Dialogue Committee

Conference Center

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1 Potomac Yard South

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P R O C E E D I N G S

DAY TWO - JULY 11, 2013

MR. BRADBURY: Good morning, everyone, how are you? I hope you all had a good evening. I heard one contingent try to go see a baseball game last night, and went to the car, drove to the game to watch the storm clouds come in, and the game get rained out, so maybe next trip extracurricular activities will be a little more fruitful.

So thank you again for, I -- I think, a very good discussion yesterday. We covered some -- some important topics from endangered species, to -- to school IPM, and budget, and that was good. And we also touched base on the human-health benchmarks for interpretation of monitoring data from drinking water sources.

Today we have another full schedule and a lot of key topics. First session this morning will be addressing 21st century toxicology activities of the -- of our work group; and following that report out from that work group, we'll hear from Mary Manibusan, an update on the endocrine disruptor screening program; then take a break; and then Marty Monell will provide an update on the work of the -- of the work group dealing with comparative safety statements; then after lunch we'll have a, I think, fairly in-depth report out from

the pollinator protection work group, and -- and they've been covering a lot of different topics and we'll -- I'm confident we're going to be getting some recommendations to consider in moving forward; then Lois Rossi will give us an update on the efforts of the public health work group; and then we'll wrap it up with thinking about what we want to take on over the next six months and when we meet again.

So with that, I'll turn it over to Jennifer McLain, who chairs and helps facilitate our 21st century toxicology work group.

MS. MCLAIN: Hi, good morning. I wanted to start out at the beginning of this talk, since some of you are new to the work group, and talk a little bit about OPP's 21st century vision, and some of the activities that we're doing here in the office before I introduce you to what the work group has been doing, so you understand a little bit more of the context that the work group is working in.

So OPP's 21st century vision is to really look to new science to transform our risk-assessment paradigm so that it's more integrative, and hypothesis driven, and we are focusing our resources and society's resources on the risks of greatest concern. We really, of course, want to ensure that we're doing that with a -- a sound,

strong science foundation that meets our risk-management needs, and we'll do that through mechanisms of peer review and science consensus to make sure that before we're using any new tools there's a broad acceptance of those tools within the scientific community.

All of this is things on -- in a wide variety of partnerships with federal agencies, and with our stakeholders, and with international communities. And that stakeholder involvement throughout is really critical, as you'll -- as you'll hear in just a couple minutes when we talk a little bit about what the work group has been doing, the PPDC work group.

So a few things that have been going on in the Office of Pesticide Programs over the past six months, the first is that we have put out a policy to replace the specific in vivo acute toxicity test for irritation with the in vitro -- set of in vitro tests. And this is specifically for antimicrobial products with cleaning claims, because those are the products for which we have a data set for which to establish the policy, but we'll be considering other chemistries on a case-by-case basis. So we're really excited about the fact that we have this policy in place, we started it with a pilot program a few years ago, and it looks like it works really well.

The next thing that we've -- that's up here is a

guidance for OPP staff on waivers for specific studies, and this is basically when we've made a -- a science-based decision that we don't need the information from these studies for making our risk-management decision, so it talks about the type of weight-of-evidence evaluation that the staff should do in order to make that decision, to decide whether or not to grant a waiver, and also to decide, for example in the case of a registration review, that we don't need additional data provided by such a study. It also provides the staff with guidance on how to incorporate -- incorporate that determination into the risk assessment, this guidance covers all of the pesticides that we regulate here in OPP.

And the next exciting accomplishment the office has made is to have this antimicrobial pesticides' data requirement rule finalized just in May. It will -- it is effective this month, July 2013, and it establishes data requirements for antimicrobials, because antimicrobials are very different than conventional pesticides. Those rules were updated a few years ago, and it really brings the antimicrobial data requirement rules up to -- up to speed with the changes that have gone on in law and most particularly the changes that have gone on in science.

And the reason I'm mentioning it here today, is because we view this rule as a significant milestone in

our 21st century vision and using 21 century science. Antimicrobials, as exemplified by the first policy I talked about, is -- is one place that we see as a launching pad for a lot of -- of these new tools, and testing them out, and using them, and integrating them into the way that we do our daily business.

We also put out in May another guidance for staff on -- this is -- these are very overarching principals on data requirements, so for all of our data requirements this guidance is to staff to ensure that they are making good decisions about when we need data and when it's appropriate to waive.

So this is somewhat similar to the guidance document I talked about earlier that was specific to certain studies, but this is more overarching in its concept to ensure that staff have the understanding of how to look at all of the information in front of them and decide whether or not a study is necessary to make the risk management decision that's in front of them, or whether they can move forward with the information at hand in the context of that specific decision and not request a certain study, so it's -- and trying to move away from a thinking that you need every -- every piece of data just because it's on the list, to thinking contextually about what you have in front of you and what

decision that you're trying to make.

And I just put this in the presentation that began, I mentioned it the last time I gave a presentation to you all, because it fits so well with the other guidances we've recently put out. And this is the guidance that we have on how to evaluate literature studies and it's really an important piece of being able to use the framework, the principals for data requirement, because staff really need to understand the criteria and the methods by which to go about looking at open literature, because we do want staff to use open literature if it's available and if it -- if it meets the -- the quality standards that -- that we've laid out here in this guidance. There's a separate guidance for human health and ecological studies that you can find on our website.

Give me the other presentations, please. So I'm going to transition now to talking about the work group, and then I'll hand it over to the work group, but -- so our work group is the PPDC 21st century toxicology new integrated testing strategies work group, a very long title. We were established in 2008, and the objective of this PPDC work group is to help the Office of Pesticide Programs focus on communication and transition issues as we phase in new molecular and computational tools, this

new 21st century science.

So the -- the transition activities that we envisioned when we establish this work group were looking at specific applications in the Office of Pesticide Programs of new tools, looking at biomarkers, and helping us figure out how best to -- to outreach and have discussions with stakeholders about the direction that we're going in.

It was -- it was right the -- the last time. So I'm -- I'm going to turn the presentation over to Erik Janus, who's a member of our work group. And before I do that, I just want to really thank all the work-group members, many of them are here in the room. Over the past, I guess, four or five years that we've been a work group, we've really accomplished a lot, it's been great working with everyone, and we get a lot of support from our secretary at Garland Well Echo (phonetic,) which we all appreciate very much.

So today Erik's going to talk about the -- the workshop that we had a couple days ago, and then Kristie Sullivan's going to talk about the metrics' proposal that we have for you, and Dr. Roberts is going to give an update on the biomonitoring subgroup project.

MR. JANUS: Thank you, Jennifer. So, yeah, on Tuesday we were able to -- I guess we can move to the

next slide. Oh, there it is. Sorry. Thank you, I'll do it myself. The workshop we had on Tuesday, as Jennifer alluded to, was somewhat of a capstone to a certain degree of the work that we've been doing for the last five years. And I've been a -- I've been a member of this group since its inception, so it's -- I've been involved in all of these and it has been an awful lot of work. And Jennifer's to be thanked a lot too for her leadership in all of this, as well as Steve, and Vicki Dellarco, who started this group many years ago.

This was building off of a couple of prior efforts. In 2010 we staged our first workshop, which was to try to orient the PPDC members to what is TOX-21, and, you know, what does it mean, and -- and why are we even bringing it up, and why are we going down this road, it was sort of to introduce the strategic vision, as it were.

And then the following year we dug a little bit deeper into what will be needed to provide ground truth to bottom-up, molecular-pathway driven decision-making by looking at what happens in human populations. And so in this case it was to look at diagnostic tools and biomarkers which will eventually provide some sort of, like I said, a -- a reality check for what we determine from the molecular level.

And so moving forward Tuesday, what we wanted to try to present to everybody was, well, where the vision needs action, what -- what actions can we take, what sort of tools exist now that we can start implementing the vision as that's been rolled out, and I won't say, recently. It's probably been, you know, at least 10 years or so that this has been worked on in the EPA and comparing stages or -- or one another. And I want to point out that we actually were able to put together enough of a captivating program to hold Dr. Bradbury's attention for the majority of the day, so we wanted to take -- we wanted to -- we made note of that, it was great.

So the purpose of this workshop, it was really intended to be sort of a -- a -- we tend -- the work group mission is to sort of help cheerlead for the -- the vision and sort of provide direction on communication. So we're not really particularly a technical work group, so we tried to provide mostly a nontechnical workshop to -- just to dialogue with the stakeholders on how EPA envisions the rollout and the implementation of the TOX-21 vision, and so specifically we wanted to look at regulatory applications of alternative testing, the challenges of making that transition, and -- and how we build confidence to make sure that this will work going

forward.

And I mentioned this was already built off of efforts over the last five years, specifically the work group, and then much longer for the agency, so here's the agenda just really quickly. And I apologize for the small print, but we had a couple of excellent overview speakers in the -- in the beginning of the day, including Tina Bahadori, who runs the functional area in ORD where this -- this work is housed, following by -- followed by a session where we wanted to orient the attendees to what exactly is an adverse-outcome pathway, this is sort of the -- the meat of the workshop, it's a -- an -- well, we'll get into that in a second.

The next session was to look at, in a series of case studies, how these adverse-outcome pathways can be used to understand endocrine mode of action, how to understand ecological effects from environmental exposures, how to understand the dermal-sensitization effect. And then the latter half of the day was devoted to exploring the challenges and the benefits of the vision, and we had a series of speakers from multiple walks of life to -- to put us through that, and then we wrapped up with a -- a panel discussion on how to build confidence in the -- in the method and sort of try to explore things that may need to be done in order to

ensure that this works.

So the adversed-outcome pathway is really a framework for organizing and analyzing information related to toxicological mode-of-action data. It underlies essentially the entire sort of 21st century toolbox and the vision essentially, so, however, there are some challenges that still remain, you know, there's still lots of chemicals out there that -- that need decisions made. There are possible many adverse affects to many different types of receptors, both human and -- and wildlife, but there's only so much time, there's only so much money, and there's a need to make sound, transparent decisions every time.

Some of the uses, the current applications that we can use adversed-outcome pathways, and I'll show you what one looks like so you can get a better sense of this in a second, but, you know, it really allows for improved predictions of toxicity, we can set better endpoints based on more refined data, it increases the level of confidence we have in understanding all of these things, and it's -- and, you know, being able to more critically understand tox endpoints leads to better risk assessment essentially, it can be tailored to life stages, it can be used to help understand species-to-species extrapolation, I think most importantly it can help understand data gaps

versus data need.

You know, there is data necessary to build a model, and then there's data that may not be necessary to building a model, and understanding and organizing all this information helps one understand where you might need to collect more information and -- and where you don't need to collect more information. Really the -- the holy grail here is to be able to build predictive computation models on some initial event or some tipping point along the molecular pathway that leads to an -- an adversed outcome, so that you don't need to measure the actual -- the outcome itself.

Now, to sort of show you some of this madness, it is, like I said, an organizational framework, it -- it encompasses a lot of different ideas. What you're looking at here is the adversed-outcome pathway put together by a -- one of our speakers from the Department of Defense, and they were interested in sort of understanding per-chlorate effects to populations of fish, and so what you're looking at here is essentially the entire cascade of boxes up there is what's known as the source outcome continuum. There's a release somewhere under the environment and eventually it finds yourself to the lower right through molecular events through organ-level effects up to individual, up to

population levels, so it's a way of organizing information.

Now, there are a lot of different terms you may have heard bandied about by this group over time, and this is sort of to help you understand that the exposure component in the source-to-outcome pathway is different than mode of action, it's different than an adversed-outcome pathway, it really just looks at how the -- it gets from the point of release to the target tissue essentially.

Now, looking at the toxicity pathway is really the -- sort of the molecular event, that leads to the tipping point, that leads to an adversed outcome, and then the cellular response, where as mode of action talks about how you get from the molecular event all the way up to a response -- and observable response in an individual. And then this adverse-outcome pathway actually takes that out to understanding and being able to organize effects to population, aggregated effects in individuals essentially.

Just to sort of show you really quickly what some -- the information that's needed to populate these things, now we are looking at the skin-sensitization, adverse-outcome pathway, and you can see that there's a number of areas where you need to have good data and be

able to come up with sort of quantitative linkages across these various functional areas as you proceed from left to right as you understand the molecule itself moving to how it comes -- it induces an effect in a -- in a while organ.

Now, of course, there are -- there's a tradeoff between uncertainty and data needs as you move across the different applications of an adversed-outcome pathway. There are simple applications that you can use where you don't need a whole lot of data, but there is a -- a -- more uncertainty involved. For example, if you look to the upper right, you could use a read-across technique, which is essentially taking information from a structurally-related compound to make a decision. You can do it quickly, it would be a simple correlative exercise, but it would entail probably more uncertainty than it would if you were to proceed to a full quantitative model and risk assessment, which, of course, needs more data.

We've covered most of this, focusing on the lower-third of the pyramid here, this is a slide from one of the OPP presentations at the -- at the meeting sort of highlighting the -- some of the additional utilities of the adversed-outcome pathway. It assists someone helping to make data-bridging, read-across arguments, and

decisions, and it also could help with cumulative risk assessments to a certain degree, and dealing with transformation products. I mean, not to mention that this is -- the whole idea here is to reduce animal use by making smarter decisions, kind of going back to this data-gaps versus data-need ideas.

Now, to sort of get into some more of the things that we talked about at the meeting, some of -- these are -- what -- it is very difficult to capture eight hours in -- in 20 minutes, so, you know, we tried to sort of boil down sort of the major themes, the repeated things, the things that we felt were important out of -- out of the day, so you'll have to forgive me if we've forgotten your particular pet topic for those of you that were there and helped to organize it.

But really these new tools will provide, as I've mentioned, sort of a more-informed risk assessment through better selection of endpoints, reduction of better characterization of uncertainty. And it works well with statues that the agency has written, including 158-W, which Jennifer just told you about, that allow for sort of greater flexibility to use the best science possible. However, there's a need to implant the stuff today so we can -- there was a -- a lot of discussion on what can you do today.

And it was -- it came to light through a lot of the talks that some of registrants gave, that really you can make some significant achievements by sort of working on a one-on-one level with the agency to sort of develop new testing strategies that are clearly grounded in biology that answer the data-needs' question. So, you know, you really can do it smarter, sort of on a one-on-one basis right now, given -- given the existing tools that we've got.

One of the things that Tina Bahadori brought up, which I thought was interesting that we wanted to capture, is that the research program, the Office of Research and Development, which is where a lot of this information is -- is housed, the -- the activity -- the research activity, they're going through a reorganization process and they would like to actually move from sort of a -- a more-perfect science to a more impactable, timely, relevant science that's fit for a purpose.

Again, this goes back to the concept of data gaps versus data needs, what is your mandate, what question do you need an answer, and what information do you need to actually answer that question. That's something that's very important to ORD, and -- and so that's something they're thinking about as they're reorganizing and building to be able to support the basic

research function to be able to make these integrated-testing decisions at the program level.

In addition to be able to reduce animal tests and of course cost, what another great benefit of this is the ability to maybe do more efficient assessment -- toxicological assessment by being able to combine studies where possible, add -- for example, add immune or neurological endpoints into a 90-day oral study which can actually get a significant reduction on animal use.

There are challenges that still remain, we mentioned some of them, but, you know, models aren't perfect. And it's important not to let -- as one of the stakeholders mentioned, it's important not to let the mechanistic data overwhelm some of the other data that may be available, so it's important to look at all of this in a weight-of-evidence procedure.

It became very apparent in listening to the ongoing activities of FDA, the Consumer Product Safety Commission, the Department of Defense that we could actually, probably make greater progress quicker if we had a little bit more collaboration between the groups, so that was brought to light, which is great.

One thing that was also brought to light was data management, tools to do it, and resources to do it were brought up. And then, of course, there was --

there's always this issue of how do we validate new methods in a way that doesn't take a very long time and the science is out date by the time you get out -- back into the validation process; how do you do it in a way that ensures regulatory acceptance, and -- and that there's no sort of discomfort at the -- at the -- sort of the worker-bee level who are processing these packages as they come in, in the future; and, of course global harmonization of the test guidelines would be -- would be very helpful, of course.

One thing that was mentioned during the panel discussion and a couple of other times during the meeting was that sort of -- I just alluded to this, classical validation may not work, and this is a concept that was actually shared in 158-W, there may be other ways to do this. One way -- we didn't have any answers really in eight hours, but using sort of more performance-based methods is one thing that was suggested by multiple stakeholders.

Another interesting question that came up was how much is enough, when do you know when an AOP is ready for use, how do you know when you've got enough data? Well, that kind of depends on the -- again, what's the mandate you're under, and what's the question you're trying to answer, and do you have enough data to be able

to demonstrate clear, quantitative linkages across the boxes that -- that I showed you? So, for example, you know, the DOD example I -- I showed, it's very advanced, it's very -- probably close to ready for prime time. However, will it meet OPP's needs? Probably not.

Again, we need to be sort of open and transparent in terms of peer reviewing all these methods, making sure that we're taking into account all of the stakeholder viewpoints and other things that came out in the panel discussion. And it was mentioned that one of the best places to -- to go in terms of information is actually the OECD at this point, they have -- they have a good compilation of -- of outcome pathways and it was thought that that actually may be the hub through which global validation, acceptance, harmonization may occur.

And then lastly we -- we covered, you know, how can we continue to drive this work, you know, what's -- can we establish metrics for success, can we ensure that the process-related issues are in place, such as the resources and tools for data management? So that was really what we talked through in the eight hours that was had. Thanks. Okay. Anybody have any questions about the meeting, or its contents, or where we're headed as a work group? Thanks. Okay.

MR. BRADBURY: Sheryl?

MR. JANUS: Oh.

MS. KUNICKIS: Yeah, so I'm part of the work group too and I just want to say I -- I did think that this was a -- a -- a very -- and, Erik, even in your summary there was a very balanced presentation of what got presented for -- for eight hours. I wanted to make the call that I -- I don't know if we've decided there will be another one, but there's been three. If there's a fourth, this broader group really needs to come and listen to some of this, rather than the 20-minute distillation, because there's a lot here and there's a lot of effort put on to engage a -- a broad, you know, set of experts to come in and talk about it and -- and I was kind of sad that a lot more of the actual PPDC wasn't there to listen to it.

MR. BRADBURY: Matt?

MR. KEIFER: I -- I agree this was a -- a very interesting meeting, the last 45 minutes of which I caught. The -- but the -- in summary what I heard in a -- the information I could gather on the meeting, it really is very exciting progress and very rapid progress.

The one thing that continues to concern me, and I will not stop talking about it, is the fact that we still have to build the public-health safety net that lets us know that the models that we develop molecularly

predict the behavior we expect in humans, we have to maintain that, there was no discussion of that, and we need to continue to have that issue on the table.

MR. BRADBURY: (Inaudible.)

UNIDENTIFIED MALE: Sort of starting where Matt left off, I think that this technology is -- is actually very useful for identifying things like clinical biomarkers and environmental endpoints. And I think that -- that as this progresses, that -- that, you know, EPA needs to really think about, well, how do we -- how do we use this to -- you know, we're talking about evaluating impacts, not just in a predicted way, but once things get out there, well, we can apply these tools and link them back to the -- the vast amount of data that's generated and -- and do a better job of evaluating environmental and -- and -- and health endpoints.

MR. BRADBURY: Steve?

MR. COY: Yeah, I didn't find out about the meeting until it was too late to -- to get scheduled to be here. You mentioned a couple times, "Use the best science possible," there was another phrase I can't -- that's similar to that, can you expound on that a little bit exactly, does that mean -- how does that relate to using science as -- with a -- what is it, the GLP?

MR. JANUS: Well, you know, in general science

is a moving target, you know, it's sort of based on -- it's -- it's sort of the best trend line through the information that we have at our disposal. And so given sort of emerging technology, sometimes not necessarily all the information is there, but you still have to make a decision. So that's sort of the basic tension I see here with this, is that people want the best decisions, the -- the soundest and safest decisions made, but you still have to go forward with PRIA timelines and other things like that.

So, I mean, really the best available science is what we -- the best that -- the best decision we can make today based on what we know now, which changes over time. And -- and, no, it's not really related to the GLP at this point in time, but it could be at some point in time. I mean, GLP is a way of recording information in a systematic fashion so that things can be reproduceable, and auditable, and understandable, but that's generally done once you actually have a toxicity test that turned into a test guideline and is -- is available from EPA as an actual protocol. These are new tools that don't necessarily have that luxury yet, it doesn't mean that we won't be careful in recording the information like GLP.

MS. MCLAIN: I just want to add a little bit to that, that -- that another aspect of that is also in

terms of using the new tools, looking to see if there are new tools out there, and determining whether or not the data from those are acceptable. Even though we may not have the guidelines established and looking to things like the -- like open literature, like I talked about earlier, that there's sometimes where the information contained in the study and the literature will be sufficient to meet our needs for information on a particular endpoint that we -- that may be of concern or to let us know that it's not of concern, so there's a lot of different ways to look at the information that's available to us and not just to concentrate only on the guidelines studies that we are -- that we're used to looking at historically.

MR. BRADBURY: And I -- and I'll insert 30 seconds. If you go to that NRC report at 2007, which was sort of a critical document, NRC was charged by EPA, FDA, and IH to -- to take a look at what's the state of the science and what the future could be about, and a big part of that report talks about, make sure you really mind all the answers, because the answer may be there staring you in the face and you really don't need to test anything, because you've got the data. You may just have to look at the data maybe a little differently, and the pathway concept may help you organize the data you

already have and realize you've got your answer. Or if you don't have your answer, you may have a very focused way to get that last bit of information you need to get your answer.

So some of 21st century toxicology isn't fancy robots or -- or hyperspace of statistical analyses, it's just thinking smart with the information you have before you and make a sound decision, or if you do need more data, realizing how to pinpoint the data you need, how to use a laser scalpel instead of a hammer to get the answers. We'll go Mark and then Pat.

MR. WHALON: My question's a two-part question really, and -- and the first part of it relates to the -- the importance of the structure of consensus development for transition to these better, faster, less animal-intensive studies, which I think most of us would adhere to in -- in support, and I'd like to hear more about that consensus-development process and -- and bringing things on, that would be useful, I think, to -- to -- to this whole group.

The second one is the -- the OECD QSAR process was mentioned a number -- a number of times, but I didn't hear very much about, in the part that I was able to attend, the -- how that integration's going to happen. I mean, that -- that -- that -- I heard that there was a

great interest in that and a process headed that way, but how and, you know, timeline kind of thing, what -- what are -- what's the process for moving ahead in that way? Thanks.

MS. MCLAIN: I'll start out with a few comments, and I think Kristie wants to talk a little bit about the OECD process. The -- so one thing that we talked about in the panel discussion at the end of the day is that there's not one way to get to this consensus-driven point or there's -- where it's -- there's the scientific acceptance. There are multiple routes of achieving that, and we don't want to have everything funneled through one -- only one avenue for, you know, quote/unquote, validation.

So there are going to be specific tools that go through a -- a very formal validation, there will be other things that are looked at in the peer review -- you know, substantial number of peer-review literature studies where there becomes a general agreement over time that those methods are acceptable and deliver data of high quality.

Internally here at OPP, of course, we have our science advisory panel, which -- which we use for some of the tools that we develop, or for some tools that are developed elsewhere, but we want to apply. Then, of

course, we also do use and participate in the OECD as another way to develop many of the guidelines or testing strategies, and that was the example of the skin sensitization that Erik put up, there was that -- an -- the first AOP that OECD established in -- sort of in -- in total that they put out last year, so that was really exciting. So we -- we are participating in that process, and that's a really good way of -- of getting to that point of acceptance. And I don't know if you have anything to add on the OECD.

MS. SULLIVAN: Well, I think you covered it. I mean, basically that the OECD is -- the U.S. is a member country of the OECD, and so it participates in all the -- their deliberations and expert groups. They have a number of different groups that work on various projects, and to use the example of the -- the skin sensitization AOP, it was written by a few experts, and then circulated through all of the experts in all of the member countries, and we're able to provide input.

Industry was able to provide input, and -- and other stakeholder groups can provide input, so -- and it's a consensus process, so what comes out OECD is -- is really reviewed quite extensively by a lot of different experts in the topic, and their goal with their whole project, now they've got about 22 AOP in -- in the work

plan, and you can view all of the different AOPs that are being worked on right now and you can get involved if you -- if you feel like you want to, and they plan to publish these.

And once they're published and finished, they're -- they're living documents to take a -- a town of advancing science, but the aim is to -- once you -- to use the skin sensitization again, once you have an AOP, you -- you understand and -- and -- and understand the scientific support in the literature behind that molecular initiating event, that, an event, can be put into the OECD's QSAR toolbox. And so as each of these are developed, you can build your toolbox, your QSAR methods, around the scientific basis, the framework of this AOP. Sorry, that was getting maybe a little bit too into the weeds.

But to use an example that came from AOP -- or from EPA actually, excuse me, is the laboratory in Duluth that came up with the estrogen expert system, that was developed by EPA. It went through a consensus process at OECD and also went through EPA's own scientific advisory panel, and so there is a lot of cross talk between the experts in each country at the OECD, and so it is truly a consensus process.

MR. BRADBURY: And to build off your point,

Mark, given Kristie's point about the QSAR validation principals, as Kristie said of the consensus logic, and how do you evaluate a model. And using the example Kristie talked about, one of the accomplishments we reported out six months ago was the development of the NASDA QSAR guidance documents, and that is the partnership between PMRA and EPA. And Mary Manibusan and other helped build that guidance, and that used the OECD QSAR principal that is the basis for how PMRA and EPA, who were working in joint efforts, will use the same approach.

So part of that consensus building, getting into the day-to-day regulatory work, not only NAFTA, and -- and we'll -- and with OECD as well starting to use the same mind set as we approach the kinds of risk assessments we're doing, when we can use some of these tools, so lots of different venues to get input, both scientific peer review and input from stakeholders. And that's why we have this work group, to be a sounding board for -- not the gory science, but as a science that is starting to evolve, how does it interface with decision making and issues which you've been thinking about for using the tools to make decisions, helping form decisions.

MR. JANUS: This comment I -- I -- I was able to

hear part of the -- the skin sensitization process and some of the comments that were made there, and also the earlier more -- more molecular-science-based stuff that came before that, and it was pretty impressive. The -- the real challenge I see is, is that as -- as has been mentioned a couple times, is that you get lost in the muddy water, so it's -- it's complex.

And -- and to -- to have a clear pathway in any biological system is unusual, mostly you have pathways that go like that, so that the -- the challenge is -- is very significant and the goal is outstanding to reduce the -- the use of animals in -- in -- in studies, so I go with all of that. I'm just not doubting or anything like that, I'm just along for the ride. It's pretty fascinating in a lot of ways, but the outcomes that are -- that are coming now, the sensitization process, I think is well down the road, it looked very, to me, impressive with my chemical back ground.

And one of the things that would be really good for this group I think is at some point to have a section where we focus on something that's more pesticide toxicological brought -- brought to us to look at through a -- through -- through -- through the process. Now, I think that would be helpful for us.

MR. BRADBURY: Thanks. Good idea. Pat?

MS. BISHOP: Yeah, I just wanted to remind folks that I think one of the big goals of the TOX-21 method is to be more human relevant with respect to, you know, protecting public health and making sure that these methods work with greater understanding of the pathways and how things actually occur, rather than a -- you know, a black-box wrap model that, you know, may tell you something about humans or it may not. I think that's one of the most exciting things about these methods, is hopefully they actually will provide better methods, more human-relevant methods.

And when -- it's interesting that I -- I think a lot of the validation and peer review will -- will help drive the acceptability of these, whereas it -- you know, many of the animal methods in use now probably weren't even ever validated or, you know, to -- will not be undergoing the type -- or did not undergo the type of scrutiny that these will, so I'm hoping that, you know, this is going to be a -- a major step forward in -- in doing some of this work.

MR. BRADBURY: Nichelle?

MS. HARRIOTT: Is there a timeline for integrating the use of these new tools and models into the risk assessment process, and are any of these tools or models ready been used in some of the risk assessments

that EPA has conducted?

MS. MCLAIN: So, our goal is to integrate tools over time so that -- I mean, the time is now and -- and -- and has been for many years, and there are a few -- you know, over the years we've built our ability to use QSAR models and -- and read-across methods, we're looking at new high throughput system tools that -- to evaluate the science.

We have the theories of SAPs going on this year to look at those tools in the context of endocrine disruption and, you know, small things like the in vitro tests that I mentioned -- mentioned earlier as a replacement for in vivo, so there is -- there is a lot going on here at EPA. Actually, Mary's going to be talking about the SAP next, so you'll year a lot about that, but -- but all of this is sort of integrated together towards this common goal.

MR. BRADBURY: Okay. Why don't we turn it over, back to Jennifer --

MS. MCLAIN: Yeah.

MR. BRADBURY: -- and the next topic.

MS. SULLIVAN: Okay. Excuse me. Okay. Many of you know me, I -- I was recently on the PPDC, and so I'm continuing to work with the work groups. I'm Kristie Sullivan, from the Physicians' Committee For Responsible

Medicine. And can we have a --

MS. MCLAIN: I'm sorry.

MS. SULLIVAN: -- oh, sorry. Oh, great. Okay. So one of the first projects that the work group undertook, was to come up with some suggested metrics for ways that EPA could track and show success as they move towards this long-term goal. But we thought that while the agency is working on these long-term goals in TOX-21 initiatives, we wanted to see if we could also look at some shorter-term goals, and so we took -- took another look at the metrics and tried to adapt them for taking a look at the acute-hazard labeling studies that are currently conducted for a pesticide and basically wanted to be able to -- oh, usually there's a -- wanted to be able to help the agency come up with some -- some metrics to be able to track progress towards getting rid of some shorter-term acute tests as well.

So just to make sure everyone understands what we're talking about, we're talking about what's normally termed a six-pack, and so these are consensitization, acute dermal, oral, and inhalation toxicity, and skin and eye irritation sites, and so over the past year the work group has been working on coming up with some goals to replace these studies with alternative methods or approaches.

So the goals that we've come up with are to phase out -- in general, to phase out animal testing for the acute six-pack endpoints, and to see consistent regular reductions in the number of animals used, and at the same time consistent increases in the use of non-animal methods and other approaches.

And specifically we came up with a couple of goals, one was to -- some of these in vitro methods already exist, and so we're looking at how to implement them into the -- the pesticide process. Yes, you guys have a table, I was going to say, I think that's next. That's okay. You guys have a table of some of the existing methods and approaches, and we put this together just to kind of show where everything is now and -- so that we could get a handle on that and -- and figure out where -- what we need to do to get where we want to be.

So specifically we -- we want to move towards having in vitro skin-irritation methods for registration during the 2015 calendar year; we want to aim towards accepting the suite of -- of in vitro tests for skin sensitization, which is after the AOP, these in vitro tests are going through the OECD process within six months of acceptance to OECD, and to try to phase out multiple routes of exposure for the acute toxicity tests. For example, the acute dermal test, to phase that out

within three years.

So this is the table that I just mentioned that you have in front of you. I'm not going to go into it in detail, but if you have any questions feel free to ask me now or -- or later. We also put together a Gantt chart, and this was basically a way to figure out all of the steps. And I'm sorry, on yours -- it's not readable on your slides, but I just wanted to show you the -- the work that we've been doing to try to figure out the steps that need to be accomplished in order to get to these goals and the timing that we might see.

So to the metrics, we had a lot of discussions about the metrics themselves and how you track progress. There -- there is a way to measure the methods that are submitted by registrants, you can simply pull that electronically, and so you can see how many in vitro tests are submitted, or how many animal tests are submitted, but there are other ways to get the information, as we've been talking about, and it's a little more difficult to track those kinds of submissions.

So we had a lot of discussions about that, about ways that both registrants and EPA could -- could help come up with ways to track alternative approaches, as we're calling them, and those are things like QSARs,

read-across, and other things. One of the discussions we're having is whether we need to have a baseline, so do we need to go back into currently-submitted registrations and count all of -- all of these alternative approaches, or can we just simply go forward from now and set up a tracking system and -- and do it that way. So -- so we are still working out some of those tracking methods and details, but ultimately these are some of the metrics that we want to be able to measure and try to measure.

And finally, of course, we want to be able to measure improved efficiency and quality of risk assessment, so there are some things that we're still, as a work group, working to try to discuss how we can do that. I think that's it for me. Yeah, if we can -- so any comments on the proposals of the goals, or the metrics, or -- or anything that I've said?

MR. BRADBURY: Mark, and then Scott, and then Cheryl.

MR. WHALON: Thanks, I appreciate that greatly. The thing I would also appreciate is, is two of these slides that I could read, the methods' acceptance status and the methods' acceptance Gantt chart, that would be great if we could get something big enough to see. I'll probably use some of this in the chemistry course I teach, so I'd like to -- good job.

MR. BRADBURY: The -- the presentation should go up on the PPDC website.

MR. WHALON: That would be great.

MS. SULLIVAN: So, Mark, I want to -- also wanted to point out that the -- the slide, the methods' acceptance status is this table that you have, just in a bigger form.

MR. WHALON: Okay.

MR. BRADBURY: Scott and then Cheryl.

MR. GORDON/SCHERTZ: I just -- I just had a -- a couple questions, what's the -- do you have any -- any estimates on what's the cost to run the traditional six-pack versus the -- you know, the new alternative, non-animal use six-pack, and then the second one was say, for like the -- it's not here, the eye irritation? There's like one, two, three -- about six different tests, do you run just like a -- choose one of them, or do you -- you do a couple of them?

MS. SULLIVAN: It depends. The -- actually, the guidance documents that Jennifer talked about, the policies for eye-hazard labeling, goes into detail about the eye irritation specifically, and so that would --

MR. GORDON/SCHERTZ: So there's --

MS. SULLIVAN: -- have more detail.

MR. GORDON/SCHERTZ: -- more to read?

MS. SULLIVAN: Yeah.

MR. GORDON/SCHERTZ: Okay.

MS. SULLIVAN: It depends on your chemical, it depends on what information you might already have, whether you can waive a couple of tests, or whether you need to do a QSAR read-across assessment. That's a computer program, so it doesn't -- it's not laboratory cost. Some in vitro methods may be more expensive than the -- the rabbit skin test, for example, but overall you might see a reduction in costs. I mean, it just depends.

MR. BRADBURY: One more, Cheryl?

MS. CLEVELAND: Yeah, I think that question about cost is a good lead in, because I think we hear over and over again in this discussion that some of the goals are that we'll get better information, the goals are that we'll reduce animals, and the goals are that ultimately we'll reduce costs, but I actually think that's the order in which we're going to get the benefits. We're going to get a lot more information a lot faster than we're going to see the reduction in the animals, and we're going to see the reductions in cost once we've figured out how to validate the studies well.

And the one caveat there is that we would -- we would like to come up with alternate ways of validating the studies, rather than going backwards when we already

have a -- a goal test for animals, and then to test backward just to validate the information. I mean, I think that is one thing that the registrant industry and -- and the industry in general has been a little bit reluctant to do, so I'm just trying to think going forward if we can kind of have a different corrective action.

And the -- the one other comment that I wanted to make, is I think it's really important that there's OECD engagement, But it's also important to be engaged beyond just OECD, or at least lead the way, or at least get into not just OECD, but leading a stronger effort with other regulatory bodies, the ones that really count. Because even if EPA leads the way and accepts all of these things and Japan doesn't come onboard, you're still going to have animal use, you -- you know this.

I just want to bring this back up to this boarder group and then say, with budget cuts and -- and loss of staff, what can this group do to -- to help continue to support those international efforts on this front, because that's really where you'll start to see, you know, cost reductions at the end of the day and reduced animal use. And I don't know the answer to that, but I do know that that's one of the charges of this broader group.

And we've been so focused on the interesting science and -- and watching this, because there's so much base there, but that real -- the -- part of the charge is how do you start to use this in regulation? And part of that charge is how you start to use that truly in the -- in the international arena.

MR. BRADBURY: Cynthia?

MS. PALMER: Cynthia Palmer, American Bird Conservancy. I think this is a really exciting effort in bringing us toward more efficient, and effective, and humane methodologies. A couple of items, given all of the diverse endpoints in humans, and wildlife, and with the acute studies, but ultimately with long-term endpoints, and reproductive endpoints, and so forth. I think that this would be -- it would be great to move forward and ramp up the incident reporting system and the 60 -- 682 reporting requirement as we move forward with these alternative methodologies, just to make sure that we're not making some mistakes along the way.

And then also just a question. When you go to the health-food store certain brands say that they're not animal tested, and so and I'm wondering if those companies are working with you or funding these efforts, particularly the dermal sensitization effort, it seems like they should be major players in this effort.

MS. MCLAIN: Actually, that topic is going to be coming up at 11:00, so we'll -- we'll look forward to responding to you then.

MR. BRADBURY: Thanks. We're talking to Jennifer, so Jimmy you've got the last -- last part.

MR. ROBERTS: Thanks. So I'd like to take just a second and put everybody's mind into that of a clinician. I'm glad that several people have brought up -- Cynthia, and Matt, and -- and Tricia brought up the issue of keeping the human-health side in mind as we go through this whole process.

As a clinician, just imagine you've got your patient in front of you and they're -- they might be violently ill or they might be just a little bit ill, but you've got to figure out what's wrong with them and you have to ask them questions. You've got to ask the right questions to kind of figure out what the problem is, and then you can do a physical exam. And if you know exactly what you're looking for, then you can figure it out with just your history and physical, and a lot of times that's just not the case.

And so then we have to run tests and, you know, maybe good or bad. Some clinicians run lots and lots of tests, probably more than we need to. But then from pesticide poisoning you've got the erythrocyte

cholinesterase enzyme, and after that you don't have any other tests really to run, for the most part, for most pesticides, and that's sort of the context with which our work group became borne.

When they first started talking about the 21st century tox work group, Matthew Keifer was on the phone, and I guess he couldn't make it in from Seattle that day, but he said, you know, through the speaker up there that, "We clinicians really need to have some way of testing or figuring out what pesticides that person has been exposed to." And as importantly, rule out that they weren't expose to, because sometimes it's a matter of, well, they could have pesticide poisonings, but we may not really know. And then ruling them out is, I think, equally important as figuring out what they might be exposed to.

So with that in mind, our work group was formed and the goal was to develop a list of candidate pesticides, in which we would then look at biomarkers and diagnostic testing for those certain pesticides. We initially started with a work group at the PPDC and we were charge with developing a list of those candidate pesticides. But also as we explored the process, we put on, as Erik mentioned, the diagnostic tools and biomarkers in pesticide medical management.

In that larger workshop, sort of like yesterday,

really explored a lot of the different issues involved with human-health exposure, assessment, and poisoning management. So from there we created -- we created a -- definitions, we created a list of initial candidate pesticides that might be important to look for in diagnostic testing, and then from there we developed an expert working group to really look into this into more detail.

So this is the expert group that we have, and it's hard -- it is hard to read. There are a number of people in the room who are on the expert group, Jeff, and -- excuse me, Jeff, and Matt, myself, Cheryl Cleveland. And then we have a couple of others who are medical toxicologists and also some who -- some of the medical toxicologists do have experience in emergency medicine as well. And we also have a toxicologist from Dow Chemical on there, and as well as a number of EPA employees as well.

So at our first couple of meetings over the phone we used some conference calls and we took what was originally our preliminary list of pesticides that the work group came up with, which include pyrethroids, organophosphates, carbamates, perpinill (phonetic,) and nicotinoids. And we began talking, and -- and -- and the first thing we came up with is we've got to have some

criteria of what constitutes the important features of the different pesticides to make them on the list. And then once we have that working list, we would then make recommendations about doing more exploring of diagnostic biomarkers and diagnostic testing.

So we had -- we first talked about a number of different criteria, and then we ranked them. Each of the members put in their -- their preference or ranking for each of the criteria, and the top three are -- these pesticides should have a high prevalence of reported poisonings with a moderate or -- or sever toxic effect. Now, these poisonings -- or these pesticides, there should be a high prevalence of exposure, regardless of toxicity. The idea behind that is that a lot of pesticides that are used commonly might look a lot like organophosphates in terms of some of the clinical findings, but the treatment is obviously not nearly the same. And then the other is high acute toxicity and lethality, regardless of exposure.

And then some of the other criteria we consider as -- as secondary criteria would be some pesticides in which you might end up having inappropriate treatment given, or delayed, or misdiagnosed for the pesticide; another is whether there's a treatment available; and then a third criteria would be types of pesticide use,

whether in the homes, or the schools, or the pests. And then in general the -- the working group agreed that we should really be looking at the chemical class, not the individual active ingredient, because then you're looking at many, many compounds and I think it makes more sense to look at the overall class.

So the group has identified a number of different data sources, poison control center, there's some California pesticide incident-prevalence program data, the sensor data from Geoff Calvert, Ed Hanes (phonetic,) there's also a California use-reporting database, and some EPA usage data, and toxicity data. Certainly if there's any other data sources that the PPDC has that would be useful for us to look at, we would be open to that.

And then the idea is to take these databases and apply the criteria that we have in the previous slide to help refine the pesticide priority lists that we have. I will say that we -- some in the expert group have added on phosphene, based especially on the sever toxicity and difficulty in treatment with that from either aluminum or zinc phosphides, and then we also added on paraquat and diquat. Particularly paraquat from the -- (inaudible.)

So that's where we're at right now, and we have another conference call we need to be scheduling. And as

I mentioned, if there's any other input that PPDC has, we would like to hear it.

MR. BRADBURY: Matt?

MR. KEIFER: Jimmy, I'd just add the 682 data might be of value in terms of adding to that list, and then also the Washington State Pesticide Reporting System is pretty thorough, those are two other sources that -- that we might want to take a look at.

MR. ROBERTS: We -- we talked a little bit about the 682, and one of the questions that came up was whether there is too many identifying information pieces in there, HIPAA. HIPAA.

MR. KEIFER: You mean it's a HIPAA --

MR. ROBERTS: Yes --

MR. KEIFER: -- problem for us?

MR. ROBERTS: -- for us.

MR. KEIFER: But if it becomes a public -- I mean, if it becomes public material, you can strip the identifiers, can't you, for you to give them to us? I would think we'd be able to access them without identifiers. Plus, we're not a covered entity. EPA's not a covered entity, so we wouldn't be covered by HIPAA.

MR. KEIFER: I guess -- I guess a lot of this thinking in terms of --

MR. ROBERTS: No.

MR. KEIFER: -- our ourselves as opposed --

MR. ROBERTS: No.

MR. KEIFER: -- EPA, yeah.

MR. ROBERTS: All right.

MR. BRADBURY: You guys. Sheryl, the last comment.

MS. KUNICKIS: So -- so I'd say, you know, being involved in some of this, this has come a long way, because what you've -- what you've had to do is corral a whole lot of people with a whole lot of individual agendas and get to some kind of priority lists. And just getting a list of priority criteria was not easy, so I think there will be another round of trying to sort through all of that.

It's a long road when you're looking for this goal, because everybody wants everything. On that first phone call everybody wanted everything, you know, I want my little pet thing, and -- and so what you're trying to do here is trying to find and identify at least consensus on something that makes a good pilot and -- because we had said we were headed towards a -- a pilot program. So just a lot of work to get that far, I just wanted to point that out to the broader team.

MR. BRADBURY: Thanks. Mae?

MS. WU: At the risk of saying something that

Sheryl had just -- just kind of addressed, that I'm -- I'm curious whether -- and I acknowledge that you all are way more expert on this stuff than I am, whether you're looking also at the kinds of things that might be in personal-care products, not just like used on, say, like, out uses or outside uses as far as, like, exposures being a lot higher. I'm just thinking, like, you know, with the daily uses and things like that.

MR. ROBERTS: We -- we would be looking at anything that comes into human contact, so, you know, for certainly some pesticides that are on those products there would certainly be things we would be interested in, in knowing about.

MS. WU: Um-hum.

MR. ROBERTS: The difficulty becomes in the figuring out beyond our own personal use, but constitutes really high usage, I think that's where some of the usage data can come into play in terms of high prevalence of exposure. And we briefly talked in the small group, not even in our whole work -- work group yet, but how to take these data sets and then begin to try to apply that criteria. And, you know, one proposal would be to take, say, the top 10 percent or so of the usage chemicals, in the classes at least, and then kind of go from there.

It's arbitrary, the 10 percent, it could be --

by the time we see the number of different products, it might be the top five percent. The idea though is to cast as broad of a net as we can to -- to kind of find -- identify some of these chemicals that clearly -- and I can assure you that they're not on most physicians' radar screens.

MS. WU: Yeah. I guess my -- the -- the one I had in mind and one of the pet issues is, and the other question would maybe be the EPAs, whether it would even be able to fall under this, is because of the uses is Triclosan, which is an FDA-regulated use when it's in the -- so, but it is something that I'm sure the exposures are really high that we know from, like, the state and things like that. But I'm curious whether the group could look at something like that, that may have both FDA and EPA-regulated uses, but the FDA uses might be the -- might be the higher source of exposure, but, you know, putting that on the table.

MR. BRADBURY: Why don't I -- I'll respond to that.

MS. WU: Okay.

MR. BRADBURY: And then if it's okay with the rest of the committee, maybe wrap this session up so we can kind of stay on schedule. So broadly speaking, some of the -- some of the -- the discussion that Erik

mentioned from the work group, generally in the workshop, and then this specific topic of the biomarkers, and we had that October 2011 workshop on biomarkers, and then it got published in C & E News, and the next day DARPA calls and wants to know what EPA's doing in a very positive way, because they talk about -- we have technology we're trying to develop to help soldiers that may be exposed to chemicals in the field and folks on -- medics are trying to figure out what did they get exposed to and how could you rapidly -- and they also have a goal to try to see if this technology could be used in other venues in the United States in domestic, you know, situations.

And so by working through this, they basically said, if you can come up with a pilot list of chemicals, let's see if we can partner and view some of the gee-whiz technology we have and see if we can come up with some -- some technology that could be applied, so this idea of working across the federal government is really important.

And then the example of Triclosan, Jennifer and colleagues are working closely with FDA on Triclosan. Like you said, they've got the lion's share of the use of Triclosan as registered -- regulated by FDA. But we're working closely with them not only on Triclosan, but in this 21st century toxicology area. So I think that would

be -- we'll take that idea, I think bring it back through out FDA/EPA partnership, and then get the traction and you could bring it into the -- into this group, I think, and explore some of that as well.

So all these different threads you get going, sometimes you don't know how they'll weave together, but I think that generally it weaves together. And -- and I appreciate that PPDC with the patience to work through this over the last five or some years, because we knew five years out it was just an image, but it's starting to happen. But if we -- if you didn't bear with us and -- and go through these discussions, I don't think we would have had ideas that are very valuable to say, how would you ever do this, even if they can do it, and then the different facets you all bring in to us.

So, and I know sometimes we get into the weeds, we try to keep altitude, but I appreciate the -- the whole committee giving us the advice, it's been very helpful. Okay. Matt, quick.

MR. KEIFER: Quick. I just wanted to say that the committee that Jimmy just described, the working group that we just described, was an offshoot of the 21st century toxicology, at the present time we're sort of working slightly independently of what we heard presented. In the end, the goal would be to bring the

needs created and identified in this group back to that 21st century toxicology, so that the interests can merge using that same toxicology to identify those bioassays that we ultimately will use for diagnosis to meet the needs of -- of what was described as that safety net for human toxicity that we really need to have to understand whether our models are working.

MR. BRADBURY: And I agree. And -- and that image that Erik had, I think in his power point, showed the NRC 2007 concept. And that outer circle is the surveillance, it's the diagnostic to open that, that whole document doesn't work. And the NRC, the NAS said this isn't going to work without -- it's in the outer circle of that figure, but it's what's going on in wildlife populations. They -- they only talk about human health, we're talking about everything, human health and wildlife populations, what's happening out there, and then how does that relate to what we know inside a cell, and how do you connect all that up. And you -- you have to have both when you don't have it, so we're going to figure it and we're going to do it.

So why don't we move on to the next part of the agenda, which relates to some of these very topics, and you can see how some of these very concepts in part are playing out in the endocrine disruption screening

program. Mary Manibusan is the director of the program, and as in previous meetings giving you updates on -- on where we are in moving that program forward.

MS. MANIBUSAN: Okay. Good morning, everybody, and thank you so much for inviting me to come back and give you an update about the endocrine-disruptor screening program. It's been a quick six months since we've met and have much to report.

But let me start by sharing with you that, you know, I come from a place where I've had the fortunate ability to work across the agency, and the Office of Water, Office of Research and Development, and more previously to the job I hold now, I spent some time in the Office of Pesticide Programs, and what has impressed me about staying with the agency across those different offices is this consistency in having the courage to move forward on science, pressing the boundaries to such an extent that we're making sure that we're utilizing all the advanced technologies that we have to do our jobs most efficiently, effectively, the swiftest, and quickest way, but with the cost-effectiveness in mind and, of course, the assurance that we're meeting our mission to protect the public health and the environment, and no more -- nowhere is that more true than where I work currently in the endocrine program.

So my update to you this morning is entirely focused on the state of the science, because that's what we've spend the last months -- six months doing, just anchoring down what is the state of the science, how can we move forward, and to what technologies can we begin to transition the program into. And so with this particular overview, I'd like to set the stage by giving you a really brief background on the program and the particular statutes that we work under. I'll talk with you about SACA process that really provided a key recommendation to what our program looks like today and then how we build out from there.

And then I'll quicken the pace a bit and perhaps in a more brocado fashion, walk you through each of the science-advisory panel meetings that we've had since we've met and the one SAP that still remains, which is scheduled for later this month, and then I will try to tread the needle a little bit and link up the SAPs with some of the work that we're doing on the information-collection rule and putting and assembling pieces of the program together so that we're most effective.

And lastly I'll -- I'll end with giving you a glimpse of beyond this year into 2014, how we're beginning to think about transitioning this new technology into the program, and, more in particular as

it relates to your conversation just a minute ago, how do we bring together the community so that we're assuring that we're walking through this transition together, and what might some of the expectations be as we begin to retool our program and start incorporating some of these new tests.

So I always like to start my presentation with the end game, what do we have as our mission. And it's stated very clearly here, it's a very narrow mission, in my mind, and that is to protect public health and wildlife by screening and testing chemicals for endocrine-disrupting capability. And if and when we find risk, we need to take action on those, that is not new to our program or any other program across our agency.

We work under very specific legislative mandates, and they're listed here. The first is a 1996 Federal Food, Drug, and Cosmetic Act, it's Section 408(P). Here it's defined that the agency needs to develop a program, it needs to develop a program specifically that utilizes validated test systems, and that's an important word for our program as we look to developing test methods that focus in on the endocrine system, and more specifically it looks to certain chemicals that may have an effect similar to an effect produced by naturally-occurring estrogen and other

endocrine effects as the administrator may designate, so I just want you to hold on to those particular thoughts. As -- as I move through, I'll show you how we've progressed beyond the estrogen pathway and beyond the human population.

Beyond the FFDCA, which requires us to screen all pesticide chemicals, we also work under the 1996 Safe Drinking Water Act Amendment, Section 1457. Here -- very different from FFDCA, the focus here is on testing chemical substances that may have an -- an exposure in substantial-population drinking-water sources, so here we need to make an exposure finding before those chemicals fall under the purview of endocrine screening.

Following shortly, we looked to our Federal Advisory Committee and we developed the Endocrine-Disruptor Screening and Testing Advisory Committee. In 1998 they put forward some key recommendations to the agency, and we've wholly adopted those as policy. Some of those key recommendations include expanding the protection to include not only human health, but also wildlife, just the recognition that humans live in the environment and environmental species are often early indicators of impacts from endocrine-disrupting chemicals.

It also suggested that we expand beyond the

estrogen pathways to be inclusive of androgen thyroid, at that time those were the three most common pathways for endocrine disruption. But the EDSTAC also recognized that science is advancing very, very quickly, and so there are other modes of action to be considered and suggests that the agency considered that as we go forward.

But perhaps one of the most critical recommendations that really led to what the program looks like today is the development of a tier-two screening and testing program in recognition that we not test every chemical in long-term complex studies, we're beginning to be smart about which chemicals we move forward to higher levels of testing. And that tier-one screen, as it's listed here, the question for the agency to answer is whether a chemical has the potential to interact with the endocrine system and it's focusing on the estrogen, androgen, and fibroid-hormone systems.

And if chemicals are deemed to have the potentials to interact, then they would move forward perhaps to tier-two testing. And tier-two tests are very liken to part 158 studies and it's intended to determine whether that chemical indeed has an interaction, and then at what particular dose, because that dose information will be fed back into the risk assessment and ensure that

our risk assessments are protective of not only endocrine-disrupting potential, but all other adverse outcomes.

So here's just a slide to show you what our tier-one screening battery looks like. This screening battery was reviewed and validated in 2008 by the science advisory panel and it's comprised of five in vitro assays and six in vivo assays. Here's another look at the tier-one screening assays. They're built to work together, and so we often describe it as a battery, because it clicks together like a puzzle piece. Every piece is intended to inform each other, so in my mind it's -- it's almost liken to an impressionist painting where up close you might see just dabs of paint, but as you step back you begin to elucidate the bigger picture, what's going on, is there really interaction.

And if you'll see the way that this matrix is put together, it demonstrates how the in vitro studies are really informing the in vivo studies. And they're built together along the E, A, and T pathways, so the estrogen, androgen, and thyroid pathways. So even at that time in 1998 or 2008, there wasn't the term, adverse outcome pathway.

There certainly was a recognition that we needed to understand what was happening at different levels of

biological organization starting from the molecular level, moving into the organismal, and -- and -- and so on, into the population. And in vivo studies are clearly the anchor for this set, because in vivo studies not only capture the specific modes of actions that we have from the in vitro, but they cover all other effects that could only happen in, in vivo systems. For example, compensatory mechanisms out of patients, other modes of action, that's the beauty of this complementaryness of the entire battery.

If chemicals again are deemed to have that potential to interact with the endocrine system, it could move forward into tier-two testing. And within our collection, our tool box for tier-two, we have covered both the mammalian aspect as well as the ecological, again going back to the ed sec recommendation that we cover both human health and wildlife.

Here just listed for you is the tier-two site starting with the mammalian two-generation reproduction study, this is already a validated study included in your 158 testing requirement. We also offer the option to submit an extended one-generation reproduction study, and that is more focused on endocrine effects because there are specific endpoints included there that are not so captured in the two-generation study.

And that kind of economy of scale is something that we've looked to, to apply for the ecological studies, which -- which has just recently been peer reviewed, and I'll talk with you a little bit about that in a few minutes. And again I just want to demonstrate here just the coverage of different species, including the bird, the frog, fish, and invertebrate, and all those particular tasks are incredibly important to informing the agency of whether that chemical interacts, and again at what dose for risk-assessment purposes.

We are not a program just focused on test-method development. And this slide is just to snap everything together for you to give you that conceptual framework of how we're thinking about strategically approaching this testing and screening of chemicals, so if you can visualize this more of a -- as a funnel. On the top, the -- the largest piece of that funnel, is where we're looking to screen our universal for chemicals, which includes about 10,341 unique chemicals. And it moves those, only those, with high probability of having the potential to interact into the tier-one screen and in performing our whole weight of evidence determination in bringing not only the tier-one data, but also other scientifically-relevant information.

So going back to that notion that we take into

account all available information, whether it be published literature, in silico bottles, in vitro, or in vivo studies, we bring that all together to make a decision of whether that chemical needs to move forward for tier-two testing, and that is the last step in this funnel.

Alongside on the left, I just want to remind everyone that we're not only just focusing on human health, but making sure that we're covering ecological impacts as well. So to the degree that we're prescreening and we're walking through the tier-one and tier-two, that's what we're going to be thinking about.

So here's a -- a quick timeline snapshot of where our program's been, this program is not without much criticism. There are folks who believe that we've not moved fast enough since 1999 when we developed the endocrine program and there are folks who think we're moving too fast, in my mind I think we're kind of in the middle.

Here's where we are to date. Since 1999, when EPA established the endocrine program, we took a decade to develop the 11 tier-one assays and had those validated at the science advisory panel meeting in 2008. Shortly thereafter, in 2009, we started issuing out initial test orders for tier-one assays for 67 pesticide chemicals,

that was inclusive of 58 active ingredients and nine high-production volume and inert ingredients. Since test order issuance, 15 has -- 15 of those chemicals have opted out of the pesticide market or has voluntarily cancelled their registration, so we're left with 52 chemicals of that initial list that we're -- that we've received initial tier-one data for.

Shortly thereafter, in 2010, the agency received house-appropriation directive language to issue no less than 100 more chemicals for tier-two testing, that's inclusive of drinking-water contaminants, so we issued that draft list November 17th of 2010. And just recently, as you may be aware, we issued that final list in 2013 for public comments.

In 2011 we started receiving all the tier-one data, because we allowed for two years for the data to be generated, and so from 2011 up until early 2013 we started receiving all that data and we're in the process of data reviewing all that information and putting together our assemblage of the weight-of-evidence assessment.

At the same time we recognized that we needed to put forward some clear guidance on how the agency was going to perform this integrative analysis utilizing the tier-one data and other scientifically-relevant

information, so in September of 2011 we issued our guidance for how we're beginning to think about weight of evidence, how do we do this, how do we make a decision whether a chemical interacts and if it needs to proceed to tier-two testing.

At the same time in that same month, we also issued a critical document that I'll talk to you a little bit more about, it's the EDSP-21 work plan. Here's where we articulate not only our vision in moving forward with computational toxicology methods, but how would we begin to implement to apply that across time, ensuring that we're building on confidence as we move along.

The last two items on this timeline I'm going to spend a -- a lot more time in updating you on, and -- and that is the development and issuance of our first EDSP comprehensive management plan, which is really a critical impetus for us moving forward the way we have been in the past year.

And, of course, lastly I'm going to spend a lot more time just walking through with you the SAPs and linking them together for you, so that you begin to -- to see the bigger picture of where we're trying to head, and then talk with you about the day-to-day work of putting together the ICR and where we invite your comments on the -- on the burden estimation.

So here is a slide on the comprehensive management plan, again, it was issued in June of 2012 and this is a response to our Office of Inspector General's report where they evaluated the program and determined that we were not being as effective or efficient because we didn't have the necessary work plan laid out, so that is what the -- this particular plan was intended to do. It was an internal -- an internally-developed document that worked across our partnering offices, inclusive, of course, the Office of Pesticide Program, Office of Pollution, Prevention, and Toxics, Office of Research and Development, as well as our Office of Water partners.

It's a strategic guidance to our EPA staff and managers for how we put together our operational plan for the next five years, just looking across a five-year horizon, how do we work together, how do we make sure that we set up milestones to ensure that we're achieving the goals that we were intended to at the very beginning in 1999. It's very clear that we were not intending to establish any policies, or new procedures, or imposing any new requirements or guidance.

And -- and lastly it's important to note that this is a living document, we're not stopping after five years, we're -- we're annually updating this comprehensive management plan. And, in fact, we're in

the process of updating it through this year, as we expect a new version to be launched at the end of fiscal year.

So embedded in the comprehensive management plan is this table that lays out the key milestones that we had identified for 2013. Starting from the top, we talked about the need for chemical prioritization using computational toxicology. So using some of the advanced technology, how do we strategically and smartly identify those chemicals that should be screened first, again just recognizing that resources are every limited and we want to pay attention to those that really deserve the screening level evaluation.

The next row identifies the need to complete the data reviews for the initial tier-one data and conduct weight-of-evidence reviews, and I'll talk a little bit about that as well. And then here we've listed a series of scientific advisory panels, both on the tier-one battery, as well as how we're thinking through the weight-of-evidence determinations, because we think that's really important for this initial set that we lay down the ground works for how do we do this and how do we do this consistently across chemical.

We're also closing out on the tier-two inter-laboratory test methods. This work has really started

since 2001, so it's -- it's not been a very expeditious validation process. But in 2013 we took a lot of that information, just last month, to our SAP, and I'll talk with you about that.

And then lastly on the table is the issuance of list-two chemicals and tier-one test orders, and, of course, that is connected with the information collection rule and our finalization of list two, so I'm going to use this particular table and kind of walk you through and give you an update on where we have been in our program and how we've done.

So starting from the top on the use of computational toxicology for prioritization, as I stated, in September 2011 we put out our work plan, and this was in recognition that -- that, you know, the work and the pace that we're currently on in terms of issuing test orders, it's a -- it takes a long time and we're looking at a universe of 10,000 chemicals. So to really think about the timeline with respect to 2009 issuing our initial list of test orders, 2011 receiving the data submitted for review, and then coming back in 2013 to -- to actually do a peer review of that data, we're talking about no less than five years for just the initial tier and then probably another five more for the second tier.

So 10 years in combination, the set of tier-one

assays cost upwards of half a million to three-quarters of a million dollars per chemical, so we're talking about a substantial amount of resources, a lot of time. And with the current projectory, it would take decades for us to go through 10,000 chemicals. That being said, we understand that, you know, that science has advanced, and this computational toxicology is really calling for us to do our jobs a little differently and recognizing that data could drive us to work a little bit faster in screening and tests a bit smarter.

So to really address the thousands of chemicals that have the potential to interact with the endocrine system, we do have to begin to develop a prioritization method. In the EDSP-21 work plan currently stands, here's just a -- a pictorial of the -- of the core work that's -- that's explained there. I -- I don't want to go through each of these particular phases, only to recognize that there are three -- three steps here.

The first phase is thinking about how do we utilize high-throughput or computational tox methods, whether they be QSAR or other in silico technologies, to help us prioritize chemicals, deciding which chemicals to screen and test first. There the uncertainty that's tolerated is the -- probably -- probably a lot more than if we were making the decision of whether that chemical

has the potential to interact with the endocrine system, so that that level of confidence needs to be a lot higher as we move down the second phase, and it's nominally given two to five years and I wouldn't pay too much attention to that.

But after we've established the confidence of using some of these high throughput technologies for prioritization purposes, then we can move forward deciding, well, can we use that to help target our testing. So maybe we don't have to ask for all 11 assays within the tier-one battery, maybe with high -- high through technology it will help us focus in on the specific assays that we really need to better understand.

And then lastly on a longer-term phase basis, we're looking to make determinations that this high throughput technology has enough confidence in it, have enough robustness in it that we can go forward and replace the entire tier-one battery with the high throughput and in silico technologies, but that's on a longer-term basis. I think the key message I want to send to you here is that we're looking to transition these test methods slowly and incrementally, and we want to make sure that we're establishing confidence as we move forward, and that we're not rushing to the end simply because these technologies are available.

So the first step in that work plan calls for the agency to look to prioritizing the universal chemicals for EDSP, and some of the thoughts and concepts here are laid out. We're looking at the three top ways, estrogen, androgen, and -- and thyroid, and looking to meld together, integrate the high throughput technology. And for those who are not very family with high throughput, it's just thousands of cells that you can run very quickly and using robotics. It's very similar to an in vitro petri dish, but it's done in a high-volume scale.

Inherent chemical properties, so what does that chemical look like, what's the structure, is it corrosive, is it charged, is it acidic? Those properties are really important, as you'll see, because they help us define the chemical universe that really warrants screening and is testable.

The model predictions in the previous talk, we already mentioned the ER expert system that went through SAP review, but there are other SAR methods that -- that would come online, it's a recognition of that. Exposure data, this is something that our panel just in -- in June had already mentioned, the importance of considering exposure information as we begin to prioritize chemicals.

And then looking at structural analog, so maybe

we don't have to test every pyrethrum, maybe we can pick a surrogate and just test that, so, again, opportunities for read-across is certainly very important. And then making sure that we're anchoring all the work that we're considering, all the data together, and providing in a framework. So we've talked about the adverse-outcome pathway being that framework of how we lay down the information, and so we have much more certainty about the endpoints that we're choosing for risk assessments.

So in January we worked together with our office in research development, our national computational tox-center colleagues to put together a prioritization method that relies not only on newer, swifter technologies, like high throughput, the ER expert system, but looking at older technologies or things that we've taken for granted. But we're looking at them in a -- in a different light, so a lot of the physical chemical properties were brought together alongside with these newer technologies.

And the -- the final report from the SAP was received by the agency in May, and we thought the -- a lot of the recommendations were incredibly, incredibly informative and very, very helpful. Just to set the stage, the focus was primarily zooming in on the estrogen pathway as a demonstration for the androgen and thyroid,

because, again, we were trying to elucidate the -- the methodology.

And then taking that approach, we would apply it for the androgen and thyroid as it -- as it was deemed fit, so the focus here was obtaining some input and recommendations on the -- on the scientific concept, and principals, and -- and processes as we begin to explore prioritizing with some of these technologies. So this is a figure that we presenting at the SAP, and we've -- we've adapted it since based on some of their core recommendations, so I just want to walk you through some of the thought logic.

It starts on the top, our universe, like chemicals, comprised of 10,341 chemicals split across the Safe Drinking Water Act, CCL lists, the inert chemical universe, as well as the active ingredients. We've separated the active-ingredients' process to the left in recognition that there is an existent schedule, the registration-review schedule, that would drive when those chemicals would come in line. Again, just to think about dovetailing the processes so that we're not spending resources unwisely.

So let me start with the left-hand side where we start with the Safe Drinking Water Act and the inert universe, and that's comprised of about 9,000 chemicals,

what we took to the SAP was the consideration of some sequential filters. And perhaps they're not that sequential, because they do overlap with each other. So in terms of physical chemical properties, here the questioning we were -- we are asking is, can we glean from its characteristic, whether it's an acidic, or basic compound, where that chemical is testable in some of the in vitro/in vivo test -- test methods that we have, but more importantly to have the ability to become bio-available so that you can have systemic absorption and thus to elicit endocrine disruption potential.

We -- we brought to the panel some cutoffs for acidity, when a chemical is too acidic or too basic; we considered things like when the chemical's too large, it's a polymer, so it can't even fit into the receptor pocket to initiate the molecular initiating event; we -- we considered things like charged characteristics of that chemical; as well as the environmental half-life. The environmental half-life is can it -- can it stick around and is it stable enough to -- to allow for human or wildlife exposure, because if it isn't, it's -- it's of not concern to our program.

And that -- and that half-life information really speaks to exposure, so that's captured in the next diamond which combines the hazard exposure, because the

recommendation of the panel was, hey, consider more than just the hazard, think about exposure as well when you're prioritizing chemicals, because certainly if there's no exposure there's no risk of concern. So the hazard call, we are looking to utilize not only the high throughput technologies but also the ER expert system, and those were the two tools that we brought to the SAP. And this was the first time that we had brought high throughput assays to the panel, and there's certainly some work needed on both models, so we feel pretty confident that the overall process was very acceptable to the panel itself.

And then lastly the box here is just for the agency to make sure that there is a chemical manufacturer existent in the U.S., because without which we do not have the authority to issue test orders. We also consider other scientifically-relevant information before we move chemicals into our -- our bucket, if you will, for -- for tier-one screening.

On the left-hand side, very, very similar, we'd utilized the registration-review schedule for active ingredients, we think about applying phys chem properties to consider chemicals that are not testable, the acid-bases, all that applies as well. Well, think about some exposure considerations for the uniqueness of the

different active ingredients, whether they have human exposure, or wildlife exposure, and to what extent, and then certainly when applied to our considerations of read-across and chemical categories, as we've just talked about.

This is where the January SAP came out. Some of their key recommendations of really high level are listed here, they talked about the prioritization scheme being very-well organized and very clearly described. And as noted, they asked the agency to consider exposure earlier in the prioritization process, because they felt that was really, really important.

On the phys chem property filter, they are very, very complimentary and they found that this was based on strong scientific principals and very consistent with the recommendations made in 1998 by the EDSTAC at that time, but also asked us to think about the adverse-outcome pathway and think about the molecular initiating events and creating probably some criteria for deciding, based on p-chem property, if a chemical can even initiate that -- that early precursor event. And if not, that should be considered in that filter.

On the expert system and high throughput assays, again they felt that both -- both tools were very complimentary in design, was able to be very informative

for how we think about that in combination with exposure in a -- in what we're calling a risk-based model approach. And then speaking about other pathways, as estrogen's more akin to androgen, the prioritization method would be more applicable to that pathway. But certainly the thyroid would involve additional research, because there are multiple ways of initiating thyroid perturbation, and so that information, those assays will be in the domain of our office in research and development before we begin to prioritize for that pathway.

Moving forward to EDSP-21, we'll continue to refine and apply some of the recommendations that we've received from the SAP. More importantly, we'll look to update the EDSP-21 work plan, because that's our way of articulating to the public where the agency plans to head, how do we plan to move forward in implementation, and what time scale, and what sequence.

But -- but the last bullet here is just to remind ourselves, remind you, that our domain includes more than the estrogen pathway, we're looking to developing AOPs for the androgen, thyroid, and surrogenesis, and using our science advisory panel as a forum to engage with the public as well as with experts across the country.

The next SAP I wanted to talk with you about is the tier-one assays and battery review, and that was conducted in May. The focus of the SAP was on the performance of the tier-one individual assays and tier-one battery. A lot of the impetuous for this review came from the SAB/SAP panel back in 1999 where they recommended to the agency, hey, agency, once you validate it, these tier-one assays, in several different labs, we recognize that when you put this on a larger scale things might be different. So when you have about 50 to 100 chemicals that have been run through tier-one, bring them back to an external peer-review panel with an eye towards optimizing or revising that process. And more importantly to note, eliminating those methods that just don't work, so, again, looking for that efficiency, doing things faster, better, swifter.

Back in 2008, again the tier-one battery was reviewed, this was a very open and transparent peer-review process, and what they had to say at the time was that this is an appropriate starting point to starting to detect whether chemicals have the potential to interact with the endocrine system looking across multiple taxa, looking across multiple modes of action endpoints, and a range of metabolism, and that necessary complimentaryness and redundancy, if you will, is built in and is a good

place to start.

In 2013, again in May, the EPA looked at 21 chemicals specifically, that was a subset of the 52 that we brought to the panel. Because it was a broader representation of the 52, it encompassed a range of p-chem properties, a lot of TOWs, as well as different biological activities, herbicides, eudenticides (phonetic,) et cetera, captured in that 21 subsample.

What we concluded in -- in May is that the tier-one assays provide useful information, and continues to do so, to indicate to the agency whether a chemical has the potential to interact with the E, A or T pathways. There were, in essence, in general, no major problems identified with the tier-one assays in performance, laboratories were able to execute each of the assay protocols with respect to the test guidelines and achieve that specified performance criteria.

There were opportunities for us to look at some flexibility with some of the performance criteria, but all in all the assays seem to be executed quite well. Some -- there were some minor deviations from the performance criteria, but, again the differences were not substantial.

The panel as a whole looked at this review, and at least verbally what the agency heard was that there

was concurrence with this 2008 SAP. It still is a good battery to help us determine whether a chemical has the potential to interact with the endocrine system, but, again, we are waiting for the final report that will be issued 90 days after the May meeting.

The next meeting that we had with the science advisory panel focused on our tier-two test method, and this particular SAP was focusing on the validation efforts that the agency has been processing from 2001 up until today. And here is a quote from ECVAM on validation, “That is a scientific process by which the reliability and relevance of an assay method are evaluated for the purpose of supporting a specific use.”

And reliability, as defined here, is that root producibility of results from an assay within and between laboratories, so within a lab can they do it, and then across several labs with different abilities can they still follow the protocol and execute. The relevance is defined here as whether a chemical -- whether a test is meaningful, can it -- can it answer the questions that we’re seeking to answer and is it fit for purpose.

The agency followed a five-step validation process for all of the four ecological tier-two test methods that we have presented to the SAP, the first involves the method development and preparation of a

detailed review paper. This involves a lot of published literature searching, just seeing what's out there so that we're not starting from scratch or that we're not being redundant to existent test methods of building on what's already been done.

The second step is a prevalidation step, and this is what we term as intra-laboratory validation where we're making sure that the test method can be done within a lab with sever different chemicals and then we're -- we're optimizing that protocol as we move forward.

So getting it ready for that next step of validation, which is the third step, and that's an inter-laboratory phase and that's what we vantaged in the Office of Science Coordination and Policies where we chose very wide-ranging laboratories, some labs that just have no experience running fish assays or frog assays, all the way to laboratories that really are proficient, they have demonstrated that they've been doing this. We wanted to get that range of experience, so that we can be informed as an agency for how do we need to build that test guideline so that it can be reproduceable and that labs, whether they be inexperienced labs or most-experienced labs, can actually get them to work.

The fourth step is what we -- we denote as our science advisory panel review that we just had, that's

very important to receive expert opinion on how well these study protocols were executed in the different laboratories. But more importantly, how can the agency improve upon that to ensure that, again, contract labs can do these studies, and that's prior to regulatory acceptance, of course. There's several steps that are not listed here that, you know, is required before a test method is wholly adopted, and that is the development of a test guideline as well as standard evaluation procedures.

Here's a listing of the tier-two test methods, again we talked about the RAT as being already validated and OECD approved. As we walk through the ecological toxicity sites, I just want to emphasize that a lot of the work was done in collaboration with international partners, so the fish and the frog studies were done in collaboration under a U.S./Japan bilateral with the Ministry of Environment where they have a lot of experience working with Mendonca, as well as with veinapeslavis (phonetic), and there -- again, there was definitely a leveraging of resources where we optimize both experience as well as just conducting the studies themselves.

We also collaborated with NOAA on the invertebrate studies, again, lots and lots of experience

working with mice and copepods, as well as with the U.S. Army and USGS on the bird study, so a lot of experience has been put together here and over -- over a decade of work in terms of the validation effort. But starting from the bird, the bird is a unique species because it helps us determine long-term effects of maternal transfer. We look to the Japanese quail and other species listed here, because of its reliability and robustness in a laboratory setting for a long-term study, so, again, looking for that practicality was really important to us.

The fish study, I just want to note here that we have a multi-generation toxicity test developed by our Duluth laboratory, as well as the Mendonca -- Mendonca reproduction test. And here we look to economizing from a multi-generation study to a single-generation study, so similar to the RAT study is what we've presented for the fish.

For the frog study, here we're looking at characterizing perturbation, especially in the thyroid effect for normal developments and growth in veinapeslavis. And then lastly the invertebrates, we have a lot of experience using mice because this is a 158 required study, a life-cycle study, and we are extending this to a multi-generation study for use in our tier-two

test methods.

The SAP for the tier-two test methods, we received a lot of invaluable recommendations. And one of the take-home messages that we heard from the meeting was the need to not only put forward a very clear test guideline with very specific performance criteria that need to be met and then where flexibility could be allowed to -- to articulate that, but also a need to follow up with training and providing expert consultation. So that we're not just issuing a test guideline, but making sure that we walk through the process with the contract laboratories or those who are conducting these assays, and we certainly have taken -- taken note to that.

There are a couple of other recommendations that were made by the panel that we're working actively in putting together, and that is a histopathology workshop looking at ensuring that slides for histopathology are read consistently across species and across the three studies, minus the invertebrate, because we don't do histopath on invertebrates.

And the second workshop to focus primarily on statistical methods, because a lot of the data will be coming in and there will be opportunities for metadata analysis. It was important from the panel's point of

view, and ours as well, to ensure that we have sound statistical methods designed to fit the test methods themselves, and that report will be, again, coming out in 90 days. So early October we should be receiving that final report, but we're moving forward again on some of these activities that we can do so now.

The last SAP is scheduled for this month, July 30th to August 2nd, and this one focusing on the weight of evidence. So if you can note that from the beginning of January up until now, we're just increasing in complexity on the issues, but this final report will be due to the agency in November of 2013.

The focus of this particular SAP at the end of the month will be on the reliance on the weight of evidence report that we had issued back in September of 2011, there we articulated how the agency was going to consider the endpoint that was elucidated in the tier-one data, as well as how we consider other scientifically-relevant information, and more particular the 158 data, that can be very informative to dose setting, modes of action, what we know about that chemical and bringing that all to bear.

So what -- what the agency has done is that we've selected from the 21 subsample and that we brought to the SAP when -- when evaluating the tier-one assay and

battery review, we chose specific case studies to help us demonstrate to the panel some of the challenges that the agency will encounter when we're blending those two data sets together. But more importantly, asking the question of whether the agency has interpreted that weight of evidence accurately to ensure that we've identified whether a chemical has the potential to interact with the endocrine system.

Some of the focus questions for this review will be on, you know, again, just -- just making the decision of whether that chemical has an interaction with the E pathway, the A pathway, or the P pathway, because that will be informative to the agency on how do we move forward. And what we mean about moving forward doesn't necessarily automatically mean moving forward to tier-two, we can, in -- in fact, decide that there's an interim assay that we can -- we can ask for that will help us answer the question.

For example, if we see a thyroid perturbation occurring, we're not quite sure and it's a little bit fuzzy within the tier-one data set. We don't necessarily have to jump into a multi-generation study, we can certainly ask for a thyroid-specific assay, and we've done that in the past. So that's a specific focus for this last SAP.

Here's a slide that I've shown -- I'm showing a parallel process both for the SAPs, for the external peer review, as well as for how the agency's moving forward on our information-question request. So we just talked about the SAP schedule and -- and that report, just to note, as our anchor date is in November of 2013. Starting from the top information question request for the initial ICR, and that's relating back to the list-one chemicals, tier-one, that particular ICR has just recently been approved by OMB July 3rd and that allows the agency to issue catch-up orders for the list-one chemical.

The second ICR that was just issued for a 30-day public-comment period on -- on June 30th is focusing on the list-two, tier-one test orders. So list-two was moved -- was reduced from 134, that we had issued back in November of 2010, to 109 based on looking at physical chemical properties, chemicals that we've already issued to the agency that are voluntary cancellations or their interest in leaving the pesticide market, those chemicals were removed and that left us 109 chemicals. What we also issued in that package was our policies and procedures for how we plan to procedurally process the test orders for Safe Drinking Water Act chemicals, as well the ICR that defines the estimate of burden for --

for calling in the tier-one data, as well as processing it.

The third ICR that came out for a 60-day comment period, so this is at the very front end of the process, was that for our list-one, tier-two test orders, and this in -- again, in anticipation that when we -- when we conclude our weight-of-evidence assessments, we will have not only the science in place, including the tier-one test methods, but we will also have an ICR that will allow us to issue test orders for any necessary tier-two tests needed for a chemical. And that had started back in June of 2004, so all of that -- all of these particular activities are really interconnected and they all fit together to ensure that we're operationally moving forward on a very efficient time scale.

So this particular slide is a little bit of a report-card slide, just going back to what we had presented in the comprehensive management plan and seeing how well we've done. So from the top, SAP on chemical prioritization, that was completed in January. The next cell here, of course we won't be completing any of the DRs or weight of evidence until after the SAP in November, the November report's received. The agency will consider all the recommendations before completing the weight of evidence, and the final reports will be

proceeding from that point forward.

The next cell here, again the SAP for tier-one assay and battery, was conducted in May, and then the weight of evidence will be at the end of the month. Our intralaboratory validation efforts for tier-two test methods proceed forward, we await the recommendations from the SAP, and we'll look forward to clarifying our test guidelines in ensuring that it's going to be readable, and executable, and -- and -- and certainly clear enough that we can move forward.

And then the last item here, ICR for public comment, was issued for the list-two chemicals, but, of course, noting that there are several additional steps that need to be had before the agency even begins to issue test orders, and that is the 30-day public-comment period that's available, and then another 30 days for RMB for determination review of the ICR.

So that completes our milestones for 2013. As we look forward to 2014 and beyond, the -- the program is looking to again maximize on the use of the current technology, the advancements that we've been just talking about through the TOX-21 effort. I think it's important to note that in our work plan we had described as incremental step-wise progression before we start utilizing those test methods in risk assessment, so it's

not going to be an on/off light switch, it's not going to be a -- a clearly-defined time point that we say, we succeeded now in incorporating computational toxicology.

I -- I think for any change there's going to be a gradual transition, and gradual sometimes means you might not see it. There might be decisions made within the Health-Effects Division and EFED that aren't -- aren't on the scale of being quantifiable, they may be just a consideration that we may not need the study because we've got an existent study. So it doesn't have to be as flashy as saying, well, we've utilized high throughput and here's the number of animals that we've saved, and I think that transition is very realistic.

So I -- I just wanted to share with you one of my favorite authors and book by Malcolm Gladwell, and it's titled, "The Tipping Point," because I believe that's where we're all approaching when we're talking about transitioning to the high throughput methods. We're at that point where we can see a change, and how we approach it is going to be really critical. His quote is that, "If you want to bring a fundamental change in people's beliefs and behavior, you need to create a community around them where those beliefs can be practiced, and expressed, and nurtured."

And I think that reminds me of the community

that we have around the table here and -- and that's really critical to reemphasize, that as we transition to these new methods we all have to come together to ensure that we're utilizing them in a way that is comfortable, that's understandable, that gives us assurance that we're not missing anything, that we're outcome neutral in our test methods and the test methods that we choose, but also to be reminded that when we're transitioning towards use of newer methods to not forget that we have existent methods that are validated. We have data already available, we have p-chem properties that you don't even need to test, and you can actually make decisions to reduce animal testing and be more efficient in your processing.

So I leave you with that thought and I thank you so much for your attention, and I open up for any comments you might have.

MR. BRADBURY: Thank you. Gabriele and then Cynthia.

MS. LUDWIG: I have a series of three questions or comments. Just for my own edification, what's -- what's the restriction of being manufactured in the United States or what's the definition of that, I'm just trying to understand that? You said earlier in the presentation that you can only ask for data call-ins if

it was manufactured in the U.S., use in the U.S., the company is based in U.S., what's that definition?

MS. MANIBUSAN: So our test order, or ability to issue a test order is defined as having someone to issue that test order to, so we need to have a chemical manufacturer, it can't be an orphan chemical, for example. And it can be an importer, so it's chemical manufacturers, or importers, pesticide registrants, those are the communities that we can issue test orders to. If there's no one manufacturing that chemical, for example, there's no one to issue that test order to, so we have no authority.

MS. LUDWIG: Okay. And the other question is, you had mentioned working with Japan, but where is -- what about EU, because they have some immediate deadlines in terms of hazard cut-off criterias for endocrine disruptors? And so I was just curious, has there been any dialogue with EU regulators as to what they're doing, are they following similar methodologies? I'm just coming back to Sheryl's point earlier that EPA's track is totally different from EU's, because the registrants will go ballistic?

MS. MANIBUSAN: So maybe I can start with how we're working internationally on test-method development, and then we can talk a little bit about the EU

activities. With regards to our test methods, for our tier-two in particular, we're working very closely with the OECD. In fact, there is an upcoming meeting planned in October in the U.S. for the OECD VMG eco group to meet specifically to discuss the tier-two test methods and adoption to the OECD process. And as you've noted, maybe for the tier-one assays we were also working very closely and many of those assays have been adopted by OECD as well.

With regards to the EU and their -- their legislative deadline, which is quickly approaching, of December 2013 to establish criteria for endocrine-disrupting chemicals across the plans' protection, as well as for the bio-side regulations, they are at the front end of where we perhaps were in 1999 in defining what EDCs are.

Since -- since that has been put out from the EU in terms of their revised criteria of having two categories, we have been meeting with the EU commission on a monthly basis just to check in on where we are, we're making sure that we are looking for opportunities to harmonize where we can and where it makes most sense. And I think it's very likened to the pesticide global reviews that we conduct here, where we're harmonizing on the definition as well as the type studies that are

supported for those definitions.

MS. LUDWIG: And then my -- my third question is, in -- in the whole presentation it was really about trying to figure out the methodologies and -- and then figuring out which chemicals do we need to get the data in from, but what's the -- what's, like, the endpoint? I mean, has there been discussions about, okay, so you find something that has a thyroid effect or has an -- an androgen effect, then what, so where's that discussion? And, I mean, I really -- it's already starting to be part of the thinking in -- in the actual risk assessments, but where's that part of the discussion on this?

MS. MANIBUSAN: So -- so that's a really good question, and I -- I go back to the FFDCA's statute where they are very specific to the agency about developing a program to screen and test chemicals for endocrine-disrupting ability, and at that time there was recognition. There -- there was no other program that can do that particular function, nor were there test methods designed to specifically target that mode of action or toxicity pathway, so a lot of the time that I've described in my timeline was spent developing those test methods and doing the work of building out that infrastructure.

So while I'm mindful that it sounds, from my

presentation, like I've strung together scientifically scientific advisory panels, that is certainly not the end game. The end game is, as you've described, to ensure that we're public-health protective in protecting wildlife from chemicals that have the ability to perturb the system, but we can't do it without test methods in place, we can't do it without ICRs in place, and we -- we can't do it without making sure that those test methods are validated, so that's the homework of 2013 that we've been doing.

The end game is going to be really important, because it will answer the question, but how we move through that is not different than any other endpoint that we're current evaluating. Whether it be carcinogenicity or developmental toxicity, all of those particular toxicity endpoints are considered when we evaluate a chemical within a risk assessment.

Where I talked about the tier-one data, that is not information that would go directly to informing the risk assessment. It would be helpful to characterize that information and present the mode of action certainly, but not give you that dose response to do a quantitative risk assessment, where that information comes into play is the tier-two test method.

So when a chemical moves into tier-two and it's

indeed demonstrating that it has ability to interact with the endocrine system, let's say there's thyroid perturbation and we have a dose associated with that effect, we'd use that information and put it together with the toxicity profile for that chemical. So, again, that chemical, if it's a pesticide active, it would have 158 information, it would have a developmental toxicity study, it would have a multi-generation reproduction study, it would have a carcinogenicity study.

All of those endpoints would be put together in an integrated evaluation, weight of evidence, if you will, and a determination would be made on what is the most sensitive endpoint. It may not be the endocrine endpoint that is the most sensitive, it may be a carcinogenicity endpoint, it may be a liver-toxicity endpoint, there are other toxicities that could be at play at lower doses.

Our assurance, when we're melding that tier-two data alongside with the 158, is that we're ensuring that we're capturing that sensitivity. If it in deed is the most sensitive endpoint, then that will drive the point of departure and it will drive the risk assessment. Does that make sense?

MR. BRADBURY: Thanks. Cynthia and then Cheryl/Sheryl.

MS. PALMER: That was a fascinating presentation, so thank you very much. I'm very happy that EPA is doing this effort and I'm happy that you're at the helm. My question is you've talked about FIFRA, and FFDCA, and the Safe Drinking Water Act, and I'm just wondering if EPA has a parallel track for the industrial chemicals, the TOSCA chemicals, and if not, as the nation thinks about TOSCA reform, are there lessons learned, do you think that you would be able to jumpstart a similar effort for industrial chemicals or that to become part of your jurisdiction?

MS. MANIBUSAN: Great question. Thank you very much for the compliment. Let me use the list-two chemicals in answering your question. So list-two chemicals is inclusive of 41 active ingredients from the '07/'08 registration-review schedule, as well as 68 CIDWA nominated chemicals from their CCL-3 list. Of that list, there's 20 TOSCA chemicals that are in parallel with their -- with their work plan. And so my short answer is when we're considering Safe Drinking Water Act chemicals, they are inclusive, if not overlapping, with industrial chemicals.

And furthermore, the -- the agency has the ability to reach out under different statutes if we find that a chemical needs to be considered for endocrine-

disruption screening, there's certainly a lot of flexibility there already built into FFDCA.

MR. BRADBURY: Cheryl/Sheryl and then Pat.

MS. CLEVELAND/KUNICKIS: I too want to thank you. That was a great, much-better, in-depth presentation than we've gotten in the past when we just got some timelines and some updates, so really thank you for threading that together. This is such -- can be such a contentious thing for timelines or testing orders, so it's great to get that overview and realize how far you've come.

My question has to go back actually a little bit to the -- the legacy question, the manufacturing test-order questions, because the original list, when it was drafted, did have some legacy. It sounds like some of that's fallen off, if you didn't have somebody to issue a test order to.

There are also some legacy uses that may have been shifted, and so that your actual enclosure now may be much -- far left than -- so my question is, as you mentioned several times, exposure, exposure through here and -- and the -- well, I have a comment question. The -- the -- the Elsie Hessey (phonetic) group that was looking at this through risk 21 on the drinking water test -- test case, one of the things they kept coming

back to is rather than refining the hazard side completely, make sure you're refining the exposure side appropriately too.

So that comes into did you have some things that have ended up on that list now, because the list was drafted, and it was using old data, and 10 years down the road maybe they're not even there anymore, what effort has there been to -- done on the exposure side for that list, and is that part of what you're asking for when you say that there's this ICR out there for public comment? What do you want from the public comment, is -- are you asking for do things belong there, are you asking for quantization of exposure, are you asking for monitoring data, what -- what is the public-comment period intended to do on the -- on the list that's -- that's been posted?

MS. MANIBUSAN: Okay. So -- so just to clarify your question, which is a great one, so I -- I make sure I'm answering the right question, your -- your question is centered on the list-two and the list-two package that is out for public comment, it's a 30-day public comment period, correct?

MS. CLEVELAND/KUNICKIS: (Nods head.)

MS. MANIBUSAN: Okay. So let me just describe to you process, because that's the world I live in. So that list was, again, proposed back in 2010, and from

that initial up-front, 60-day public-comment period we received no less than 600 unique comments. And among that grouping were a lot of focus on exposure determinations for the drinking water chemicals, because, again, the statutes, CIDWA, reinforces the need to make sure that it -- it may have exposure in a drinking-water source to a substantial human population.

So we rely on Office of Water, who -- who developed their CCL-3 list based on that determination. They utilize exposure information from their ground-water, drinking-water sources, from the ambient water-quality information, as well as from TRI, so from environmental-release information, and from production information, those are the sources of information that we, as an agency, rely upon to make that exposure determination. And again, that’s the -- the same way for the CCL-3 process.

When we look to finalizing the list-two chemicals, we did a couple of things, we -- we did a really in-depth look at the chemistry, making sure that p-chem property-wise they were testable, they were -- they were stable enough for environmental from an exposure point of view, and that they were still currently manufactured, all of those feed into exposure, of course, right?

And where we look to in terms of a database to identify manufacturers that are currently listed and available to us is through our chemical-data reporting system, and that's under our Office of Pollution Prevention and Toxics, that's where we start. There's certainly some additional work needed to be done to identify all the chemical manufacturers, but that's where we start to ensure that those chemicals that we've presented in that list still has a chemical manufacturer associated with it. Does that answer your question?

MS. CLEVELAND/KUNICKIS: Almost. So what are you looking for in the current public-comment period?

MS. MANIBUSAN: Thank you. So in the -- in this public-comment period this is the final stage, if you will, before it goes to OMB, so this is our opportunity to get insight from the public on how have we done in that finalization, have we missed any new comments on the list, have we missed any comments on the ICR.

So as we've presented our cost estimate and burden of cost, that information is open for public comments. The whole package is, but recognizing, of course, that the list and the policy itself have gone through extensive public comment and review and we've spent the last three years focusing on responding. And you'll see in our response to the public-comment

document, which is about this -- this level high and deep, that we've spent a lot of time working with our partnering offices, with our Office of General Counsel, ensuring that we were responsive and we've considered all of the public comments.

MR. BRADBURY: Okay. Pat and then Ray.

MS. BISHOP: I want to thank you too, Mary, that was a great presentation. The January 2013 SAP meeting focused on the estrogen-pathway-expert system. And for those of you who weren't aware of it, it -- you had elements of, you know, looking at structure -- chemical structure, chemical properties, filters, there was a use of a lower throughput, was it a trout -- a rainbow trout liver slice system to identify ER receptor, finding chemicals, and then I think you had elements where you tried to correlate that to some of the high throughput assays that are also looking at ER.

Could you just give us a little background on what's being done for the AR binding and the thyroid pathways, you know, using that kind of process; and also, you know, what kind of timeline you're looking for, for them; and finally the -- where is the ER system at this point, are you ready to use it, I know you got a lot of feedback from SAP on that; and are you going to use that -- going to go forward with that waiting for the other

two to be done, or, you know, are you going to start using it right away?

MS. MANIBUSAN: Okay. So thank you very much for that question. The January SAP is -- is a very exciting SAP for me and for many others, because it was looking to pioneer in the direction of application for these new test methods.

The quick answer to your question is that the state of the science will drive the pace in which we demonstrate application, even for a priority setting, because the endocrine system is so integrated, and it's so complex, and the statute that we work under is so specific.

EDSTAC was even mindful of that in -- in stating that even for prioritization and especially for the tier-one screen, we want to be cognizant that we are specific and sensitive at the same time. So more accepting of perhaps some false positives when we're screening, but certainly not accepting of false negatives. So that's kind of the umbrella tenant, if you will, those guiding principals that we'll be utilizing as we move forward, regardless of whether it's E, A, or T.

For the estrogen-receptor-expert system, as we've presented in January, the coverage was excellent for food and nonfood inerts, as well as for anti-

microbials, because that's what the chemical domain space in which it was built under. It was not so good in capturing some of the fragrances, so there's still some work to be had. Having said that, based on 70 percent of that universe coverage, only five percent were identified as having ER-binding activity and gene activation, so that easily can help us prioritize, based on E alone, our next set of chemicals perhaps. And then when we consider exposure together with that, again it might -- it might whittle that down. So that's some of our thinking, there's still some work on the ER-expert system.

With respect to the high-throughput, what we heard from the panel, and especially in their final report, is, again, some additional work needs to be done on high throughput. What we brought to the panel was specifically eight assays that paralleled closely with rainbow trout data, so ER binding and gene activation. There's certainly additional high throughput assays that speak to the rest of the AOP, so downstream from those early key events that could be informative. So the agency is thinking about that information, alongside with melding together the exposure information.

As we had stated in January, the ER-expert system, the estrogen pathway, was our model, it's a demonstration of the methodology that could be applicable

for the other pathways. Those pathways are still being worked on, because it will dictated by the science and our understanding of AOPs for androgen and thyroid. I can tell you our office of research and develop are very much focused on that effort right now, because we want to make sure that we're not excluding any pathways and that we're covering across taxa.

So it's just, again, a reminder we're not just focusing on human health, but also on ecological impact as well. So there's still some research to be had, we feel that the data is very promising, the methodology is in place for us to do things much smarter, much more strategically.

MR. BRADBURY: Okay. Ray, Susan, and Mae, and then we'll close this session.

MR. MCALLISTER: Fortunately most of my questions have already been addressed, but I wanted to ask about the comprehensive management plan, how will that be kept up to date, and -- and will it, and will that updating process involve the -- the parties who are responsible for conducting the testing?

MS. MANIBUSAN: Yeah. So one of the stipulations with our Office of Inspector General, when we had produced the comprehensive management plan, was also commitment to annually update that management plan,

so we're in the process of updating it for -- for issuance of the next version by the end of the fiscal year. That updating will, of course, involve all of our partnering offices and inclusive of our office of Research and Development, because one of the primary components of that plan is how do we plan to move forward with EDSP-21, and that will be reliance on the science and its readiness for application.

MR. MCALLISTER: What -- what about the companies who are in -- responsible for conducting the testing that you come up with, I mean, what role do they have in updating this plan?

MS. MANIBUSAN: So the plan is an internal strategic plan where we have advice or recommendations from our stakeholders. We plan to, of course, consider as we move forward, as we're doing here today, as we do with our SAP reviews, we bring all of those recommendations together as we think about moving ahead to the future. The future being completion of our weight-of-evidence assessments, data-review processing, incorporation of computational test methods, introduction of new test methods perhaps that are ready and available online for utilization.

MR. BRADBURY: And, I guess, add the ICR process too, but that's opportunity to look at timelines and

various causes and procedures. Okay. Susan and then Mae.

MS. FERENC: Thanks. I'm glad you brought up the ICRs, because that's kind of what I wanted to -- to talk a little bit about. Of course, OMB's responsibility in this, and -- and this ICR for list-two is at OMB, and obviously EPA will accept comments on it, but comments also go to OMB, and it's OMB's responsibility to make sure that public and private resources are appropriately spent and allocated for the agency to make the decisions it needs to make.

And I had assumed that these SAPs you've been pulling together on the -- on that tier-one battery, and assays, the weight of evidence, and OSRE, and all of that would be -- the results of those would be included in your consideration of moving forward with how appropriately to test the list-two chemical, and it's a little disconcerting to see that the ICR looks exactly the same -- test orders are exactly the same for list two as they were for list one.

And in the ICR itself, the request and the supporting statement, there's no reference to any -- any results of the SAPs on whether or not -- and the weight of evidence is obviously the -- the most important SAP to happen yet, is, in fact, the -- the information coming

out of the tier-one, list-one chemicals, give the agency the information it needed to move on, to make the decision of whether or not a chemical does or does not have the potential to interact. And that's a lot of work that the SAPs are doing on this, and it's not -- it doesn't appear to be being incorporated at all in moving forward to list two.

Now, list two, of course, as you said, has 109 chemicals on it, so you're looking at $50 to $75 million dollars worth of testing, plus the agency's responsibility then for evaluating all the information. And I guess my question is, why the need to -- as soon as that ICR is approved in 30 days, you can send out test orders. And then whatever the SAP -- the final reports from the SAP really aren't going to be incorporated, because the test order as approved -- as written as approved, that gets the OMB control number and you're kind of good to go.

So I guess my question is, why are you pushing this ICR out now that looks exactly the same -- the test orders look exactly the same as for list one without knowing, without ever having demonstrated that, in fact, everything you collected on the tier-one battery from list one is needed, and necessary, and sufficient for -- for EPA to make their decisions on whether or not a

chemical does or does not have a potential to interact with it?

And this leads into the second ICR, or the ICR for tier two. I haven't read the transcript from the SAP yet. I read the transcript from the SAP for tier-one battery, but the -- a transcript doesn't appear to be posted yet for the -- for the list two. But, again, an ICR -- even for EPA comment right now, the ICR on -- on the tier two seems to be a -- a little bit premature, I guess, because, again, you still haven't full information, been able to integrate all the information from the SAP on this -- on this set of -- of tests to really inform whether or not, you know, the test order that you're looking to develop for all of those assays that are currently listed for -- for tier-two testing are appropriate and -- and do provide the practical utility for the agency to make the decisions you need t make.

MS. MANIBUSAN: Thank you so much for articulating that sensitivity, and it's the sensitivity that the agency shares. As I stated during my presentation, we are very cognizant of the cost of the tier-one battery. We are also very cognizant of the cost for data reviews, as many of our experts have been asked and have been working very hard on reviewing the initial lists and the tier-one data that's been received so far.

I just want to recognize that when the original ICR was approved by OMB, they also provided terms of clearance. And that terms of clearance articulated to the agency that, hey, agency, before you move forward on issuing additional test orders, we want to make sure that you're scientifically anchoring those tier-one assays, making sure that they're performing as expected, and can provide the information that the agency intended when we validated those tier-one assays.

To address that particular recommendation, the agency has, as -- as we just talked about, provided our evaluation of the initial list of chemicals to our science advisory panel for review, we expect their final report to come to the agency no sooner than September of 2013. Also in recognition of that terms of clearance, what we issued not in the ICR itself, but in the policies and procedures in the preamble, we noted that the agency would not be issuing any additional tier-one test orders until we've fully received the recommendations for our SAP and have scientifically reviewed and anchored those tier-one assays.

So in a -- in a -- kind of a -- a very optimistic, perhaps, time-frame-wise, we would not be issuing list-two, tier-one test orders earlier than when we receive the final report. And, of course, the agency

would consider the recommendations in the final report before moving forward. And we do understand and really promote practicality and utility of data, we only ask for data if we need to, and that's informative to the agency in moving forward.

Then switching onto the tier-two ICR, again, that's at the front-end stage, that is asking for a 60-day comment period. What we've presented is a very-end estimate, we noted that within our ICR, that we assumed 50 percent of list one would be moved forward for additional tier-two testing, very high end. Well, we did that based on the information that we have and it's still projected, we also assumed a very high end of requiring all five tier-two assays.

For an ICR, we are biasing toward a high-end estimate because it requires us to do so. Without that additional information, we're asking for public comments on that information. What we're also presenting to the public through SAPs is our -- our test methods for tier-two, and that has gone through SAP, but that report won't come back to us until some time in October.

There's a lot of work that's being done in a parallel process, because both the SAP, in terms of solidifying the test methods, producing test guidelines, ensuring that they're reproducible, as well as making

sure that we have an ICR in place to issue test orders, it's a multi-step process and it takes an enormous amount of time, but it also ensures that we have the insights and comments from the public in terms of, you know, the test methods and -- as well as the cost burden that we recognize. So there's many opportunities through feedback, and there are just many, many steps to be had, and we need to make sure that we're anchoring this timeline to fit the timeline that we have for the list-one chemicals as we move forward after November, receiving the weight-of-evidence report, and proceeding forward with completing those assessments.

But as we complete those assessments, it's -- it will become even more critical for the agency to ensure that if a chemical is determined to have the potential to interact with the endocrine system and show warrant tier-two test methods, that we have the science in place. But we also have an ICR in place to issue test orders, so that we're operationally moving forward. So those are the guiding requirements, if you will or need, that we're focusing on where we're putting together that multi-step process and moving them along in a parallel fashion.

MR. BRADBURY: Okay. Mae?

MS. WU: Oh, thanks. I first had a couple of just clarifying questions from your presentation, it's

the one -- the slide where you show the universe, the EDSP chemicals, there's about 10,000 you had said, and what makes up the 10,000? So you said, like, the CIDWA, and the inerts for part of it, so is it, like, the CIDWA PCL universe, less all the inerts, and then it's all -- is that -- and then all pesticides --

MS. MANIBUSAN: So --

MS. WU: -- is that right?

MS. MANIBUSAN: So the 10,341 is a summation of unique, discrete chemicals, so there are things like wood chip, and oil, and sand dust on a CCL-3 list. We removed all of those and only kept unique chemicals with specific cast members --

MS. WU: Okay.

MS. MANIBUSAN: -- so that we can test them. But you have to be reminded that there is certainly a lot of overlap across the chemical list, so the active ingredients is 1,500. There's about 6,000 chemicals --

MS. WU: Um-hum.

MS. MANIBUSAN: -- on the CIDWA CCL-3 list, and there's about 6,000 inert ingredients, so a combination of food, non-food, and fragrances.

MS. WU: Okay. Wow.

MS. MANIBUSAN: But, again, once we cull that out and we only look at discrete chemicals, that sums up

to 10,341.

MS. WU: Okay. And then later you say on the CIDWA side you say that, “The mixtures are lower priority,” and what mixtures are you referring to?

MS. MANIBUSAN: The mixtures are a combination of discrete chemicals, it can be a mixture of two active ingredients. Not pesticides, but two -- two chemicals together. My -- my frame of reference is a disinfection byproduct where it’s a mixture of different halogenated chemicals, very difficult to test.

Per the recommendation from our SAP/SAB panel, they said, hey, make sure you cover the single chemicals first before you dive into mixtures, so that’s why we put that as a lower priority. We still have our line of sight on it, it’s just not right now, it’s -- you know, it’s after we’ve gained experience and we’ve solidified our approach for a single chemical.

MS. WU: Okay. Okay. And then my final question is just trying to figure out now -- oh, this is just where I’m getting confused. So when -- let’s just, you know, try to predict a little bit. When do we think we’re going to see stuff coming out of tier two, weight of evidence, all that stuff done, and, like, incorporate into it, are we talking, like, 10 years before we see it happen for the first time, or are we talking, like, five

years, because, I mean, as you said, this has been going on for a long time, and then I'm also wondering whether, as all this stuff gets settled and then you're going on with, you know, more or less, is it going to move a lot faster once all this stuff is settled?

MS. MANIBUSAN: Okay. So I don't do predictions really well on timeline and really follow through with that, but let me kind of lay out the scenario a little bit for you. So from our experience on tier-one test orders for the initial list, it's about five years to issue a test order, two years for data generation, the data submitted to us with some extensions, because of laboratory issues and scheduling, and another complication with solubility perhaps, and then at least a year for data review in-house, so that's five years some.

And then we have to put together the weight of evidence, decide with -- with the weight of evidence approach whether a chemical warrants tier-two. For those situations, and hopefully they're rare, where a chemical warrants tier-two, we'd have to issue test orders again and allow for at least three to four years, because these are longer-term studies. These are multi-generation studies and we expect that the lab will have the capacity to accommodate for these longer-term studies in a very timely manner, a lot of assumptions built in.

Okay. So that's what five years out already before we receive the data in a timely way, and we -- we conduct our data review of the tier-two data itself another year, so I'm still calculating about 11 years now. So post-11 years we need to build that back into the risk assessment, again looking aside other toxicity information that we have from the 158 information for pesticide actives, and build that into the risk assessment, and again determine whether that endocrine endpoint is the most sensitive endpoint, is it the lowest point of departure, for example. You know, that's what's going to dictate whether or not that risk assessment is altered, in either case it would be qualitatively characterized within the risk characterization section.

MS. WU: So --

MS. MANIBUSAN: But -- but let me --

MS. WU: -- oh.

MS. MANIBUSAN: -- complete your --

MS. WU: Oh.

MS. MANIBUSAN: -- your question, because --

MS. WU: Yes.

MS. MANIBUSAN: -- you said --

MS. WU: Okay.

MS. MANIBUSAN: -- well, over time will we gain experience to move through this process swifter. And I

only want to leave you with the message that as we move forward, technology will change. And we're hopeful that computational toxicology, high throughput information, more information that we understand about chemical categories and classes of behavior where we can predict and make more-targeted testing decisions, I think will expedite the process as we move forward.

MS. WU: Okay. So the 11 years you're saying is best case scenario really, like not seeing any delays even from anything else, when we might see the first real, like, outcome from initially?

MS. MANIBUSAN: If a chemical is deemed to have no interaction after tier-one?

MS. WU: Right.

MS. MANIBUSAN: That is the --

MS. WU: Um-hum.

MS. MANIBUSAN: -- final decision.

MS. WU: Right.

MS. MANIBUSAN: So there's --

MS. WU: Okay.

MS. MANIBUSAN: -- a couple of scenarios in there --

MS. WU: Right.

MS. MANIBUSAN: -- right. There's one negative, there's no interaction.

MS. WU: Okay.

MS. MANIBUSAN: We're done, that's a decision. There's -- yes, we see some interaction, but we think we can ask for an intermediate study that can be done very expeditiously, again, middle -- middle ground. And then the worst case scenario is, yeah, a chemical does have interaction, we think it warrants multi-generation studies, longer-term studies, and they have to move forward in -- in conducting those particular long-term complex studies.

MS. WU: And when you talk about the interim ones, would that interim study be sufficient to incorporate into risk assessment once you get a -- something out of that, or then does that -- you know, depending on the outcome, could it move into, like, having to be tier-two?

MS. MANIBUSAN: So you have to just be reminded that our focus is on endocrine disruption --

MS. WU: Right.

MS. MANIBUSAN: -- and the potential to do so, and we're looking at those specific toxicity pathways. If that interim study is able to give the agency an answer to whether that chemical really initiates that toxicity pathway, then that answers our question. Quantitatively it's not necessary to inform the risk

assessment, we're just looking to answer the question of whether that chemical has the ability to interact and, if so, at what dose.

MS. WU: Okay. Thank you.

MR. BRADBURY: Now maybe I'll -- a couple of words to close our this last set of questions. We do have -- there are some things that are in play, so the -- as Mary said, the weight of evidence analyses will start to pick up after the SAP that's coming up, and we've targeted -- during 2014 we'll start to make some decisions. So we may be starting to conclude some chemicals that don't have any potential and, as Mary said, they're done.

We may see some that do have potential, and that's where a combination of these maybe short-term focus tests or having tier-two assays available so that we can get on with it and -- and -- and sort it out. I think some of the insights that may suggest that the -- it may not be quite as challenging as it seems. It's still going to be challenging, but we know from the E work that Mary indicated, five percent of that universe has the potential to bind to the estrogens out there, 95 percent of the chemicals so far look like they don't even bind to the estrogens out there. If you can't bind to the estrogens, you can't start that pathway.

Now, who knows if that's going to play out across A and T, but that my give us a sense that we may be able to focus more. And then if some of the other technology comes online, what we're doing now, five years from now looking back, we'll, go, what, gees, how do we -- we could do it a whole different way? So -- so it's sort of hard, as Mary said, to project the -- the time lines, but what we're learning so far and what this technology could provide are things that we're hoping will shorten the time, but not lose confidence in the decision making.

MS. MANIBUSAN: Just -- maybe just to -- to close out, I just remind folks that our 2013 calendar is not yet done. We still have one SAP to embark on, and that will be very informative to influencing the timeline, so that ability to use other scientifically-relevant information to inform us of whether the chemical even needs to move forward for screening is going to expedite that time frame. So I don't want to leave you on a -- on a negative note, perhaps -- perhaps that there's a lot of work still to be done, a lot of questions that still need to be answered before we can project out.

MR. BRADBURY: Okay. Thanks, Mary. And thanks everybody, great questions. We're not going to do the

break. But I think folks have been taking a break when they need to, so that's good. So we're going to move into the work group on comparative safety statements and I'll turn it over to Marty.

MS. MONELL: Thanks, Steve. I would just the presenters and my group to come on up. While they're in transition, I just want to give everybody a little bit of background for this particular work group, we -- we are a creation. It's the comparative safety statements' work group, we are a creation of CPDC that occurred about three-and-a-half, four years ago. It was to acknowledge an interest in consumers in sort of labeling information about the relative safety or greenness of products generally, consumer products generally, so the CPDC asked for the formation of a work group to sort of look at what we might be able to do for pesticide labels.

And this is in recognition of the fact that FIFRA really is quite concerned about false and misleading statements on pesticide labels, so that it was felt that we needed to be careful in -- in our -- our allowing and review of proposed statements on pesticide labels. So essentially, after about a year of intensive discussion and -- and investigation, we came up with two -- two approaches, one was to allow the use of the DFE, design for the environment logo, on a pesticide label,

assuming that -- that the -- the ingredient -- the active ingredient could pass the screen for the DFE program, which is administered through our sister organization, OPPT, and -- and then the -- the second avenue for providing information on the label was factual statements, so that certain factual statements that were very easily verified would be allowed on the label.

And then the -- the -- the emphasis at the time was on any microbial products, so we ventured down the path of having a pilot. And you're going to hear the results thus far of a pilot, and -- and which has subsequently be extended, and then a couple of new areas that we're -- that we're delving into as this -- this proceeds.

I will say that I like to talk about our approaches being one of a three-legged stool, there's the interesting consumers in -- in all things green and information about that aspect of any product; there's the interest, obviously, of the -- the industry folks in marketing to that interest in consumers; and then there's the interest of EPA in making sure that we follow the law, that we utilize good science, and that we don't allow false and misleading statements on labels; and all of that at the same time trying to create a fair, level playing field for -- for all those interested

stakeholders.

So I'm going to turn it over now to Jackie Campbell and Michael Hardy, who will give you an update on the -- the two pilots.

MS. CAMPBELL: Hello. I'm going to update on the design for the environment for the antimicrobials. As Marty indicated, we've extended the pilot for an additional two years, until May 3rd, 2015. As of today, there are nine products that have gone through the process and we've granted the logo to all nine. One company did decide not to support the logo any longer, so there's actually eight currently using the logo.

We've also expanded the active-ingredient list. We began with three actives, which are citric acid, lactic acid, and hydrogen peroxide. After working collaboratively with DFE, we expanded the active ingredients to include isopropanol and ethanol and then we also modified the qualifying criteria. Previously we allowed only TOX-3 and TOX-4 pesticides to apply for the logo, but now we expanded it to include TOX-2 products. They need to be concentrates to where when you test the use solutions for the route of exposure that's triggering the TOX-2 category, the use-solution data will demonstrate that the product is actually in category three or four. Are there any questions regarding DFE?

Well, I'll move on to the second piece, and that's the factual statements, presently there are four. Sorry. Presently there are four factual statements that are available for anti-microbial pesticides, the first is dye or fragrance-free, we currently have 35 products that have the claim on their label; the other factual statement is the corporate commitment, it appears on the label in the form of a website, there are currently 10 products that have the website; and then the last factual statement is biodegradable, you can either state that you're 100-percent biodegradable or that your -- that your product contains a biodegradable surfactant, and we only have three products that are claiming to be -- containing a biodegradable surfactant and it coincides with design for the environment products.

So the three products that support the claim are -- also supports the DFE logo, and we have not had a product come through that can claim 100-percent biodegradable. But we've had submissions, and they just have not passed because they have not submitted the appropriate data to support the claims. And I'm going to turn it over to Michael.

MR. HARDY: I'll be very brief, in essence of time. The last time we met, this -- this group discussed the feasibility of expanding the anti-microbial DFE pilot

to perhaps the biopesticides' sector. Since that time we've gone back and had a number of meetings internally, and at this point we -- we would have liked to have been further along in this particular phase of expansion of the pilot, but we've had some internal confusion actually that -- that was geared toward communications more than anything else.

So what we've done is we -- we sat down with the biopesticide industry and we said, "Let's try to go forward and -- and follow the same process we did with the anti-microbials when we initially did their pilot a few years ago when we launched the biopesticides' pilot." A few steps were actually overlooked, and so we had to actually pause our effort in order to pull back and make sure we were following the -- the same model we did initially.

So where we are today, we are actually looking to -- to have two chemicals, two active ingredients referred to the DFE program so that they can analyze these biopesticides and see if they actually meet the criteria of the existing DFE pilot that the anti-microbials have. The one criteria that is -- is in question, that -- that we've seen over the past few months, is whether or not PPE, or personal protective equipment, should be a requirement for something that's

used or -- or criterion for the pilot if it's being used outdoors. And so we're going to pick two active ingredients that have actual outdoor use, that have the -- the respirator-requirement or the PPE requirements with the -- the gloves, and we'll see if it actually still has enough rigor in order to pass the -- the DFE toxics general-chemical screen.

If, in fact, these chemicals, regardless of the fact that they have PPE, do, in fact, pass the -- the DFE screen, then the OPP scientists will sit down internally and decide whether or not the indoor residential uses that we saw initially for the anti-microbial pilot should, in fact, apply 100 percent to -- to the outdoor products we're now saying for the -- the biopesticides, or whether or not the -- the PPE requirement can be -- can be modified for those outdoor uses.

Yesterday I committed to the subgroup that we would try to have the two active ingredients put through the paces by the end of the summer and then report back out in terms of what the -- the synopsis was, whether or not they, in fact, passed the DFE screen and whether or not the OPP scientists agree or disagree that the PPE requirements should, in fact, be retained for the biopesticides' pilot going forward.

MS. MONELL: Thank you, Michael. Before I turn

this over to Steve and the biobased claims, I just wanted to give you a brief update on the DFE program. This has been around for a long time in the -- in the toxics' program, and it's an effort to encourage, they can say, safer chemicals in end products. And they -- they've been looking at the -- at the logo -- the DFE logo, design for the environment, and their -- their feedback from consumers has been, "This does not convey protection of human health that this program also is geared towards," so there is a large effort underway right now to convey that message through a different logo. Although it will still be US EPA's program, it will still convey the -- the -- the idea of protecting the environment and human health.

And so the end of this month there's going to be an ICR published on the federal register, and -- for comment, and I encourage you all to sort of watch for that and to provide comments, because what we're asking the -- the DFE program to do is to perhaps include a pesticides' sector to its program so that we can avail ourselves of this opportunity to -- to promote less-risky chemicals for the pesticide world.

So having said that, I'll turn it over to Steve now and he'll give you a little background on the -- the biobased efforts.

MR. SMITH: Excuse me. So, yes, real quickly, the biobased for the USDA biopreferred program was established as a statute in the 2002 Farm Bill, it's a procurement program. In 2008 it was expanded to have a -- a voluntary program for certification on product labels, this was implemented in 2011, and then shortly after the agency started getting label amendments asking to have this mark put on our pesticide labels. This was taken to the work group on comparative safety statements, I think it's our sister agency. We're interested in doing this, but we wanted to do so in a way that would not result in a -- being misleading to consumers.

Where we left off the last time we presented to you, the agency is interested in moving forward with this as a pilot and we needed -- we had not come up with some language that there was agreement from the work group on -- on -- on it being brief enough that consumers would read it, and at the same time would communicate what we wanted -- we wanted to communicate in terms of indicating to consumers that the mark did not indicate safety of -- of the product.

And so with that being said, we did come up with some language proposed by USDA that -- so the -- this would come in as a -- as an amendment to the label. The certification mark would, under it, have a statement

saying, this mark is not an indication of safety, read and follow all label instructions, this is a recommendation of the agency of a statement that would be found acceptable. If registrants wished to propose an alternate disclaimer statement, they could do so and the agency would evaluate that to determine whether they felt it was acceptable.

So with that being said, we have a -- our how-to webpage for actual statements updated. We would expand the factual statements' pilot to include the addition of the USDA biobased certification mark on pesticide labels, we're -- this is our recommendation. With the blessing of the PPDC, we would proceed with putting that -- posting that to the web and starting that pilot shortly.

MS. MONELL: Again, this is an -- this is an effort to really thread a needle. This is recognition of a USDA program that is supported heavily by this administration in terms of sustainability efforts, and so there was this biopreferred procurement aspect to the government's efforts, as well as a -- a program by which products could be recognized for their biodegradability.

And -- and, of course, this effort would apply to all products, mostly consumer-oriented, and so we tried to recognize that there's interest, you know, in consumers in whether or not the product has any

sustainability piece to it, and as well as recognizing our responsibility to -- to have a disclosure that this is -- this is not -- this -- this particular mark does not indicate that -- necessarily that it's -- it's -- it's safe, and that you must read the label, because that is the -- the law, if you will, that basically says that -- that this has been through appropriate risk assessments and -- and regulatory process under FIFRA.

So this is a pilot and we're going to -- the -- the good news is that USDA has an ICR by which they're able to -- well, a quasi-ICR. They have a method, a legal method for obtaining consumer feedback as to how the -- how the consumers really understand this mark being used on a -- on a -- on a logo, so we'll see. There's more -- more to come on it, but we thought it was a -- a fair position to take and -- and pathway forward to recognize, again, the three interests at play here.

Quickly, a followup to the conversation that you heard earlier about 21st century toxicology. Kristie Sullivan, I think she had to leave, but she -- she has been a part of our work group and one of the things she was interested in pursuing was the possibility of having a non-animal-tested claim put on a pesticide label, and we thought that there was a lot of merit in that. But it was, again, a very difficult thing to -- to get your arms

around, because there are many products -- many, many, many products would come in as a me too. And so they could come in and claim, well, we didn't test this product, we didn't use any animals, you know, but, of course, the history was such that the originally-registered product did have animal testing.

So we tried to -- we're -- we're still struggling to -- to work out something that would, A, provide the consumers with information on -- on -- as to whether animals were -- were used for testing for the -- for the product, and -- and, B, you know, enable and encourage registrants, the industry to produce products that have not or -- or minimally use animal testing.

And so we've -- at -- at this point we sort of have two levels, if you will, that we're -- we're looking into. And one is the aspirational level, I think Kristie called it, which is no animal testing period, straightforward, no history of it, no -- just not done, all -- all kinds of other alternatives were -- were utilized in the -- the production of -- of the pesticide.

And then there's the pragmatic, which would be -- could be minimal animal testing use or -- and -- and we have to figure out what exactly that would mean, but -- or -- or alternative approaches to traditional animal testing, something that would, again, be factual, but

that would recognize a reduced amount of animal testing. So more to come on that, but we think that it's a nice compliment, if you will, to the efforts of -- of the 21st century tox work group.

And then lastly we have a -- a new factual statement that was proposed by a -- by industry, and this would be to allow the use of the -- the statement, safe for use on a surface, on a particular surface, and apparently at one time in the pesticide program this was allowed. And then maybe eight to 10 years ago it was disallowed, because the feeling of the program was that, A, it was misleading, that -- that the -- a consumer could misconstrue what the meant, specifically the use of the word, "Safe," that -- that terminology is very much regulated under -- under our 156.

UNIDENTIFIED MALE: 15610.

MS. MONELL: Pardon?

UNIDENTIFIED MALE: 15610.

MS. MONELL: 15610, thank you very much. And -- but, anyway, the subject-two conversation. In any event, what we have suggested to the folks that are interested in pursuing this is that because they feel, they believe in their own industry research that consumers are interested to know what that -- whether or not the -- something containing a pesticide would injure the surface

to which they intend to apply it, so they -- that's their research, that's their -- their feeling based on their consumer research.

We, on the other hand, still have some concerns about the use of the word safe on a label, so we are -- we've asked them -- or -- or not asked them, but we have suggested that perhaps they want to continue to do this survey, making sure that they -- that it's broad, and geographically inclusive, and so forth, as all good consumer research surveys are, and then let us -- share with us the -- sort of the -- the survey and -- and the -- the results, and then we will continue the conversation, so that's what we're considering. We don't even have a recommendation one way or the other right now, just the state of play is that the -- the interested industry folks are going to go do their market research and come back with more details.

So as you can see, our little work group has evolved and we're taking on various new areas to -- to become involved with and to come back here and make some recommendations to pursue, but I think it's -- I think it's important, because I think that the consumer interest in these areas really is still very much alive and well. And our role in making sure that we don't run afoul of a FIFRA is equally important, so stay tuned.

MR. BRADBURY: Any -- yeah, Matt and then Eric.

MR. KEIFER: Marty, I'm just -- when you bring up this issue about whether it's safe on a surface, and whether EPA has to get involved in the decision making, or the adjudication as to whether that can be put on the label, that makes me -- it maybe brings home the point that it seems that the EPA is responsible for anything on the outside of the container?

MS. MONELL: On the label.

MR. KEIFER: On the label?

MS. MONELL: Yes.

MR. KEIFER: Wow. I'm sorry, I didn't realize that your -- our responsibility at the EPA was that profound, that's remarkable.

MR. BRADBURY: You wouldn't believe the hours spent each day.

MR. KEIFER: Is ariel font acceptable?

MR. BRADBURY: What?

MS. MONELL: That's a whole other can of worms.

MR. BRADBURY: Oh. Eric, right, and then Susan -- no. Yeah, I said Brian. I can't -- sorry.

MR. GJEVRE: With the two different labeling issues that you described, what safeguards are in place there, what controls are in place to prevent 25(b) products from just arbitrarily using those on the label?

MS. MONELL: Industry pretty well self-police. Honestly, we have -- most of the sort of regulatory fixes that we require and enforcement actions that are taken are as a result of tips from competitors.

MR. GJEVRE: So -- so if a 25(b) product was to use the -- the -- the environmental statement, for example, or the environmental logo on a label, if they just put it on their label and sold it over the internet, the EPA would be able to take action to --

MS. MONELL: That would --

MR. GJEVRE: -- make that --

MS. MONELL: -- yes, that would be misbranding.

MR. GJEVRE: Okay.

MR. BRADBURY: Susan and then Beth.

MS. FERENC: I -- I just had a quick comment. I want to thank Michael and -- and Marty for -- for moving the biopesticide pilot forward. There were some pitches and starts as it -- as it was getting going, and -- and I think this is really good bring it back to where we had started with the anti-microbials. But -- but I think that I really want to encourage a lot of interaction with the DFE folks on this, because, Michael, hearing you say, well, to see whether or not biopesticides fit the anti-microbial criteria, you know, maybe the broader question is, what criteria should they be meeting, as opposed to,

do they fit ones that have already been created for a completely different class of compounds.

And this gets back to the idea that we talked about, do we need to have a separate classification for pesticide, or ag chem, or something under DFE, like their industrial institutional, recognizing that this is a different set of compounds, and under a different set of authorities as well, and safety measures already in place, and that type of thing.

So we -- I think as a -- as a working group, we just encourage that continual interaction with DFE on how to really, more broadly move forward with the idea of -- of pesticides being in the DFE program and everybody being comfortable with that.

MR. BRADBURY: Beth, and then Janet, and then that's it.

MS. LAW: Well, actually, Sue stole my -- my opening comment, because I also was going to commend Marty, and -- and Michael, and Steve for the work that they've done on several initiatives in that, the comparative safety-study work group. It -- and -- and I would just say that the discussion is always good in that group, it's -- it's -- it's robust and I think everyone has an opportunity to voice their opinion. Not -- we don't always get what we'd -- what we'd like or the

answer we'd like, but at least we know we -- we are heard and, you know, the USDA, we appreciate that.

And I do think that the developments that are under discussion now will be very welcome by industry, so, as always, we'll look forward to continuing the discussion. And I think that's it, thanks.

MS. HURLEY: Thank you for -- for classifying everything for me, but I do have a couple of comments. One, I don't ever want to see safe on a label, I'm a person who has to deal with the public and do training, I think that's misleading. I would rather you say that it harms these specific surfaces, rather than it's safe for.

And I'm still a little iffy about the industry self-policeing on the 25(b), there's just too much out there. It's -- it's very controversial and it's very hard, especially in the world that I live in with school IPM, because on the 25(b) stuff a salesperson can go up to somebody and say, oh, it's safe to use, oh, you don't need to be licensed, oh, you can do this. There's -- there's several different things on that, so please be a mind that there are people out there who do not read the label and that, you know, any complements of safe sometimes gets in the wrong world.

And I'm really worried about what goes on, especially on 25(b), when we're talking about kids,

because, again, there's -- there's allergen triggers that we're just now starting to hear about, so I just wanted you guys to know that I'm speaking from -- from experience.

MS. HURLEY: I hesitate to say this, because it's a bit of cold water -- dumping cold water, and that is that having worked on sustainability issues for a while, the public's understanding of any labeling, green labeling in a broad sense is nil to minus nil. And so there's not really a scientific issue or a legal issue, maybe a scientific education issue.

But I was at the international food technologists conference two, three years ago where you have all these market people doing investigations, and they had a panel -- I mean, that was in Chicago then and they had a panel of people from the public that they had there, and the -- the -- you know, whether it was an organic label, a rain-forest label, a -- I forget the proper term for, you know, fair-trade label, they had no clue. I mean, no clue what the difference of any of them were.

So I have to admit I've gotten -- unless you can do a lot of marketing, a lot of marketing, I'm not sure really how much these labels are going to make a difference. And again, it's not to say we shouldn't be

doing it, but I just want people to understand that I am not seeing that really being a driver in the marketplace until we can get some level of education out there.

MR. BRADBURY: Okay. Thanks, I appreciate everyone hanging in there during the course of the morning, through our break. But there's lot of questions and a lot of dialogue going on, so it's greatly appreciated. I'm going to shave your lunch a little bit, we're still going to start at 1:15. So we went a little past noon, but it should be enough time to get something to eat, and we'll see you back at 1:15. Thanks.

(Whereupon, an afternoon recess was taken.)

DAY TWO - JULY 11, 2013

(AFTERNOON SESSION -- 1:15 P.M.)

MR. BRADBURY: All right. Good afternoon, we'll start the afternoon session. And we're kicking off our first session on pollinator protection and we'll go to about 2:30. And I know that the work group is big, at our opening comments the other day we talked about how the pollinator protection work group's bigger than the PPDC, which is good, it's kind of fun to manage.

And we've got breakout groups that are tackling different components, and these components intertwine, they -- they feed off each other, which is good, but I want to start it off by -- by thanking everybody on the work group. To have this many people working this hard is really helpful to not only EPA, but USDA as well. As -- as we go through this presentation, I'll -- you'll see how this is really critical for a lot of work going on.

Also in talking to Rick, and Lois, and Sheryl know that there are some specific recommendations that are going to be coming out of the work of the pollinator protection work group, so for the full committee, as we go through their presentations and -- and -- and hear about those recommendations, I'll then be systematically going through those recommendations and getting some feedback from the full committee.

So, again as we talked about it yesterday, for folks joining us, the work groups come up with ideas, they present it to the full committee, spend some time in a full committee hearing pros and cons, we may or may not reach consensus. But once I figure I -- we have, or if we haven't, but I feel like I've gotten a good indication of the pros and cons for different approaches, then we'll move on to the next one so that we stay timely, get the information, so the agency can then move forward with -- with those recommendations and make some decisions.

So with that, it's sort of a little context to how we'll manage the next hour or so, I'll turn it over to Rick Keigwin to lead off the session.

MR. KEIGWIN: Thanks, Steve. Yeah, just to highlight what Steve was saying about the size of the work group, I think we're upwards of 70 or 75 people. So at that point, if even more of you want to join, that's great. Oh, why not, double -- double the size of the PPDC. But we've had -- we've met multiple times over the -- since the last PPDC meeting, lots of conference calls, and I just wanted to express my appreciation for everyone's efforts and contribution. It's -- some of these conference calls go on for two or three hours at a time and they're always quite lively, but I feel like we make progress every time.

Just to give you all a little bit of structure for how we're going to manage the next hour, we're going to kick off by having Sheryl Kunickis give us an update and overview of USDA's role in pollinator protection as the -- the lead agency for managing the federal response on pollinator health issues. We think that's really important, because then it puts the work that this group's been doing in a -- in a perspective.

And then from that what we'll do is work through the recommendations from three of the subgroups that were established at the last PPDC meeting. And for those of you that have the slides, you'll see that we've repeated the charge from the last PPDC meeting and then what our response and recommendations are since then. I think for purposes of sort of managing the clock a little bit, what we'll do is we'll go through all three subgroups' recommendations, and then we'll circle back, once that's all done, to -- to take questions and -- and to get advice on next steps. So with that, let me ask Sheryl to kick us off.

MS. KUNICKIS: Thank you very much. I'm really pleased to be here today and talk about the importance of honey-bee health to -- to USDA, it's critically important. As you know, honey bees are part of our agricultural system, we can't have agriculture without

honey bees. It is a very complicated, very complex problem, and it takes everyone to help solve that.

As many of you know, back in October we sponsored a conference, it was funded by NIFA, the National Institute of Food and Agriculture, and we convened stakeholder groups from all different parts of the -- of interest groups to participate, to look at the state of the science on honey-bee health, as well as look at -- hear from different stakeholders, what their concerns are or what their observations were.

That conference was held in October, and I know we've talked about that before, and what we learned is there was a number of stressors that USDA needs to be paying attention to, such as nutrition, and that relates to the habitat that is declining across the country as we go into some of the monocultures, pathogens and arthropods -- arthropods, pesticides, genetics, and the management of bees, so there's a lot of different components involved in dealing with honey-bee health.

So we put together, as a followup to that conference, a report that -- it was a -- the point of the report was to capture all that we heard, the state of the science and the observations by -- observations by the -- the participants. On May 2nd we issued that report, there was a press event with the national media and with

the -- with the stakeholder groups. And we were so pleased that Deputy Secretary Merrigan and Acting Administrator Bob Perchuceppi (phonetic) were the ones who wanted to do that, they were the ones that suggested that. Unfortunately, the deputy secretary had a family emergency, and Dr. Sonny Ramaswamy stepped in to participate on behalf of USDA, so that went out.

And I will tell you that a lot of folks would think that that's where it ends, so we've done our thing, it was fun, and it's over. Well, it's not, USDA is committed to continuing to address the issue of honey-bee health. And all the different components that I talked about are things that USDA is working right now, some of -- well, with partners, some with EPA as partners, other agencies, and we're moving forward.

What we've done is we formed internally a USDA EPA work group, and we've identified all the efforts that have happened historically, what we're doing currently, and what we still need to do. We're committed, as we -- we committed to the deputy secretary and to Mr. Perchuceppi, that we would do a number of things, and -- and what I'm going to talk about are just the actions of USDA.

In the REE, which deals with research, education, and economics, there's a great interest in --

in that missionary of USDA, because they have a number of responsibilities. And what Dr. Ambar Testa (phonetic,) our deputy undersecretary, would say, ultimately all of this is a recovery plan for honey bees, and -- and so here are some of the things that have -- have just -- that are being implemented or things that are ongoing.

At the Agricultural Research Service, of course we have the -- they are the internal research arm of USDA, they are actively working on research this week, the -- one of the bee labs down in Tucson held a -- a meeting of the stakeholders to look at the research that they're doing and where they maybe need to refocus some of their efforts based on what we've learned over the last several months and what we know today.

Dr. Knipling, who is the administrator of ARS, informed us about three weeks ago that he was -- had provided one-point-three million in additional funds for research, and the ARS researchers and EPA staff have met to make sure that those research dollars are being used to address really some of the important parts that we need to have addressed, we don't want to be spending valuable research -- research resources on things that won't add value to what we need to know.

The ERS, our Economic Research Service, on Friday, Dr. Mary Bowman, who's the administrator of ERS,

sent me a message and let me know that her staff is doing an economics' report, it's just been started. As a matter of fact, her staff is on this call right now, so they're busy working to develop the focus of the report and how that will go forward. We've made contact with a number of folks to make sure they have the visit with them and get a full, full picture of what is going on.

At NIFA, Dr. Sonny Ramaswamy, as you all know, is a -- or may know, is an entomologist, and he's the director of NIFA, and he's in -- he totally gets the importance and value on honey-bee health, and so over the last -- the last few weeks what he's done is -- we're -- we're -- at USDA we're very interested in -- in education and extension, and so we -- under his signature he sent out to all the land-grant universities a message asking for their assistance to extend, beyond the agricultural, information about the value of -- or the importance of reading the pesticide label, and that it's not just about agricultural, but it's for homeowners, and urban uses, and so forth, so we're working with our land-grant universities to -- to do education and outreach.

We're working right now to develop an evidence-based approach to address some of the important questions related to honey-bee health. I can't talk a lot about that, because it's in process and it's still being

developed. You have to identify the important questions that you need answered, this approach is used a lot in the health -- in some of the health issues that they're dealing with at USDA to address some of the -- the nutrition or habitat issues in NRCS, the National Resources Conservation Service, as well as the Farm Services Agency to their programs -- conservation programs.

They have the habitat and they can help develop and improve habitats, so one of the items that came out of the conference and that we hear a lot is that the lands that are in CRP, conservation reserve program, are not eligible to have honey bees or managed bees placed on them. That's absolutely not true, but it's a -- just a communications' challenge within the agency, so the agencies are working to clarify the use of the bees -- bees being placed on CRP land. It's certainly okay, as long as it meets a certain criteria.

And then NRCS also has its plant material centers, those are all over the different parts of the country to help us identify the best plant materials or available materials for -- or planting for bees, to improve nutrition. And then during our meeting with the deputy secretary and Mr. Perchuceppi, Dr. Merrigan committed that USDA off-field employees would go through

training with USDA on honey-bee health, and so to bring awareness to all field folks so that they could help and, as they're out in the field, identify opportunities for improving -- opportunities for improving honey-bee health.

And then I have reached out to my federal partners in other agencies, because certainly it's not just USDA, and you realize a lot of the lands, within USDA's purview at least, at NRCS and FSA are private lands, there are public lands. And so I reached out to my federal partners to see if you could place managed bees on their public lands, and I received three e-mails back and each has -- they have different authority. And my colleagues at BLM responded, "Absolutely, and it's already in place, it can be done, and there's things you have to do, but it's a -- it's certainly a possibility."

My colleagues at the DOD responded also, it can be done. But, of course, you can imagine those have a little more restrictions in place, because those are defense lands or -- so, but it is a possibility. Others cannot, because managed bees are considered not domestic, so -- and so they can't have that.

Finally at USDA there's the CCD action. We've got the CCD action plan that USDA and EPA jointly have responsibility for, but USDA has the lead, so work on

updating the CCD action plan began shortly after the end of the conference, they're on a fast track, they've been meeting regularly. They meet next Monday, and I believe the goal is to have a draft by September. So those are just some of the things that are going on, there's oodles more. But there are works in plan and there will be more, you'll hear more about that later.

I just want to say the -- the -- the work group that is here and that we'll hear from today is extremely important. A lot of the work and recommendations that are coming out of that will help to be a big part of this -- ultimately, hopefully in this recovery of our honey-bee health, so thank you.

MR. KEIGWIN: Okay. Thanks, Sheryl. So now we're going to start working through each of the three subgroups. I will start with labeling, that group is chaired by Dave Epstein from USDA and Marylou Verder-Carlos from California Department of Pesticide Regulations. Dave is here today, Brian is sitting in for Marylou, I think you mentioned that yesterday afternoon, so they're going to kick things off.

And then I will say, this has -- of the three groups, as you might imagine, this has been one of the more challenging set of issues that the work group has been working on, and so we thought it would be helpful

not only to present what's on the slides that you have here, but to also hear some of the diverse opinions that led to what's ultimately on the slides. And so for that part, I -- I believe Brian, and Steve Coy, and Cindy Baker-Smith from AMVAC are going to contribute at that point, but let me turn things over to Dave and Brian.

MR. EPSTEIN: Thank you, Rick. Just before I make any -- talk about the labeling group, I just wanted to add one thing of what Sheryl just said, and that's particularly in relation to the one-point-three million dollars that ARS just made available for research. And a lot of that, the focus is, you know, traditionally research, you know, plans that go, like, five years out. Right now we're trying to put money in places where we're going to get quick answers to crisis-type problems, and a lot of this money is going to be used to look at pesticide effects on bee health, so that's -- that's that one-point-three million that Sheryl mentioned.

The labeling subgroup of the pollinator work group, we met four times since the last PPDC by phone, we do it by teleconference. And as Rick and Steve mentioned, I think we have about 180 people on the phone. And you can tell, because I made the bold statement the last time we were here to Steve, because our challenge was to define and clarify terms that could go on the

label, and I said, “Piece of cake,” and boy was I wrong. It’s -- it’s very contentious, we’re still arguing about many of the same things that we’ve been arguing about since 2000, use of foraging versus visiting.

I got waylaid and I just got here at noon today, because I was in the airport all night in Dallas. And Brian had stepped in and prepared all the voluminous notes, and so I didn’t want to disappoint him, so Brian is going to give the report on the labeling.

MR. ROWE: Thank you, Dave. And -- and I -- I’ll add to that comment that I had to step away from this group over the last three or four conference calls, because I’ve been involved with EPA region five’s development of the bee investigation or bee inspection guidance document, so that pretty much consumed my life from November to May. But I’m -- I’m with you, I’m like I went into the way-way-back machine and -- and we’re back in 2000, 1999, and -- and a lot of those discussions.

Okay. So the charge to the -- and -- and so what I’ve done to help Dave out is I -- I figured -- I didn’t even know if he was going to be able to make it here, was to -- to put together the notes from the four work group meetings, so, please, any of the other committee members that have any additional comments or if

I get something wrong, I take no offense to being corrected on the spot. I want to make sure you're providing current, accurate information, but, you know, the original charge to the group was to address problematic pollinator protection label terms and that really exist -- is on existing labels.

So these labels are, some of them, 40-years old. They're built on a acute-toxicity data, so you've got high, medium, and low risk built into that. The -- it's -- it's no less contentious as it was 13 years ago, and I think it is initially charged. The discussion was, can we come up with one to three terms to be developed that can be used as label enforcement language, and that was really the same goal back in 2000. And I think through the discussions that I've taken part in and -- and the notes I've read, I think there may be some alternative ways to go about it, rather than just defining one specific term, but we'll come back to that.

The one consistent message that the group came forward with is you've got, like, two different things on a label, it says, "Foraging, actively foraging," and then there are labels out there that say when bees are visiting the site, which is -- I don't know if that's just a fly-by, or a resting spot, or what, but the -- you know, as a state regulatory agency I can tell you that if

I have to hinge an enforcement action on whether bees are foraging, or actively foraging, or even visiting the site at the time of application, I'm out of the game, because I'm not there when the application's made, so I can't collect that piece of evidence or proof.

But bottom line is let's get rid of visiting, let's get rid of actively, and let's focus on foraging, because that is essentially the -- described as the word best what bees are doing, they're actively collecting nectar, they're actively collecting pollen from that area, they're actively foraging at the site. And -- and for -- as an -- as an aside for food source, it was in the treatment area.

All right. So foraging -- foraging versus actively foraging has -- its origins date back to when -- when we're trying to build in data that's emerging out, it's called, residual toxicity 25, or RT-25. It's like an LD-50, but it's a residual, on-plant material that will basically kill 25 percent of the -- of the test population, it's -- it's -- again, the definition is that it's -- there's a toxic effect on 25 percent of the test population of bees.

The -- the EPA white paper on pesticide risk assessment on bees defined the extended residual toxicity as an RT-25 of greater than eight hours, so essentially

at that point there's -- there's a more-significant threshold that -- with the residual and -- and -- and at the same time the message is really unclear. I mean, when you're using actively versus -- foraging versus actively foraging, an applicator doesn't know that there's a difference. What -- what was intended to be implied by the difference, actively foraging essentially means there's less residual toxicity as foraging, which is an extended or a greater risk based on extended residual toxicity.

Using actively indicates there's no extended residual toxicity, but, again, that's not a term that's been built into pesticide-applicator training or communications, it's -- it's -- it's used when data indicates that the product does not have an ERT to bees. So, again, actively foraging is essentially a -- a less-toxic situation and the term foraging is used when data indicates that the product has an extended residual toxicity, so that's clear as mud.

It was -- actually, the light bulb finally went on for me yesterday during our -- during our work group meeting. The work group did not reach consensus on which term to use if there is no residual toxicity. Basically, if there's no residual toxicity, should there be a term used? Again, we go back to if there is a term that's

going to be used, foraging should be the term that we're working with. But to reiterate, states can't use that as the regulatory threshold.

So what we were discussing a little bit yesterday was alternate use of terms, and it's been discussed in the work group, I think, repeatedly over the last four conference calls, discussing more enforceable terminology. And what is that? It's not going to be just one word, bloom, it's not going to be just one word, time of day. It's -- it's going to be really product specific, and it's going to be based on the residual toxicity and the acute toxicity. As it goes through risk assessment, it -- it's going to need to consider all of the different tools that EPA has available and in regulating and mitigating risk on pesticide labels.

So RT-25 data is based on an existing EPA guideline, basically it typically requires -- it's required when acute toxicity of the active ingredient is less than 11 micrograms per -- per bee, so you're looking at what's that residual toxicity out there at those -- the lower levels. It is not available for all products, correct me if I'm wrong, but in the notes it said that there were 54 products out and then you've got to consider other -- other factors related to that.

It's formulating specific, if you've got four

formulations for the same active ingredient you might have four RT-25s. But you might have a few others too, because maybe it's an arid zone RT-25, or a non-arid zone RT-25, so there's some geography involved in those developments as well. So registrants may choose to do more than one RT-25 development, if they wanted to, to support different uses in different -- in different areas.

RT-25 is not in and of itself enforceable. Just because it's an RT-25 of two hours or an RT-25 of eight hours makes no different from a regulatory standpoint, it's -- it's a risk assessment tool, and then from that you may be able to develop some additional language around the labeling if there's a need to do something enforcement based.

The discussion was pretty much how do we get things out there to applicators? From a -- I'll put my regulator hat on, I'm not extremely excited about a label referring people to a website, I think that's -- applicators are less prone to adopting those practices. But if we're talking about how do we deal with lots of labels that are already out in the marketplace and you can't conceivably call in all those labels and make all those changes, I think you combine an RT-25 on a website for active ingredients, you marry that up with an

educational platform, it exists, it's out there.

Pesticide safety education providers have been teaching applicators for years to give them a good, clear message, what is an RT-25. It's more than just a number, it's something that applicators should be able to use and learn to use as another tool, just like wind direction and wind speed, right? An RT-25 of -- of eight hours is a product that's got a little more toxicity to bees than an RT-25 of two hours. And if they're interchangeable in my -- in my game plan and my production systems, maybe I choose the RT-25 with two hours and I -- and I essentially, hopefully reduce the risk to bees out there in the environment.

So this is where the discussion threads in the work group went back to the best-management practices' work group, the communications' work group. I know there's been a lot of work out there on where to house information on best-management practices, USDA is, I think, supporting in -- in that effort. But bottom line, if you can package it up and wrap it up in a simple to deliberate way and you can make it clear, I think it means a lot more to an applicator than foraging versus actively foraging, I think it really carries the message, sure.

MR. BRADBURY: So we had a lot of very lively

discussion around the fact that what we're doing here is trying to provide the grower with information and particularly the -- the bee keepers on the call, we had -- Steve Coy was very active. There's a -- there's a -- a distinct feeling that we have to raise the issue with growers that they're as aware of whether or not the bees are in the orchard or the -- the crop system. You can tell I used to be a tree/fruit guy. That they're in the cropping system as -- as much as they're aware of what the pest levels are.

You know, we -- we tell growers that they need to treat when, you know, they're at a certain threshold. Up until now we had -- we do not have those biological scouts, the consultants going out and actively scouting for the -- the presence for foraging bees, and what we're saying is all this information is going to feed back into the educational program working with growers to raise these issues and -- and make them more usable.

MR. ROWE: And -- and I guess I'll -- I'll come back to the thought that, you know, if there is a need for an enforceable label language, if there's a need in that risk assessment that says this product is -- has a residual toxicity or an acute toxicity to bees, then the labeling that used to rely on actively or not being actively needs to have some other constructive language

built into that, that says -- or enforceable, I mean, is the word I wanted to use. Enforceable language built into that, that does give us a leg to stand on in the field when we can -- so we can say a bee kill resulted in a misapplication of pesticide, Mr. Grower, you are responsible.

And not only that, but it gives the grower good, clear information as they read that label and they're training on those labels to understand what it is that they're supposed to do to protect the pollinators, so we're not trying to bury the thought that there's a toxicity issue and there shouldn't be labeling. Best-manager practices and -- and all the other things we talk about are voluntary, but if there's a need for a regulatory foothold then we need to establish that.

Yeah. Okay. And then there was just an example share in the slides as far as honey-bee -- honey-bee active ingredients and how best -- how the RT-25s might be displayed, and then the last slide here was -- I think we've kind of talked about most of this. Going forward, the risk assessment needs to build in an enforcement tool, best-management tool, and a risk-communication tool, the -- and -- and it's not going to be as prescriptive as one term.

The work group acknowledges not all labels can

be fixed at once, this is going to be a process over time. Visiting equals foraging, so foraging is the -- is the term for use and the best-management practices, including the availability of an RT-25 database, should be part of an effort to clarify the existing labels, reducing risks to pollinators.

The other part of it is, when it comes to the point of actually putting together language to include the regulatory component, ABCO supply rig and others, should be involved from an effort of drafting guidance on terms for existing labels as well as possibly terms to be used for enforcement label language later on.

MR. KEIGWIN: All right. To ensure that we have enough time for discussion, I think we're going to move on to the BMP and the enforcement piece. But then I think Steve, I know, had wanted to chime in, as did Cindy, and so we'll make sure that we get those comments in on the -- on the labeling piece. So on the BMP piece, Bret (phonetic,) AD, as well as Rick Bireley from California Department of Pesticide Regulations have been chairing this group. And so I think Bret was going to read us through this next slide.

MR. BRETON: BMPs, unfortunately they're all voluntary. But I guess that's the good thing too, because they can be implemented fast. You know, we were

charged with trying to find the best site available to -- where BMPs could be found, and the RT-25 data, and then also point of contact for BMPs. The test site stewardship organization website is what we chose, it's been populated really well, we encourage everybody to look at it.

And I would go back to what was just presented, it -- the whole idea is good. But it's incomplete, because growers don't have time to look at the website when they've got problems, they've just got to solve the problem. And so the -- the information is there and I think one of the things -- our -- our last point on this slide is probably the most key point here, you know, the -- and I don't know if it's written correctly, but we need interagency cooperation and extension, a huge need for extension. Extension for the last 20-plus years has always dealt with the problem and not the benefit of insects, and there used to be a huge educational model here to bring home the beneficial insects.

I mean, we've always just dealt with the problem insects and I think that is our key point we have. We have good websites, they've been collecting, and I highly encourage everybody to look at it, to use it. But we need extension to get it from the universities and to the farmers so it's first nature, it's not something they

thought about in the winter, and when there was a problem they didn't time to remember it. We -- we need guys in the field bringing it to the farmers, that's -- that's the most take-home thing I can tell you right now.

MR. KEIGWIN: Thanks, Bret. And then our last area that we've been focusing on was enforcement issues, and this group has been chaired by Gabriele Ludwig, with the Almond Board of California, as well as Darren Cox. I think Gabriele was going to help us with this one.

MS. LUDWIG: I'm going to preface this as -- as some background information of why -- where I see some of the enforcement issues playing a role, and that is one of the fundamental disconnects -- disconnects between bee keepers' experiences and EPA's world is that there's a lack of data saying where there's some acute -- possibly acute bee kill is actually due to pesticides or not. So where I see this enforcement issue coming in is how can we develop data to say, is this really -- when is there really a problem or not? And if there is a problem, what was the cause?

And -- and so just by way of background, that that's one of the big disconnects between, you know, the experiences of bee keepers and the experiences of EPA, because when EPA goes to look for data. There really is very limited data for them to do any work with, so that

-- just put that as part of the background.

The work group did not meet in this between the last two PPDC meetings, partly because for bee keepers it has been a rough spring. But in the meanwhile, EPA region nine did come out with a draft guidance on two state lead agencies that do enforcement about what steps they should be taking, and that's -- definitely a lot of work went into that. And -- and from my first read-through of it, I think it covers definitely all the basic needs.

Now, you have to remember that a lot of those people hear, bees, and they go, oh, my God, I need to go near a bee? So there's a whole also education issue that's necessary to happen for -- for -- for the inspectors to figure out how to handle bees or -- or deal with those situations.

Next step for us are to review that more carefully and provide feedback, because it's essentially in testing now being put out in the field to say, okay, what's working and it -- what needs more refinement or clarification, get that feedback back via EPA to -- to EPA region nine, that's --

UNIDENTIFIED MALE: Five.

MS. LUDWIG: -- five. I'm sorry, my world. And -- and -- and so that next year they can come out with

the refined version of that guidance. I think the other thing that we would like to see happening is the other question that happens next is, okay, there's the guidance, but you still have the issue as to what extent will state lead agencies pick up the ball and actually do followups when there's possible bee kill incidents. And there again, for us to hear what efforts EPA is doing, I know that in regs there's been some things, there's -- I forget the name of the proper money -- for money that goes to states, but anything that you can help us keep informed about how you're encouraging states to be engaged on this is helpful.

And then I think we may need to have some further discussion about what other resources there may be available to help with the education. So someone mentioned to me Web NR was someone from Washington State is a possibly, so I think those are some things we also need to explore some more about. Now that we have the guidance, how do we make sure it's getting used by states. Anybody else, any comments on this?

MR. KEIGWIN: So in a few short slides, that sort of summarizes where we've been for the past six months. And I think, Steve, we turn it back and see what questions.

MR. BRADBURY: All right. So what I'd like to

do is go through the three areas, the labeling, the BMPs, and the enforcement. And labeling, there's some specific recommendations that -- that came out, so we want to have a discussion among the -- the full committee, and with the BMP, and -- and recommendations of the next steps on enforcement, so let's start with the labeling group first.

And the first thing we'll do is to have Steve and -- and Cindy speak, and then I'll open it up to others. And what -- what I want to -- if you have a clarifying question, that's -- that's fine. But to the extent you have a -- a thought, say, on the labeling one, foraging, actively foraging, what -- what the recommendations were from -- from the group, I'd like to get a sense of what you all -- what you're thinking.

Now, if you hear a colleague on the panel say the exact same thing you would say, you don't have to say it again. I'm not -- I'm not weighting things, I'm listening to insight and that -- it doesn't -- I'm not, like, going, oh, five said that and two said that, it's -- because I want to sort of balance all the different things we need to talk about with getting input. I haven't said that you can do whatever you want, but eventually I will have to watch the clock and do stuff, so at your discretion. So with that, let's start with

Steve and Cindy though, because I know you have some additional insights on labeling, or Cindy and Steve, however you guys want to do it.

MS. BAKER-SMITH: I tried to be nice and let you go, huh, and you're going to push me first, that's fine. So, Steve, just to your point, the -- the registrants that are represented on the work group got together and talked about these things so that we could come with the unified recommendations, so we would support the words, foraging.

The -- the -- we also understand through the context of the conversation in the work group meeting the other morning that actively foraging and foraging creates, we think, some unnecessary confusion if it is code for what is an RT-25. I mean, the -- the whole objectives that we understand it is to have a -- a description of when the bee is in the area and you're going to spray, so we think foraging is an appropriate word to put on the labels.

With respect to the RT-25 value, we recognize that's a -- a lower-tier hazard value. In -- in and of itself may not have significant meaning to put on a label, so three of us, myself with AMVAC, Dow Agrosciences, and Bayer Cropscience volunteered a couple of RAIs to share with the work group what those RT-25

values were, so we could get a sense for all the nuances that -- that they may or may not be of value to you so we could support a pilot where you would put those on a website with some context.

So, for example, from the time that that RT-25 value was generated through data, the label may have changed substantially. So the use rate may be less, so some context is important for how you put in there. The application method may be different, maybe that RT-25 value was generated 15 ago and now the product is only soil applied, for example, so I think the context of -- of that information is really important and it is, frankly, why we don't believe it serves a great purpose on the label, we think it's probably more useful to -- to put it on a website.

And I would say to the -- to the comments about contention and -- and arguments, David, maybe I've been doing this too long, I didn't think it was that bad. I mean, I thought we actually worked through some -- some very difficult things and came to some -- some area of -- or areas of agreement that's good. And I think one that is consistent throughout all of the different stakeholders there was that we want clear, understandable language, we want language that's protective, and we want -- and we want language that's enforceable.

And, frankly, that's where we really start to stumble is what's enforceable, what's clear enough to be enforceable. Because we hear loud and clear that if you say bees are foraging, what people really want to know is how long after you spray can the bees be back in the area, and that is dependent on a risk assessment that is product specific. And so we don't see a way around having to, you know, have EPA continue to do what they've been doing, which is use the data that they have, do a risk assessment, and then determine. You know, don't apply for eight hours, two hours, 48 hours, whatever it is based on the risk assessment for the product.

MR. BRADBURY: And Steve?

MR. COY: Wow, glad -- I'm glad I let you go first. So I'm going to be somewhat the harbinger of doom and gloom, and -- and I am pretty assertive in these calls, but the subgroup was not able to complete the charge. We were able to agree on -- on what the problem is, like, as you described. You know, the best thing we could come up with was that foraging was what -- what needed to be used, and that's what the EPA was already working towards. Many of the current labels, the way they're written, it's -- are pretty good, except they're just not quite enforceable, and -- and that's -- that's really the meat and potatoes of it.

Early on we asked for lists of these terms, like actively, some of the other terms that are used in the label, so that we could get a sense of why they were being used, and I guess that list doesn't exist and -- and -- and it's -- it's too difficult to -- to create it. So my hopes -- my hopes was that we could use the RT-25 data, and -- and this is mostly based on my ignorance of what RT-25 is. But my hopes was that we could use the RT-25 as a -- as a way to, I guess for lack of a better word, restrict timing of applications or at least set the timing of -- when timing of application would be allowed, and it -- it may not -- it may not work out the best what to do.

But the single biggest issue is that the labels are not enforceable in the areas of pollinator protection and we need to work towards a way to make them enforceable, and if RT-25's not that way then we need to find out -- figure out how we can do that. And -- and in that discussion of -- of 25s, it was brought out that Oregon State, I believe, has had that data published or available for 10 or -- 10 or more years. And it -- it was -- my question is, who could evaluate how effective that was? Because I think putting that information on a website, having it on the label that you look at a website for that information, it's not going to be very

effective at protecting pollinators, which is the whole purpose of this discussion. So if -- if someone could -- could evaluate how effective Oregon's site is at making that data useful, I think that would be our process alone.

MR. BRADBURY: I open it up to other members of the committee, questions, or suggestions, or feedback on -- Mae?

MS. WU: It would be helpful for me to understand a little bit more about what the larger regulatory context is here, it's sort of -- we heard about USDA and some of the things that are going on there in terms of pollinator protection, great, tweaking labels to make them more enforceable, lots of arguments, perfect, what's -- what's EPA doing in a larger sense? I would love to hear more about sort of regulatory actions, other things that are happening, because this is a pretty big crisis and I don't -- I haven't heard a response on that level yet, I think I just might need more context.

MR. BRADBURY: Right, and I want to be respectful to your request, but I also have to deal with a history of how we're going. If we got a little bit of time, we can go through everything in our web page, it's fairly current and it lays out everything we're doing from advancing the science, to enforcement, to some of

the things we're talking about here in terms of BMPs, the labeling, the -- it goes back to about 2009, you can see the whole trajectory of things that are going on, and informed that this work group in 2011, as I recall, to start to help us figure out how to move forward on labeling, how to move forward on education and training, how to move forward on BMPs, how to move forward on enforcement, and so what you're hearing in this meeting is the report out from some of the tasks that either 75 or 180 people are -- are working on.

And so we'll figure out a way to maybe, maybe not right now, go through the last four or five years of efforts in space, and undertakings, and our sense of urgency of moving forward, and one area we want to move forward would be if the risk assessment and the labeling language was intended to protect bees.

But if you read the label, you can't understand what the label means, then all the work on the risk assessment, and all the work on the risk mitigation, and the intent isn't going to be fulfilled, because people of good wills don't understand how to do the right thing. And so this group is trying to give us some advice not to solve the entire problem of the tens of thousands of labels that are out there, but if we could start ticking off some low-hanging fruit, what would be some initial

steps we could do to try to -- to get there. Sorry. I lost track of order. Mae?

MS. WU: I think it would be useful -- I forgot who was talking about enforcement. I think Brian is understanding, like, why a term like presence isn't enforceable, because -- and -- and what makes a -- you know, and what it would require to make a term more enforceable, just like an act of congress to define the term or what is it that you -=-

MR. ROWE: Okay. In 10 seconds or less, when we get a pesticide complaint, we go out and investigate, we collect evidence, we take statements, and we make a determination as to whether there's been compliance with state law and primarily the use on the pesticide label.

So a pesticide label, it says, apply two ounces per thousand square feet, and I've got a record, and I know how much is applied over a square foot area, it's linear, I can measure it, I can calculate it out. You put it on at three ounces per thousand square feet, that's a violation.

All right. Now you say the -- the -- the product says, do not apply when bees are actively foraging in the area, the only way I can collect that piece of evidence is to be there when the application is made to see if bees are actively foraging. If we get the

complaint 10 seconds after the application, I can't -- I have missed that window for that evidence.

So it's -- it's -- it's not that I don't suspect the bees might have been killed by the pesticide application, I can collect a sample, the pesticide's there, but it -- you know, dead bees, they come back positive for the product that the farmer next door sprayed, but the piece of evidence that makes it a label violation is that I can prove that bees were present.

And it's not -- there is -- there is a reasonable doubt when you start to put all the other dynamics of bees and how -- I'll let -- I'll let beekeepers chime in too. You know, bees forage over a five -- you know, two -- what, maybe typically two-mile radius, but may go five miles, and my numbers might not be correct, but -- and in that area there was also 12 other people that applied that corn herbicide on -- you know, within that time frame or whatever, so how do -- how do I prove beyond a shadow of a doubt that it was that area?

MS. WU: Okay. So -- so I understand, you're saying that foraging isn't even enforceable, is that right?

MR. ROWE: Well, what I'm saying is that if I have to prove that bees were foraging in the area, I have

to be there to collect that evidence at the time of the application.

MS. WU: Oh. So, so far, like, none of the recommendations really --

MR. ROWE: Well --

MS. WU: -- coming from the --

MR. ROWE: -- no. No, I don't think so, because I think part of what the recommendations are is that if there's a need, I'll go back to product specific -- a product-specific issue has a specific need. You could put something on the label like, do not apply between the hours of two hours after sunup and two hours below -- before sundown, because that's when bees are actively foraging. And now if a guy applied it at noon, I don't have to be there at the --

MS. WU: -- right.

MR. ROWE: -- time of the application.

MS. WU: Right.

MR. ROWE: This is what -- this is the tool, if you're going to call it a label violation, that Steve was alluding to. And -- and it -- you can't make one cookie cutter for every label, it won't work that way.

MS. WU: Okay.

MR. ROWE: It's going to have to be product RT-25 whatever specific.

MS. WU: And so what you just described, they don't apply at these times, is that on the table, is that -- that's not -- I -- okay.

MR. BRADBURY: Okay.

MS. BAKER-SMITH: Just -- just -- this may -- for your explanation, coming back to -- it's not just product specific, it's also crop specific, because you -- when pollen is shed, when you need to do an application, and so, again, this is actually a really complicated question. And I think the other element is how much of the label are you focusing on, enforceable components versus educational components, so I think to me the foraging is very much about these are the things you need to watch out for.

So I think the other part of this dialogue is distinguishing between what's to be enforceable, versus what's to try and make sure these are the things that are considered before you do an application.

MR. BRADBURY: Thanks. And I was going to clarify too that language on the labels can also be advisory or helpful for an applicator to be thinking about how to do things to hopefully avoid a situation where you'd even need to have --

MS. WU: Um-hum.

MR. BRADBURY: -- an incident to -- to -- to

investigate. So some of the dialogue here, it is important to keep track of the point that I think the group is raising. So you've got some words that say visiting, you've got some words that say active foraging, you've got some labels that say foraging. Given that may be not in the hardcore-enforceable zone in the label, if it's intended to provide information to an applicator to -- to look at this product and think about when should I use it, how should I use it, if it's confusing it's not helpful.

But I think one of the things this group was looking at is if there's visiting, actively foraging, foraging, maybe there's -- I think the proposal was, maybe foraging is just crisper, cleaner, maybe less confusing to provide advice to the applicator.

MS. WU: Oh. Okay. Well, in my ignorance, which may be useful --

MR. BRADBURY: Um-hum.

MS. WU: -- as, like, you know, ignorant as, you know, somebody who's just a homeowner who's spraying, or whatever, it's like the term foraging to me actually I feel like I -- it would conjure up, like, is the bee eating in this property, versus, like, a present term, which is, oh, I see a bee, I can't spray right here. So I'm thinking of, like, a big Wal Mart bee kill, right,

where it's just some guy at Wal Mart decides to spray the trees. And so if -- you know, if the term foraging had been on there, I'm not even sure that that would have been helpful in that kind of -- like, the unexperienced applicator.

MR. BRADBURY: Scott and then Tom.

MR. GORDON/SCHERTZ: Okay. First off, I think a fair amount of this discussion is a bit myopic of putting all the responsibility on applicators and growers. I mean, this is about the keepers also. So when you start talking about restricting application time, it's also restricting when the bees are there. And Cindy alluded to it, but I will bring it up more clearly, that they are responsibilities upon notification in many areas.

Also, I do take offense that the term, "During bloom," is seen as an improvement, I -- I do think there's real problems with that also. But I won't take this too far, but I think the overall purpose of this discussion is to protect pollinators and grow crops, it isn't just to protect pollinators. Yes, we do want to respect them, we obviously want to do the BMPs around them, and we still have valid insect control needs even during the daytime. Thank you.

MR. BRADBURY: Tom and then Ray.

MR. GREEN/DELANEY: I think as far as

professional applicators, at least in the ornamental and turf area, I think it's not as much important what words you use, as how you define it and -- and how you to train to them. And, you know, the state regulators are the -- are the final decision makers on how they want to interpret and -- and make the decision.

I think we look back maybe on the -- the drift labeling, and I'm not saying I like all what's happening with that, but just when Dave Scott did that survey of all the states on how they interpreted drift and whatever, and then giving actual examples where you could read and understand what a violation was by reading an example. So you define the word, and you read an example, and then, you know, actual cases -- bee-kill cases having information about them, people learn from other people's mistakes a lot.

So I think maybe if we look back at the drift language and we look how some of that was researched, it might help us with the bee situation, bee kills, and protecting pollinators.

MR. BRADBURY: I think I said, Ray, and then Cheryl/Sheryl.

MR. MCALLISTER: By the time it gets here, most of what I had to say has been said. But I -- it doesn't -- foraging, versus visiting, versus actively seems like

it's, you know, three words, small progress, but I think it's a big step. It -- having made decisions like that, it can allow us to focus on the -- the more crop-specific situations where we can make a difference in providing the best instructions for the user and determine where that needs to be in -- in a -- the realm of education versus enforcement.

MR. BRADBURY: Thanks. Cheryl/Sheryl and then Michelle.

MS. CLEVELAND/KUNICKIS: Okay. So -- so in the broader context of this whole group, I just need to bring up the point I'm sure has been covered ad nauseam down in the subcommittee, but the RT-25 is formulation specific, crop specific, biography specific, it's a screening-level tool, and it's informing some of this language. But the risk of trying to line up active, after active, after active with screening-level data that was generated 10 years apart, the risk is people are going to go down the line and say, okay, something that has 16 hours, versus nine hours, versus 48 -- well, I'm getting a little bit -- 16 versus 19 is probably no different. Three versus 48 may be -- would be different.

And I think the -- the fear is that not only would maybe this website not only be used, but it also, if it -- if the list becomes more public, it's just going

to be used as a black list and inappropriately, rather than going through and having a true screening tool that goes apples, to apples, to apples.

MR. BRADBURY: Nichelle and then Gabriele.

MS. HARRIOTT: I kind of disagree with that statement. I feel like -- and I have not been a part of these discussions for very long, but I feel like the RT-25 does serve as a -- the labels. And, of course, it's not an enforceable statement by any means, but it can help inform the farmer and the beekeeper as to what types of admonishment practices are in place while they're -- maybe something to the -- to the label, maybe something along the lines of -- for example, this is the RT-25, is it will take eight hours, maybe a statement -- a disclaimer statement saying, you know, application of this product can remain toxic, but is not on the label. You know, it can be a -- a useful educational tool when it comes to maybe that kind of best practices.

MS. LUDWIG: Yeah, different -- slightly different issues. One is just -- I keep coming back to the issue of BMPs versus label, because I know there's a lot of folks on the label language, but can EPA remind us how long it takes to change from unlabeled, what is that process?

MS. BAKER-SMITH: Well, I mean, it -- it

depends. If we have -- we -- in the past we've had label improvement programs where we've had labels come in, and had statements put on them, and we've made special efforts to approve those -- those changes, so it -- it depends. If it just comes in as a PRIA action, obviously it would get a PRIA time frame. When we had notification, we had that time frame that we did it, so it depends on how it comes in. And, of course, there's the time for the registrant to incorporate into their production schedule and into their --

MS. LUDWIG: Right.

MS. BAKER-SMITH: -- into their season, or else it can -- it can vary a little bit and then -- (inaudible) -- products.

MS. LUDWIG: Thanks.

MS. CLEVELAND/KUNICKIS: Talking -- so let's say you had the perfect deforaging label language, this is what you want to put on there. I mean, specifically what would happen is just simply as labels would be coming up for review, either through the registration review process or because a new use would come in, then you would do the review, so it would be sort of a -- or is there some time when you would actually do -- you want all the labels for these 10 products to come in so we can review them?

MS. BAKER-SMITH: And we've done that before.
MS. CLEVELAND/KUNICKIS: Okay.
MS. BAKER-SMITH: Throughout history of --
MS. LUDWIG: Yeah.
MS. BAKER-SMITH: -- my career, at least. This is a long time, so you can -- you can do that. And then we've also done the other approach where it's been incorporated into re-registration or the next time the product comes in the door.
MS. CLEVELAND/KUNICKIS: Um-hum.
MS. BAKER-SMITH: But, you know, it depends on how -- it's -- it's risk driven really, and how important it is to get the labeling which -- on the product.
MS. CLEVELAND/KUNICKIS: Okay.
MS. BAKER-SMITH: We've done -- we've done both of those for years.
MS. CLEVELAND/KUNICKIS: Okay. And then one -- one thing I was wondering, what -- with the BMP discussion, is -- you know, and I just can't -- I've been part of that, was how much of BMPs for beekeepers' pesticide application, since part of the discussion are also captured on that website, I just don't remember, don't -- just don't know where that's been in the full discussion, there is a section on that?
MR. BRADBURY: Yeah, that -- and I remember

Wayne Buhler's presentation last time where there's a place to click and it also provides in the site --

MS. CLEVELAND/KUNICKIS: Okay.

MR. BRADBURY: -- some light controls. Okay.

MS. CLEVELAND/KUNICKIS: I just wanted to check, because I couldn't remember that. Thank you.

MR. BRADBURY: Okay. Andy and then Brian.

MR. WHITTINGTON: Again, I'm very new and I don't know who I really made mad, but I apologize if -- if -- if this is ground that's been covered before, but as -- as far as -- a the RT values in -- in bees, are we talking about crops where the -- where the farmer brings in bees for the sole purpose of pollinating his crops, so it -- you could bring the bees in and then inform the beekeeper that you need to spray. He can pick -- he can remove the colonies, and as an RT value there's 48 hours, just not bringing those back for 48 hours, as opposed to I spray 4,000 acres of cotton and I don't know when bees are going back and forth, they don't leave, return entry intervals, fine.

And not to be glib, but it's -- but it's -- it's -- you know, the label is the law, you don't want to wind up with somebody that -- I -- I mean, this is -- there's a huge difference, you know, in variability of farms and farm size is what makes a lot of this extremely

difficult. I -- I can imagine for you, but even for me to kind of get my head around how do we work on some of these issues.

MR. BRADBURY: Thanks, fair statement. Brian?

MR. ROWE: I'll take a crack at it, yes. It -- I think there's a lot of interaction, there are a host of examples the work groups have talked about over time with regards to good, cooperative interaction between a grower who relies on a beekeeper to provide pollinators, because you won't have a crop without them, and -- or -- or she won't have a crop without them, and -- and the beekeeper -- and -- and there's a communication track there that the beekeeper, they bring them in and I've got to spray tomorrow. The beekeeper takes them out, you know, whatever the case may be, good interaction in some situations.

But there's also, I think, a lack or -- of -- of understanding in an orchard that no longer needs the pollinators, but it's going to spray for, I don't know, plumb cucurio (phonetic) or something like that. And so as a result of that spray, you're not paying attention to what's blooming on the -- on the orchard floor and bees could be actively foraging in that area. And so I -- so bees can be on site at any point in time, I think that was -- the point David was trying to make was, you know,

bees are in and out of these areas all the time and -- and -- and so the relationship between a beekeeper and a grower is probably pretty well structured.

But the relationship between not knowing that there are bees two miles over that are now hitting the -- whatever's growing along the edge of my property, and I'm spraying my property, and -- and I'm going to have an adverse effect isn't structured, there's not -- the -- the -- that's potentially going to result in a -- in an exposure and application situation. I'm not sure that's really answering your question, but it's -- the labeling is intended to sort of deal with both.

MR. BRADBURY: Maybe one or two comments on the labeling. We've sort of gotten into the RT-25 merits or not, and putting it on the web or not, so I think I've heard good conversation there. But I didn't mean we can't talk about that a little bit more, but I just wanted to make sure there was enough time to followup on the recommendations from the enforcement work group as well just to make sure we got clarify on some of our next homework, but people want to not say no to continuing the labeling. RT-25, a couple more on that, then we'll talk a little bit about enforcement.

MR. ROWE: I'm sure Andy's not the only one that has those questions, but these bees can forge in a 28-

square-mile area around that colony. But it's not only bees, we're talking about pollinators. And if a plant is blooming, then it is attractive to pollinators. And -- and it's my opinion that one should take -- make the assumption that if it's blooming, pollinators are either there, has been there, or will be there. That's -- that's -- the approach that I try to take is we're writing these label statements for pollinators that either have been there or will be there if the plant is attractive. And if it's blooming, it's going to be attractive.

MS. LUDWIG: Andy, you're starting to dawn on me how big of an issue this is. So the -- the -- it really comes down to -- help me understand on this discussion, is when -- when you're talking about growers, we need plant-protection tools. If you talk about beekeepers, they need bee-protection tools, they have pest problems just as much as -- as plant people do.

You all need pest control tools, the issue becomes how do we manage them in ways that don't hurt each other too much. And this is a really complicated issue, because it's not just for almonds during almond bloom when we need pollinators and they're purposely brought in. We have the whole issue of substantial habitat laws in place that have completely changed, you

know, what those bees that are spending time there and how much are exposed to less now.

There's a whole bunch of issue around it and it's -- the question we're all asking in this room is how do we balance the need for the plant protection, the need for pest protection, bee-protection tools, with the fact that, you know, specially insecticides are intended to hurt insects, that's the tension.

MR. BRADBURY: All right. (Inaudible.)

UNIDENTIFIED MALE: I'd like to bring up just three things. Maybe it would better if we'd change this subcommittee to honey-bee health instead of protection; and then the thing that as a grower I want to bring out is that we try and use resistence management in the pesticides that we use; and then third a lot of what we've talked about today could be targeted or nontargeted areas that have been sprayed or will affect the bees in those areas.

MR. BRADBURY: Thanks. Any comments or additional input on the enforcement group report out?

MR. ROWE: I -- I -- the reason I had my card up earlier was to make sort of an ABCO statement, which parallels what we heard from USDA, and that is now that we have some guidance the very next thing that people are looking in my direction for is training, because there is

very little bench in pesticide regulatory inspector work force that understands colony dynamics, understands what to look for when you approach a colony, what's flowering in the area, what's the cropping pattern in -- what did you say, in a 28-square-mile area around the colony, and so that's what the bee inspection guidance was intended to deliver, and -- and I think it does provide a good basis for a start.

BETA tested this year, go back and tweak it in the fall or winter months, get it ready for next year, but training is a significant need now. And so where those resources come from, whether they're the existing EPA-funded regulatory programs -- I mean, we're -- we've got one coming up in August in -- in Michigan where our marque banner topic is pollinator protection, and so anything that can be done to support training for the pesticide inspection work force out there is -- I think it will be money will spent and will support state involvement in investigation-related activities.

MR. BRADBURY: Tom?

MR. GREEN/DELANEY: Do these -- Brian -- Brian, does EPA still do priority setting on enforcement grants and stuff? I -- I wonder if, compliance monitoring, you've got any data on how many bee kills happened last year from the states and stuff on the state reporting and

whatever, and at some point, you know, they take it as a national priority, then all the states are working on it.

MR. ROWE: You want to speak to that one?

MR. BRADBURY: So we've been working with OECA, that's the Enforcement Compliance Office in lining up program priorities with enforcement and compliance priorities, and this is one of the areas that we're aligning within the region. So that -- from a program perspective this is a high priority for the pesticide program, lining that up with enforcement compliance priorities, and then that usually starts to correlate with how the state grants are going in terms of the enforcement side and the programmatic priorities.

And I think the enforcement guide that is coming out in region five is working, they took the lead in a -- on the regional perspective, it doesn't mean states in that region, working with OECA, and us, and some of you being able to provide input on the draft, it sort of illustrates how we're trying to align -- align our efforts to maximize limited resources.

Okay. So I'm going to try to give you a sense of where -- I'm going to talk to all my colleagues, of course, but sort of the sense of where I'm hearing input. And like I said in the opening day, sometimes you get -- go around the room and everybody's going, yep, yep, yep,

yep, yep, yep, and I go, that's pretty easy.

Other times, like spray drift, you can't ever quite get home, per se, but you do make progress, because you see certain areas of where you get some agreement and, you know, your choices, do you wait to start running the marathon until you finish the marathon, or do you start running, and then get to the next mile marker, and get to the next mile marker, or wait, and wait, and wait, and wait?

So my sense in hearing some of the -- the dialogue is that is there -- we don't have perfection, we're not going to solve all the label problems all at once in the next handful of days, or whatever time unit you want to use, but I'm -- I'm sensing that a general -- and where I'm internalizing it and the thing about where we're going to go is that there is some low-hanging fruit, there are some things we can start to do with getting some words clarified. That doesn't mean we solved the problem, but we started to click -- click some aspects off, okay, now let's move on to the next challenge that we need to take.

Without forward progress, you're not going forward. And we need to go forward and we will go forward, so I'm -- I'm going to be working with the team, and then we'll get back to everybody. But my sense is

there's some tangible, real things that can be started, and by starting them we can start to see what the next step is going to look like, and we'd talk a little bit about this process of how do you move labels more efficiently. Getting started with a piece of this puzzle could give us some insights also on some mechanisms by which we can see which ones belong.

The BMP part is really important, because even if we can't change all the labels all at once overnight, and even if we could, you must understand what those changes mean, right, and you've got to work with the states, colleagues, and -- and others to help communicate an extension. There are new labels on the -- in the field right now, everybody wants to do the right thing, but they have to have -- they have to understand what it means. And so by taking some steps, we can start to build up that infrastructure and that capability to start to gain more momentum in, labels are starting to change.

Here's a change you're seeing now, it's a prelude to probably other changes coming along, but it starts to help build up the momentum of -- of change. But I'm -- I'm thinking there's some things that came out in the BMP context via web, via training that I think we can start to see about making -- making it happen. And the enforcement of training recommendation, we'll be

working closely with the AWECA, and ABCO, and firing (phonetic,) and NASDA, and -- and extensions just to see how we can help make that go and get some metrics back in terms of how many -- how many opportunities do we have to work with inspectors just to get through the enforcement.

To the extent there are incidents that are showing up an the time was right, it could be tried out in guidance of how did it work, what worked, what didn't work, what was hard to understand, what was very straightforward in terms of executing what the guidance indicated. So it's sort of that level of the messages, we're going to take some of the recommendations, and we're going to start doing some, we're going to start implementing aspects of them.

But it's going to be incremental, but I think it starts to set the bar up another notch. Is it all the way? No. But is it a start? Yes, so we're going to start moving forward, and then we'll get back out to the work group, and the whole PPDC, and all the public communicating sort of the specifics of that. I also take to heart, especially in labels, work, the -- the importance of working with the states, and we've done that in the past in other programs, like the soil fumigants as odor moving forward to make sure that we had some coordination.

And that gets to another part of Gabriele's question, as -- if some of these changes are happening at the federal level, sometimes there's a ripple effect into the state registrations and to what extent there may or may not be changes there, so working closely with the state health will help to streamline some of the processes going on. If they have to be state registrations, changes that follow the federal change, so we'll definitely be working with ABCO and spy regs to -- to try to streamline that activity as well.

The RT-25 is something we'll -- we'll think about, in the concept of a pilot, to sort of help see how people are interpreting how it's being used. I mean, the RT-25 is dermal toxicity, and so it gives you a sense of this time frame, as I understand it, that a product could be toxic to 25 percent of the DE at that -- at that time window. But it doesn't necessarily tell you about oral toxicities, which is a different exposure route, and the RT-25 doesn't really get at that.

So there's some -- some important aspects that I've heard about being really clear about what it is, what it isn't, how you -- how to interpret it, how not to interpret it, just because could inadvertently find yourself picking something else that may create a different picture that -- wow, maybe that picture isn't

so good either, so you want to think about that, but -- but pilot ideas are -- are sometimes helpful in ways of seeing if what you intended to accomplish is being accomplished.

And then if you've got limited resources, not only for us, but for all of you to get the feedback, if something's working, taking a smaller step to try something out, can use resources wisely so we can maximize getting where we want to get. So we'll make -- we'll make changes in the label language, we're going to start. It won't be everything, but it will be a start. We'll also get some insights on the implementation process, we're going to have to work on education and BMP, and so we're going to ramp that up working with colleagues, and USDA, and else where.

I'm trying to think about the RT-25 thing, but I'm thinking of pilot. There's probably a way to sort of explore some of the various opinions that we've heard and get some -- get some data, get some facts and see how the different ideas actually play out once we can kind of try it out, and then we'll be working on enforcement guidance and getting feedback on how that enforcement guidance came out. That's pretty much a federal/state sort of task we have to take on, but we'll definitely be reporting back out to you as we start to -- to get these

datas on -- on how well it -- it plays out.

All right. So I wanted again to thank all of the people on the work group and all the heartfelt thoughts. I mean, this is hard and I really appreciate the fact that this work group, with folks from all sorts of different organizations, and backgrounds, and perspectives, are probably frustrated as you know what and still roll up your sleeves and still keep trying to figure out how to move forward, because I don't think there's anybody in this room or colleagues that are on these work groups that call in that don't want to ensure that we're protecting pollinators and realizing it has to happen in an agricultural production system.

We're in residential neighborhoods and we've got to figure out a way to do it. And as Sheryl/Cheryl is indicating, it's a complex problem, it's multifaceted. If it was simple, we would have done it years ago. It's not simple, it's complex, but we can solve it. But we need all of you actively contributing to help solve the problem, because none of us can -- can solve it alone. I just want to thank everyone for the hard work up until now. And I know there's a lot of hard work still before us, and I appreciate all the effort and contributions that you're all -- you're all making.

So with that, we'll close out the pollinator

protection section, and thanks, Rick, Lois for helping the group along. And we'll now move into the next section, which is our report out on the PPDC work group with health. And I'll turn it over to -- to Lois to at least -- maybe start with Rose.

MS. ROSSI: Yes.

MR. BRADBURY: So --

MS. ROSSI: Oh, here she is.

MR. BRADBURY: -- you want to start with Rose?

MS. ROSSI: Um-hum.

MR. BRADBURY: Okay. Which part is that?

(Brief break in tape.)

MS. FERENC: The public health work group met yesterday morning and we were -- we're going to give you just a little background on this health work group for those of the people who are new to PPDC, and what we do, and what we're about, and then just briefly go over what we talked about yesterday.

A lot of new people on the PPDC right now, so I'm just going to very, very briefly go through what the public health work group is and what we do, so that if anyone's interested in -- in joining the work group or following the work group activities they'll be able to do so.

Basically, the work group was created to talk

about pesticides that control pests with backdoor diseases, that's how we use the term public health. Basically, public-health pesticides, things that are used to kill rodents, mosquitos, bed bugs, the rest of them. And the issues that the work group was created to address are the broad spectrum of the regulatory policy, programmatic, the environmental issues, technical, economic reasons, science policy decisions.

I think one of the things that we were looking forward to get when we created this work group was to get some input into the public, be able to reach into that small niche of people that use this, need this to control disease. And it sometimes can be overlooked in our stakeholder processes, because the world of pesticides is so enormous and this niche is quite limited. And some of the people in that niche aren't following what we're doing quite so closely, because it is such a small piece.

So this work group was created to try to have a stakeholder group that can provide us with input into that -- into the -- that group of pesticides. And basically we've identified three critical roles for the interactions with EPA, the work group did this initially and it's -- it's an advisory panel under FACA, it's a portal for stakeholders to bring in issues of concern to us, and then a forum to discuss the -- any elements or

items of common interest that we might have, and we try to kind of distribute each meeting to be -- to address these different areas.

And the goals of our work group is, I think as I already mentioned, to kind of get a broader stakeholder input. And stakeholders include people from departments of public health, community, environmental organizations, proponents of children's health, and other government agencies.

Now I'm going to talk a little bit about what we did yesterday. We held a meeting yesterday from 9:30 to 11:30, and we had three major topics. The first one was we discussed the repellency mark program, which Rose Kyprianou's going to address and talk about our discussions when I'm through here.

We talked about the -- the draft federal bed bug strategy, which is a strategy that we have that -- that EPA has been working with CDC -- our federal partners of the CDC, DOD, USDA, NIH, and HUD, sorry, to -- to generate the strategy, and it's a joint strategy, interagency strategy, we've been working on it for, oh, probably a little bit over a year now. And so we kind of used this as an opportunity to just share our process with this work group what we -- how we are releasing it, what our plans are for it, and we can just kind of do a

brief discussion of the overview and the key parts of that.

The other third item that we discussed yesterday was a -- a discussion about efficacy data, best management practices, and informed labeling, and that was just a -- really a preliminary discussion for us to speak with the stakeholders about some of the implications of efficacy information, and -- and this is a -- particular to public health pesticides, if you have efficacy information, if there's information that has -- that -- that we know about, but that is not necessarily on the label that would provide us with additional ways that the pesticide could be used more effectively.

So, for example, and this -- this has come to the floor because of the recent movement to update the -- and to crate new bed bug guidelines. And our new bed bug guidelines are -- are not necessarily just the, you know, spray/kill type of evaluation, but it's -- also there's going to be information in those guidelines that we're going to receive about how that pesticide is used, does it kill eggs, does it work on different surfaces, things like that.

And it would be good for us to be able to put that on the label, so that the efficacy data might not -- the efficacy information might not just read into the

label as this kills bed bugs, but might say, you know, it kills -- it kills the bugs, it -- you -- you need to -- the retreatment interval, as to whether or not it kills the eggs. And you would want to specify a retreatment interval that would actually encourage good use of that product, so that people don't expect to -- to be able to spray that product, kills their bugs, and they're done, so just to better-inform labeling.

As I said, this was a very preliminary discussion, we -- we just kind of had a little bit of back and forth to start to tee-up this issue and to discuss it. And I think at the end of it we just -- it -- it was -- everyone in the room agreed that this would be beneficial information to the users and that EPA's going to look at this, investigate this a little bit further, and report back.

I -- there's -- also I had a -- a slide here, but there's -- I wanted to -- can you go to -- the very last slide is it? It that it? Yeah, that's a list of some of the topics that we have addressed in the past or we have identified as issues that this work group can and will work on, so I just wanted to put that up there in case any of you are interested in any of those issues or if you have different concerns. And if anyone is interested or would like additional information, you can

contact Lois or myself to -- to get that information. So I think we'll do -- if anybody has any comments now on this information, or do we want to turn it over to Rose and let Rose --

MR. BRADBURY: Any clarification questions for Susan? Ray?

MR. MCALLISTER: Have bed bugs actually been designated a public-health pest?

MS. FERENC: -- yes, bed bugs were designated a public-health pest in 2001 with a statement with CDC, EPA, and USDA as part of our list of public-health -- lists of pests of significant public-health importance, yes. And we also had a reaffirming, highlighting statement that we issued about two years ago with CDC, and there's a joint statement that highlights the public-health implications of bed bugs.

MR. MCALLISTER: Are those tests listed in the regulations?

MS. FERENC: They're listed in the PR notice that --

MR. MCALLISTER: Public-health tests?

MS. FERENC: -- yes.

MR. MCALLISTER: Okay.

MR. BRADBURY: Yeah?

UNIDENTIFIED MALE: I wanted just to clarify a

little bit about the bed bug issue. We talked a little bit about that in the meeting yesterday, and, you know, one of the -- the issues came up that once you get past the yuck factor and the nasty rash, how much of it really is a -- is a public-health problem compared to just little mosquitoes that will -- will carry other insect-borne diseases?

So I think that one of the issues, and I kind of look at public health a little bit differently in terms of more disease measurement in populations, and I -- I think that -- I don't know if it's a role for EPA in this public-health group or somewhere else, but maybe we can widen the scope a little bit and look into that a little bit more carefully to see, is there -- it -- it took a while before we ever realized that dust mites and cockroaches were allergenic and -- and worsened asthma.

So might there be something else involved with carrying diseases besides, you know, bites and rashes, that bed bugs would be even more -- of more importance, but I -- I think that maybe just kind of studying that a little bit more is certainly one area, but then studying in general the -- more of the relationships of -- and -- and more of the epidemiology with some of these diseases that we're really looking at trying to --

MS. FERENC: Yeah.

UNIDENTIFIED MALE: -- figure out.

MS. FERENC: And actually one of the items on our list there that we have not really quite tackled is the development of performance measures for public health, and I think it -- that would be very valuable for all of us to have -- to make some advances on that particular item. Okay.

MR. BRADBURY: Okay.

MS. FERENC: We'll turn it over to Rose.

MS. KYPRIANOU: Okay. Hello, everyone. I'd like to bring your attention first to this handout with the yellow graphic in the center of it. I believe that there are still some on the table for those in the public, if you haven't been able to get a copy of it, hopefully it's somewhere in the packet that you all have on the panel.

I -- I had the opportunity to speak with two PPDC work groups yesterday, the comparative-safety statements and the public-health work group. And for those who don't know me, I'm in the field and external affairs' division of OPP and I've been interacting with both of those work groups and talking to the full PPDC for a little over a year now about this particular program.

I'll cover four main points, I'll talk a little

bit about what the repellency awareness program is, since there are some new people, I wanted to tell you all where we're at, I'll go through some of the comments from yesterday, and -- and then I'll end with some of our needs moving forward.

So some of you who are familiar with this program may remember it by the name, and we've referred to it in the past as the repellent mark or repellency graphic. The repellency awareness program is really kind of an evolution of where we want to take this program moving forward, looking towards launching it to the public, giving it kind of a public eye, so hopefully this is the name that you'll be hearing from here on out from us.

It's a voluntary program, and it's still under development, you heard today, and it's aimed at raising public awareness of health protectiveness of skin-applied insect repellent. The basic idea is very similar to what SPF does for sunscreen products, in that there would be a standardized graphic placed on the label of insect repellent and it would express the repellency time of mosquitoes and/or ticks, so we're really honing in on the vectors of -- vectors of disease. So with that, I will stop in terms of a -- a background and -- and let folks read the handout if they want to get any more information

on it.

Where we're at right now is in the past over the winter we gave the two PPDC work groups the draft guidance, and it was also distributed to some other stakeholder groups. We've also vetted the -- both the concept and the criteria of this program through a scientific advisory panel last March, so we're preparing to announce the program broadly to the public later this summer and we plan to solicit feedback from the public on the utility of the graphs, so we want to make sure that it's meeting the needs that we think it's needing. We've done consumer research in the past, so we really think we're on the right path, but we -- we want to make sure that -- that everybody is liking it before we -- we go full on with it.

So I'll talk a little bit now about what went on in work group discussion and also this will give a better idea of -- of, for those of you who are not very familiar with the program, what it all entails. First of all, one of the topics that kind of the discussion rallied around is will there be participation. There was concern that -- that companies with currently-registered products may not want to participate, because new data may be needed or their hourly claims may be reduced because of how we are standardizing the data-evaluation process.

Now, on the flip side there was also concern that not to have new data would diversely affect the ability for the graphic to relay both reliable and consistent information. So, obviously, OPP wants the program to work, they want -- we want companies to come in to apply to put this on their products, the issue with the data is that existing -- not all existing data will support the type of claims that we want to be putting into the graphic.

So, for example, data may follow significantly different testing protocols from -- data from the past may have significantly different testing protocols than -- than studies that have been submitted more recently and that aren't according to current guidelines, and so there's a disparity on the type of data we've gotten in.

Another example of differences is that some of the existing data provided may not have enough information to inform the pest claim, this would be the case where for the claim in the repellency graphic we're going to be asking for multiple tick species to be tested. Some of the currently-registered products don't have the multiple species that we need, so it's not that the information wasn't good that was submitted, it just wasn't appropriate for this particular set of information that we wanted relayed to the public. So we're hoping

that companies see the benefits, including the graphics, on their product labels and that consumer demand will also grow, and this will help to outweigh the burdens that may be associated with adding the label -- adding the graphic to the label.

Another area of -- of discussion that comes up every time is whether or not we will be including stiffer exemptions, or otherwise known as 25(b) products, in this program. We received many comments on this topic and they all pretty much rallied around the same point, which is that 25(b) products should have the same data on the same standards that the -- the registered products should have if they're going to participate, so at this time we intend to move forward with the voluntary program for registrants of new and existing skin-applied insect repellent products that are subject to FIFRA. So if 24(b)s wish to participate, we will encourage them to become registered products.

Although not anticipated, if a 25(b) company wishes to keep its exemptive status, we will encourage them to come in to discuss an alternative way forward. But given that we would require pretty much the set of data that we would need to register the products, we really don't see a reason to not go forward with registering them.

Finally, there were a number of questions and comments about outreach to the public, what we plan to do for that in the -- in the coming months and years. And I'll just say we're -- we are definitely planning a strong public outreach campaign on the program, starting with web and moving on to other communications' media into the future.

One area of our focus will be with recognition of the graphics, another area will be to message the public on how to use the graphic, and -- and issues about surrounding variability as well, the -- the facts that -- many factors can effect whether repellent works in the time listed. Kind of the idea that the number is not an absolute, it's -- it's a very good reference and guide to help you protect yourself from vectors as it was used.

One of the things I'll just point out is if you take a look at the handout, you'll see that we're -- we're even trying to add messages around the graphic itself. The idea that we want to convey is that using the information in this graphic can help you avoid bites and that we really would like this public to -- to pay attention to applying the repellent correctly to get the best results.

So with that I'll conclude and with a few of the needs that we have moving forward, since I have the

opportunities to do so. First and foremost we're looking to our collaborators in the public health sector and other sectors to -- to show support for this initiative. One -- one way you can do that is by showing your support when we release the program to the public, there will be an opportunity to comment. And for those of you who wish to offer something other than support, we -- we will be more than happy to receive your feedback as well.

We need participants in industry to come forward to do this with us, without industry participants the graphic will never be seen or used in the -- or -- or offer any benefits to the public. We need help in reaching consumers once we know products will be coming out with the graphic on their labels, and finally I -- we really need your -- your continued feedback.

I thank you for the input that we've already received through you and through others, it -- it has helped to make the program what it is today. And with your continued contributions that are -- your continued contributions are what will make this program have a long and sustainable future and a positive impact on public health, so, thanks.

MR. BRADBURY: Okay. Take some questions or comments. Steve?

MR. SMITH: Rose, you asked for support or

feedback, I'm -- I'm going to give you both. So SC Johnson is a consumer-products' company, of course supports any initiative that clarifies labels for consumers. But we do have the same concerns that you've raised about the test methods, so we look forward to working with you to clarify the requirements in testing for this mark and we're happy to participate in any way we can.

MR. BRADBURY: Any other comments? Cynthia and then Beth.

MS. PALMER: I'm just wondering if a company tests the product, and it doesn't do so well, and it decides no to publish that information, will that -- will those findings still be publically available, like if it gets a zero for ticks?

MS. KYPRIANOU: Well, I -- I don't think that they would probably apply to -- to get the graphic if -- if it was a zero, so probably the -- because it's a voluntary program, if it's -- they're not going to have a -- a claim based on the information that we would -- would want from them, then my guess is that they would never apply for it.

MS. PALMER: Okay.

MS. KYPRIANOU: Also -- also, we would -- we would re-examine the claims on the label, because the

claims on the label are supported by efficacy data for public health pesticides. So if we got efficacy data in showing that it didn't work and it was a valid study and all that, we would have to re-examine the claims on the label.

MR. BRADBURY: Beth?

MS. LAW: I think the -- the effort has a -- a commendable goal and, you know, we, the FDA, will, as always, are definitely willing to provide input to -- to EPA concerning our -- you know, our -- our concerns, as well as our -- our -- our support. I think the discussion in the work group yesterday indicated that there are -- there are concerns with the data-testing method and just with, you know, variabilities. So, you know, you said you'd like to have ongoing comments, so we will take that up -- take you up on that, on that offer. Thank you.

MS. KYPRIANOU: All right.

MR. BRADBURY: Any other comments or questions? Okay. Thanks, Rose, Susan, Lois, and comments and input going forward. And as Rose indicated, we'll be moving forward by taking comments and -- and looking forward to parties that -- that may want to help push this forward and -- and see how it goes, but taking the input as -- as we go forward.

Okay. So move into the last session, which is mostly just sort of -- a little bit of touching base on -- on what we accomplished through the work groups and discussions here over the last day or couple days, kind of highlight next steps that would come out from our -- our discussion, and then spend a little time hearing from all of you if there's specific topics you'd like to -- to see on the agenda. And we don't decide, but we kind of get the list going and -- and maybe chat a little bit about it. And then Margie does magical stuff, and we reach out to all of you, and we come up with an agenda for -- for the next time, it is sort of magical.

So just sort of going back through our -- through what we -- what we worked on, I'll -- I -- I guarantee you when we come back next time we'll -- Marty will give you an update of where we are on -- on the budget and -- and how that's all playing out, because it's -- that's very dynamic and you are all picking up some of the things we're talking about, things to do, there's a dollar and a time unit associated with every one of them and every choice we make. They've always been careful choices, but now it's a -- really a zero-sum game, and so you'll get a -- you'll gt the feedback from Marty and you may see how some of that's starting to ripple into some of the activities we -- we can take on.

Endangered species, we'll be at a -- we'll -- we'll be down past the -- Rick, and Don, who couldn't make it, and Paul, and Cheryl, and Helen talked about yesterday, so we'll definitely be giving you a status report. And depending upon where we are on different issues, papers coming out, we may be close to -- I can't remember the exact timeline, but close to or within periods of time you may be having things out for public comments and -- and there may be some opportunity to actually zero in on a few components, depending upon exactly where we are and what the topics are that are starting to heat up.

Having said that, if there's some specific aspects of the endangered-species implementation, we'd like to make sure we weave in this over the course of the next month, few months. You can shoot e-mails to -- to Margie, and we can kind of weave in any specific updates along with getting you progress and getting feedback from you on that.

Integrated pest management, I know that was -- got a little confused in -- in the conversation and I did my best to try to synthesize what it is going to be going forward as a major task. So just to clarify the metrics, how to -- how to measure whether or not a -- a district is starting to make progress in implementing school IPM

we talked about, and, Frank, I'll turn it over to you.

MR. ELLIS: We're going to pass these around and Allison's going to also pull it up. You can see it on the screen here, it's some work group recommendations. Dave Tamayo, the -- is going to do the report out for the group, because Steve asked yesterday that we do a little clarification work. So most of the folks that were here grabbed a muffin outside, and came upstairs, and met with us at lunchtime today, and -- and dedicated their lunch hour towards this effort, so we appreciate that. And I'll turn it over to Dave to kind of walk us through our -- our clarifying efforts.

MR. TAMAYO: Well, this piece of paper here really just -- the -- the first half of it really pretty much just puts down in writing what I presented yesterday verbally. And just to reiterate, the -- the main concept is that the recommendation of our work group to -- which we hope will be adopted by PPDC is that EPA implement a school IPM pilot project working with -- working in a -- a -- a few targeted states to help bump up the level of -- of school IPM implementation. And then the rest of this really just talks about, you know, a -- a few of the work products that we envision coming up with in -- in the process of doing that, and then it sort of outlines the -- actually, a fairly-aggressive work plan to start

moving in that direction.

So I think there were some concerns about, you know, whether we were following our charge, and I just wanted to clarify. And that -- this isn't so much put in here, but -- but we're -- we've -- we've done the -- the -- the first part of the charge and identified metrics for implementation in school IPM, and we're really at a stage where -- let's -- and we've -- EPA has hired staff, established the center in Dallas, and we're really kind of at the stage where, let's start using the things that we have gathered and using the things that -- that are already out there that have been created by NGOs, by states, by universities, by school IPM programs, consolidate those, and use those resources to -- to help -- have EPA use those resources to start moving the ball forward in -- in -- in some other states and seeing what we -- what they can do on a national basis to really move this whole -- whole concept forward.

So, and I don't -- I don't know if you want -- I don't think that it's really necessary for me to read through the things that are here -- here before you on -- on this, but the other -- one of the things is that we'd like the -- the -- the recommendation is -- is to do it and it sort of creates -- we're proposing that there's a different role for the work group to have now, and that's

to advise the ongoing implementation of this, and not so much having it be, well, the work group will work on some things and the come to PPDC and say, hey, is this okay.

What we're asking is, you know, is to adopt the recommendation of -- we move forward and then convening some sort of advisory group -- that EPA would convene an -- an advisory group that would just help them really shape what that implementation is going to be like. That doesn't mean there won't be reporting -- wouldn't be reporting back and plenty of opportunity for the whole PPDC to -- to comment on things, but it's just -- it doesn't seem very workable to -- to just have it be that every step that EPA takes needs to step back and get -- get feedback before they can move forward.

MR. BRADBURY: Okay. Dave laid it out to the whole committee, I think this does -- this is good and it tracks sort of what I was thinking, and thank you for putting it in words. Just to -- to clarify, we probably -- we would use -- as an advisory group, we'd use the PPDC IPM work group as the advisory group, A, because it's done under our FACA, so we can take advice from our federal advisory committee.

And as I said, the first day, as long as it got some -- at least one, I guess, permanent member of the PPDC on any work group, the membership on a work group

can be -- is beyond the PPDC, so it's a way to reach out to other partners that are working in the area. And having it under our FACA, then it makes it good, legal, proper. So open it up to the -- to the full group. Susan?

MS. FERENC: I just have a quick question. I -- I need the time -- you know, they're such a good group, and they've got lots of input, and, you know, we can't even -- the rest of us who aren't working on that can't even really keep up with how much they're doing, so -- so I -- I'm personally comfortable that we can defer to them, you know, rather than coming back to us all the time.

But -- but the one thing I'd ask is that if you don't -- if you decide not to follow through on a recommendation coming out of -- of the group -- the work group, that you would let the full PPDC know why you didn't do that, so that we've got at least some way to -- to just be sort of seeing how the recommendations from the advisory body are actually taken up by the agency.

MR. BRADBURY: I would -- I'd say that every single meeting we'll make sure it's on the agenda. And it may be -- sometimes it may be short, here's where we are on implementation, the advisory group suggested that we do bang, bang, bang, we're in various stages of

implementing it, you haven't gone far enough, you have to find out if it worked or not, to maybe some sessions that may be more in-depth, because we were hitting some options and -- and we want to share with you what some of those options are like, or what -- what worked, what didn't work. So I -- I conform that every single meeting it will at be at least an update, and sometimes it may be more in-depth based on where we're at.

UNIDENTIFIED FEMALE: Just a quick question if whether the school IPM program is being defined broadly to include childcare centers as well, or it's just more specifically focused on schools?

MR. TAMAYO: Right now we're focusing our efforts strictly on schools, but we do -- we have received that comment a lot from our internal EPA folks, as well as lots of partners and stakeholders, and it's something we have our eye on kind of down the road. We want to get schools were we think they need to be and where our program needs to be, and then we'll look to broaden out towards these other areas that are -- have a lot of similarities.

MR. BRADBURY: Ray?

MR. MCALLISTER: It's late in the day, late in the meeting, our ranks are depleted, and on -- on the surface, to me personally, it looks like a good idea.

But I represent a larger constituency, maybe they have an interest in how this comes out, maybe they don't, and I'm saying it in this meeting for the first time.

Perhaps some of those who do have a strong -- even a stronger interest than I do aren't here to comment at this stage, so what I'm trying to get to is -- is perhaps there can be a couple of weeks for PPDC members to respond to this after having a chance to consult with its constituency. And I can't see anything on the surface that would -- that would detract from it, but then I don't see the whole picture either.

MR. BRADBURY: Well, that would be fine if -- if members wanted to submit some ideas. Having said that, the IPM school strategy -- EPA's IPM school strategy and implementation plan has been on the web for a couple of years now, so it's happening, it's moving forward, we've made the investments. So I would suggest -- I'm -- I'm really looking forward to comments on how to help improve the ways in which we can get advice through the work group, as opposed to, are you going to do it or not, because it's already happening.

And so to the extent this work group can provide us good, timely input and help make sure -- the networks to all the various practitioners that are out there, to make sure we're getting the biggest bang for our

collective buck is what we want to do. So I really look forward if there's additional augmentation of how to make this work well, that would be -- that would be very helpful, I'm sure the work group would appreciate -- appreciate that. So comments in terms of moving forward would be -- be very helpful.

Thanks, Ray. Okay. So we will have a -- definitely get a report out the next PPDC. And -- and as Dave's indicated on behalf of the group, there's some aggressive steps that are going to be taken and that's good. The comparative safety group and -- and the group you just heard from, we'll see sort of how developments go, either written or maybe short verbal updates, I would imagine. We'll especially be reporting back on the repellency mark, and we could be in a very interesting phase of -- of where we are in -- in steps going forward there.

I don't know, the pollinator protection -- we'll definitely have quite a bit on pollinator protection and, you know, the work group's got a lot going. And I -- I just know for sure we'll have another probably round as -- of activities we can take on and maybe circle back around to all of you, but just making -- just letting you know there will be a good chunk of time on the agenda next time. And with that, probably some updates on

things like endocrine disruption and things like that.

So now I'll open it up to all of you, again with the idea we want to try to use this session less on us being talking heads, to the extent possible, and more in hearing from the work groups and -- and talking about recommendations for next steps. Gabriele and then Cynthia.

MS. LUDWIG: I wasn't -- I'm not so much thinking about work groups, I'm thinking more about discussion topics in general for PPDC. So we're sort of, what, a third of the way getting to half of the way into registration review, and there seems to be some changes or some new risk assessment ideas coming out fairly -- for those of us who were around for re-registration. So whether it's in this whole core pureafos (phonetic,) air quality, volatileazation risk assessment, which was completely new -- I mean, the science wasn't new from a -- for those of us who saw fumigants, instead of be applied to a traditional pesticide was, like, what?

So -- and then on -- on -- on the water quality, I'm hearing rumors for -- both for drinking -- bottled drinking water seeing assessment, again, I'm just hearing rumors. I, again, have come back to what I said when I first joined the PPDC, is that I would like to hear about things that are really getting into some of those

fundamental risk-assessment decisions that go on here.

I heard today on the -- on the endocrine disruptor, I really appreciate it, because it was a -- much more in-depth information and it was an opportunity for some real feedback on some things that, you know, help clarify and -- and say, hey, have you thought about this?

So I just come back to, you know, it's nice that we have a work group providing these updates and so forth, but there's some really substantive changes going on in how you're doing your risk assessments that I don't feel like have come back to this committee in the last two-and-a-half years at least, so just putting that on the agenda. Okay. And -- and -- and it may be that you need to do some separate meetings, and this may be a point of sort of asking for how do we do that, I don't know how best to organize it.

MR. BRADBURY: Cynthia and then Ray.

MS. PALMER: For the next meeting I'm hoping that we can broaden somewhat the focus of the pollinator discussions. They have been useful, focusing on RT-25s, and enforcement, and BMP -- BMPs, and so forth, but that's just a small subset of the issues. So I'm hoping we can put on the table a broader discussion of EPA's work on systemic insecticides, and the discussion could

include everything from seed treatment affecting birds and bees and other pollinators, to water monitoring, and the whole range of effects of these systemic pesticides that we are moving toward using more and more.

MR. BRADBURY: Ray and then Susan.

MR. MCALLISTER: Earlier today I was talking with some of my colleagues and we felt it would be very useful for the PPDC to have an -- an understanding of EPA's role and participation in international forums in support of U.S. agriculture. We -- we're aware you do a lot of work with OECD, it's been mentioned a couple of times in the last couple of days.

Lois Rossi does a lot of work on harmonizing MRLs, and -- but many of us on the PPDC probably don't have a -- a good understanding of how important that work is and what exactly the agency's role is. And USDA has a strong role there -- there too, because they have the pesticide data program, and IR-4, which have reach into international programs and -- and implications, so I think it would be helpful to have a session on that.

MR. BRADBURY: Thanks. Susan and then Tom.

MS. FERENC: You -- you can probably guess what I'm going to say, thank you. I know it might be a little premature, because November's coming up as you're finishing off all these SAPs for EDSP, but it would be

nice to -- to get just generally a -- a summary of -- of how you're taking the information out of the SAPs and integrating that all together, because it's -- it's such a -- an active program.

I mean, what's going to happen in the future is still going to feedback on what's already happening now and -- and -- and it's -- it's integrative, so it would be nice to have just even some sort of short report on -- on if there's any changes to the -- to the EDSP policy now, or, you know, that may -- that may actually happen as a result of -- of when you have your cumulative SAP information in hand.

And, like I said, it may be too premature, because the final report from the weight of evidence isn't even going to be done until November, but just sort of an -- an update on -- on if you're getting -- as you look at it all, if you're getting anything out of it that might lead you to -- to possibly change some -- some direction for the program.

MR. BRADBURY: Okay. Good. Tom and then Beth.

MR. GREEN/DELANEY: Let's see, I think you've got three things here. So one is the PestWise program, the pesticide environmental stewardship program, that seems like it spent a decade reinventing itself, and then took itself out, and shot itself or something, it

disappeared. We have a current PRIA grant where we committed to enrolling schools in the program, but then we were asked to put that on hold. I think there was an information, data-collection problem with the -- the new concept for PestWise that may put things on hold, but we'd really like to hear where that's at and where that's going next time around.

And then this one's from Mark Lane, the American Academy of pediatrics last December put out a -- a report that included some recommendations for governments in terms of policies to reduce children's exposure to pesticides, and I'm wondering if there was any response to that or what you thought of those ideas, that would be nice to -- to hear.

And then the third thing that's come up a number of times that's just been nagging me is that I think we're not doing as good a job as we could in terms of communicating to pesticide users. So Gabriele made a comment about labels really don't mean anything, I heard a couple times people say, well, we know people don't read labels. We talked about information going on the web, heard about -- heard a recommendation about focusing on extension in terms of bringing the pollinator BMPs forward, and the information from USDA's survey shows that ag retailers are two waters of magnitude more

important in terms of influencing pesticide application by applicators.

So I'm not sure exactly how to frame it, but just do we -- are we really on top of the science in communicating BMPs and other critical information to pesticide users? We've sort of got some shortcoming there that should be addressed if we are really focused on what we've learned and what new science has come into the universe about accomplishing that task, I just wanted to acknowledge it.

MR. BRADBURY: Beth and then Steve.

MS. LAW: I also want to support Ray's request for international updates. And I think to the topic that he -- he mentioned, I would add your sort of an update on the -- I'll just call it the beyond-the-border initiative with -- that involves no customs, and EPA, and several agencies, sort of rewrite your -- your -- your -- the basic regulations that govern movement of pesticides across the border. Also, the -- the RCC, the regulatory cooperation counsel, the work plan, and any -- any new reports you might have regarding that.

And the other thing that -- that we've talked about a lot is just whether or not there -- and I think Ray mentioned OECD, but if there are any efforts underway to not only adopt, you know, the OECD dossier approach in

-- so that we can -- can submit chemicals and pesticides, you know, much more easily with Europe. But if there's an effort to do that with other countries, we'd be most interested in -- in hearing about that as well. Thanks.

MR. BRADBURY: Steve and then Tom.

MR. SMITH: I know these have been covered a little bit, but to -- maybe just to be a little bit more specific, I -- I agree with Ray, that we might be interested in international work, but I would extend it beyond agricultural work to include what OECD in Europe being called biocides, nonagricultural pesticides. I'd be especially interested to see an update of Oscar Morales' (phonetic) very interesting presentation two meetings ago, because I think he was having a meeting since then to see where they are with the electronic submission and the electronic dossiers.

There is an OECD dossier template for agricultural pesticides, even microbial agricultural pesticides, but not for nonagricultural pesticides, so I'm wonder if that would be of interest for people in -- in the -- in the panel, particularly at the product, because they see from a resource standpoint maybe that's where we can get some leverage and gain some real ground is at -- at the products. Because if you look at PPD, for example, they've got 15,000 products they're going to

be looking at in the next 10 years, but only 300 actives, so it may be balanced products versus actives a little bit.

MR. BRADBURY: Tom and then Robyn.

MR. GREEN/DELANEY: Well, I'd like to hear how EPA deals with epidemiology studies and -- and such, and I know some may -- it's kind of a broad topic, but some, I think, falls in OPP, but then in their other divisions within EPA that deal with epidemiology studies have hit the -- hit the news and then, you know, somebody reviewing those studies and things like that.

MR. BRADBURY: Robyn?

MS. GILDEN: Insofar as there may be any new developments to report, I would love to hear an update on the worker protection standard and what's going on with those things.

MR. BRADBURY: With any luck, we'll have good news.

MS. GILDEN: That would be awesome.

UNIDENTIFIED MALE: Sort of -- of following up on -- on Gabriele's concern about, you know, some of the water quality issues and then also how risk assessments are -- are done. And I -- I think you realize that we're -- you know, from an urban storm water perspective we've been concerned about some gaps, and how -- how risk

assessments and other -- other regulatory actions are -- are accomplished, and -- and the need to sort of address those gaps and better evaluate how pesticides can impact urban water -- urban water bodies, and then also drinking water sources.

And, you know, I -- I was going to be speaking to you when you're outside of the meeting about that, but I'd like to see if there's some sort of a -- if -- if there would be an opportunity to sort of address some of the changes that at least we think need to be made. And I think the agency also recognizes some of the changes that need to be made and there's some issues you have to deal with, because it -- it would be great if we could touch on that and -- and get people's feedback on, you know, a way forward to -- to improve how that -- all that's done.

UNIDENTIFIED FEMALE: A few of the voluntary programs that you're opening up now are things that the PPDC has dealt with through the work groups, or whatever, for years, and maybe you could work into the -- these meetings just a quick update on which of those voluntary programs are moving forward, are they meeting your expectations, have you gotten any feedback for why people aren't stepping up to the plate, because there's the DRT, there will be the repellency mark, there's the web-

distributed labeling, all those things are kind of ongoing, voluntary programs, some open, some not.

So -- so if we could just kind of get a sense, there's really no other way to get feedback on -- on how those programs are -- are progress or not progressing, and if there's something that -- that we can do to -- to help.

MR. BRADBURY: Thanks, good -- good suggestions. So as typical meeting, the list gets long, and that's good, and -- and I hear a combination of us reporting out with feedback coming in. So Margie took good notes, I took not-so-good notes, but we'll combine them and we'll probably get back to some of you that -- that provided some suggestions and try to zoom in a little bit more, and so some of them may -- we may play them out in terms of just some written material, give you some background, and maybe set up -- well, if you've done some years, I know a 20-minute chunk of time where we say, okay, here's your three topics, we gave you a written backdrop, you know, we can do a couple of clarifying questions.

Some are obviously more in-depth, for example, the registration review and water quality. As an example, registration review and ensuring that our re-evaluation decisions are hitting the mark for water qualities and objectives. And there may be a combination

there in terms of explaining what we're trying to do, and then giving feedback to you all that when we open up these dockets we're not hearing -- sometimes we're not hearing anything, but we know there's something going on.

So there may be some dialogue about what do we need to do to better get information coming in to help us do it, so we'll take a look at some of these that -- some may be a combination of reporting out, but also maybe zoom in on a couple of subtopics where we want to get some -- some back and forth, and we may lean on some of you to help make that session go so it's -- it's not just a bunch of talking heads, we actually get some -- some feedback.

Some topics may be more in the science-advisory-panel world, sort of more the hardcore -- harder -- harder core on the science side, so those may be a combination of some background information and -- and some reason pointing you to things that are ongoing and -- and may be a window at time to see some clarifying questions.

So Margie and I will kind of try to synthesize, we may be calling some of you back just to kind of zoom in a little bit tighter. I think we usually then try to send evolving concepts out to all of you, so you can -- you can weigh in. And as we get closer to the dates that

Margie will share with you, we'll -- we'll -- we'll hone it up in terms of what's going to be on the agenda and how we'll execute it. Well, I'll turn it over to Margie to let you know the time frame for the next meeting.

MS. FEHRENBACH: Okay. Well, we're looking at November and there are a limited number of days that this room's available. But at this point, November 7th and 8th appear to be pretty available. But if you could let me know generally your -- any time frame that maybe wouldn't work in November, that would be helpful and we will avoid Thanksgiving.

MR. BRADBURY: Okay.

UNIDENTIFIED FEMALE: Just the MBAO conference is in San Diego, I can't remember, November 6th and November 7th, and then around that, November 7th, Korea has asked for people to come and talk about MRLs, so for those of us who work on international trade issues it may be not a good day.

MS. FEHRENBACH: Okay. If you could send me the specifics, and that way we'll try to work with --

UNIDENTIFIED FEMALE: Well, it --

MS. FEHRENBACH: -- the dates.

UNIDENTIFIED FEMALE: -- would have the Korea stuff.

MS. FEHRENBACH: Okay.

MR. BRADBURY: Okay. Any others? So let Margie know if -- but soon, because it's amazing -- for a while when we were in Potomac Yards, nobody knew we were here and we could -- we could get free reign over the place, along with a couple other parts of EPA. Now people have started to discover this location and it's an EPA-wide facility, so anybody in EPA can use it.

And then the good news is the federal government is saying, unless you've got a really good reason you should be using federal facilities to have meetings technically. So that means this place becomes even more popular than it -- than it was before, so that's why Margie's putting out -- these windows of time are now a little more challenging than they were back in 2008 and '09 when we were just stating to go in this place.

So it may be, like happened this time, that some permanent members just couldn't make it. Mark Lane had to take a bunch of students from Indiana University to -- to London for part of their, you know, training, and so he couldn't be here, but he managed to get Tom Green to be his -- his proxy, so -- yeah, but he said to stay here.

So it may be that we may not be able to get 100 percent of you to -- to line up, and then I ask you to -- to work for somebody that might be able to sit -- sit in

their chair during that time, because usually it gets really hard. But we would -- do want to know if there's something that's going to -- a couple or three things that would just wipe that window of time out, and we'd definitely have to be a group and -- and look for something else.

MS. FEHRENBACH: Early December too, let me know about those dates.

MR. BRADBURY: All right. Any public comments?

MS. FEHRENBACH: I don't hear any.

MR. BRADBURY: Okay. No, we don't have anybody for public comment, so I want to -- let me just check that I didn't -- I didn't forget anything. So I want to thank you all for a very good meeting. And all the new members, welcome and looking forward to -- to your input and contributions as we go forward.

Stay in -- Margie will be in touch, and we'll be working towards setting up the -- the next agenda. And good input, I know the work groups have a lot going on already. Okay. And the letters of invitation are in the mail. You're all legal, it's just -- don't ask.

And -- and before we close, I also want to use this opportunity again to thank Margie for all her work in -- in planning and executing everything. All right. Everybody have safe travels home and we'll see you again

before you know it.

(Whereupon, the meeting was concluded.)

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