UNITED STATES

ENVIRONMENTAL PROTECTION AGENCY

# PESTICIDE PROGRAM DIALOGUE COMMITTEE MEETING

November 29-30, 2012

Conference Center - Lobby Level
2777 Crystal Drive
One Potomac Yard South
Arlington, VA 22202

P R O C E E D I N G S

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MR. BRADBURY: Well, good morning, everyone. Steve Bradbury speaking, Office Director for the Pesticide Programs, for those on the phone. Want to welcome all the members of the committee for our fall meeting, as well as members of the public both here at Potomac Yards in Crystal City, Virginia, as well as folks that are on the phone.

We'll spend some time going around and introducing ourselves and touch on the agenda that's coming up. But before we do that, I'd like to welcome Jim Jones, who is the acting assistant administrator for the Office of Chemical Safety and Pollution Prevention, who is going to be able to join us for a bit this morning to give some opening comments.

With no further ado, I want to turn it over to Jim.

MR. JONES: Thank you, Steve. Good morning, everyone. It's nice to see so many familiar faces around the table, and there's some new faces. So, actually I look forward to the introductions to get to meet some new

individuals who are participating in the Pesticide Program Dialogue Committee.

I think many of you know I've got a long history with the pesticides program, dating back to 1991, actually, when I was a special assistant to the assistant administrator. Then I spent a good 15 years in the program, ending as the office director in the first part of the 21st century.

I've got a long career in the EPA, most of it in the chemical space. And then, in January of this year, the president nominated me to be the assistant administrator. My nomination continues to pend before the United States Senate.

But, after the events of early November, it looks like I'll be around for a while, hopefully. Well, who knows how long, but, hopefully, for as long as four more years. So, I look forward to working with all of you in the coming years on what has been, since January of 2009, one of the administrator's top priorities, which is improving chemical safety in the United States.

A big part of doing that is through the work that the Office of Pesticides program does, which is

ensuring the safety of the pesticides in the United States, which touch everybody in the United States, actually everyone worldwide, but certainly, everyone in the United States is touched in their lives by pesticides. Thus, our role of ensuring that they are safe is critically important. So, it's all Americans and, arguably, to people around the world.

I also want to thank all of you for the energy that you put into the opportunity that we provide here. Participatory government is a hallmark of the United States. But, as you well know, it isn't as easy as just saying I want to participate. It often involves, really, rolling up your sleeves. That's what all of you do, not only by coming to meetings such as this, which are held a couple of times a year, but, arguably, on the kinds of issues that we struggle with, it takes a little more time and energy than a couple of days a year to give the government really meaningful, thoughtful advice.

So, I think that the energy that you all put in and some of the people who you work with put in into some of the workgroups that we're going to hear from over the next day and a half is really important if we're going to

get the kind of advice that we're looking for, which is the whole point of an advisory committee, to give the government some advice so that we can make more informed decisions that reflect the interest, the knowledge, the experience of stakeholders. It takes some time on the kinds of dense issues that we struggle with.

So, thanks not only for the day and a half you're going to spend here but all of the time that you spend not only in workgroup meetings but preparing for the workgroup meetings. I know we're going to hear again from four of the workgroups, the subgroups that the PPDC has.

So, again, I look forward to meeting some new stakeholders. You're probably not new stakeholders; you're just new to me. It's good to see the familiar faces. I'm sure you'll have a really productive day and a half, and I expect that we're going to get some good advice over the next day and a half.

So, with that, I will turn this back over to Steve. I'll be able to stay for the first hour or so and then I've got to head back across the river. All right, thanks.

MR. BRADBURY: Thanks, Jim. I also want to thank all of you for traveling from all parts of the country to be here for the next day and a half, and, actually, many of you yesterday, working on workgroup activities. As Jim said, we really appreciate the time and energy that you put in. Really, it's the meetings between the two meetings that are the most critical for the work that you all do in giving us the advice as we move forward on a number of challenging issues.

I think our agenda reflects some of the challenging issues that we're facing. We appreciate the time and effort you're putting in to help us see through different approaches for taking on these issues. Jim mentioned the workgroups are a really critical component to the efforts of the PPDC. Yesterday, a number of the workgroups met, including the pollinator protection group, the integrated pest management group, and the comparative safety standards workgroup. The toxicology 21 workgroup is meeting today at lunch. So, it's a good example again as the efforts are going on through the workgroups.

Jim mentioned the important role the PPDC plays

in the pesticide program. I don't think we can underestimate the efforts that you invest and the return on that investment. As a federal advisory committee, our goal is to try to hear from all of the stakeholders and hear from all the stakeholders in an equitable way so that we get a good balance reflection of the issues and the topics and the issue that we should be thinking about. It's getting that integration of ideas and that blending of ideas that's really important to seeing how we can balance different options in moving forward on the given topics.

As we've talked about at other meetings, the goals aren't necessary to reach consensus. It's kind of cool if you can, but what's really important is that collaborative constructive dialogue that you all exhibit so that we can understand what the strengths and limitations are of different approaches, even if there isn't consensus, because it enriches our decision making and enriches the information base from which to draw possibilities and to move forward.

I'd say more often than not, we do find a lot of common ground, even if we don't all agree on all the

details that we have to deal with. Not to say that details aren't important things, but I think more often than not we find a lot of common ground. When I say we, I mean you. It's very impressive how these workgroups can tackle really tough problems and see how from a variety of perspectives we can find common ground. That helps us move forward.

Again, if there isn't common ground, that's okay because I've found that you all help us crystalize and clarify where the different viewpoints are and what the different science or policy or legal aspects that we should be considering. That makes it a very powerful component to our overall efforts.

As I indicated a few seconds ago, we've got a pretty challenging agenda, which is sort of norm for this group, I'd say. I'll touch on the agenda in a bit. Again, we've tried to strike a balance in these meetings as a combination of outputs from the workgroups to give recommendations to the full committee. Assuming the full committee is pleased with the recommendations of a workgroup, we can then start to work on it in the program and put things into implementation. So, there's a heavy

dose, if you will, of that component to the agenda for this day and a half.

But also, try to balance that with some updates so that you can hear about things that are happening in the program and pose some questions, get a little bit of input into some of the ongoing activities. We're not going to spend a lot of time talking about them in detail. The agenda sort of brings a balance, I hope, for that. Then, we're always titrating out the two different components, I know. We'll see how this next day and a half goes.

So, let me just real briefly go over the agenda. After we do that, we'll go around and do some introductions. So, we're going to start off the day and a half with Marty Monell providing an update on our budget and a snapshot of PRIA-3, which was passed by congress just before things sort of rolled up, which was pretty amazing. So, we'll talk a little bit about the components of PRIA-3 and how that plays out into our budget arena.

The second session will be a report out from one of the workgroups, in particular the pollinator

protection workgroup. We'll hear about the recommendations that have come from that workgroup, which, as you know, has many subcomponents to it. So, I think we're going to get a blending or a representation from a number of subtopics within that workgroup in terms of things we can start working on.

Following lunch, we'll hear from the integrated pest management workgroup in session 3. Again, we'll get a report out on some recommendations from the group for moving forward. We'll have some time to get feedback from the full committee on that. Also, Keith Matthews will provide an update on some of the efforts that are moving forward in the area of school IPM.

After that session, Marty Monell will lead a discussion on the comparative safety statements workgroup. We'll get some information from the Wednesday meeting and perhaps some recommendations or thoughts, at least on the pilots that are underway and perhaps new pilots that she might be launching shortly.

Then, session 5 this afternoon, Oscar Morales is going to give an update on a variety of information technology initiatives that are underway, in particular,

activities that we're undertaking to try to help get information out to all our stakeholders in terms of regulatory decisions, information associated with the products and the risk assessments and the risk management decisions, and a little bit of a look to the future and some other options we may be able to start implementing in terms of just helping information flow going, helping things to be easier to get access to information in our programs.

Then, the last session today is to go through some updates. At the last PPDC meeting -- and there were some e-mails over the course of the last six months -- there are a lot of requests for updates. There was no way we were going to put all of those into the formal agenda, again trying to strike our balance. So, in your packets, you have one-pagers on 10 topics that came out either at the last PPDC meeting or within e-mails with requests.

So, we'll use that hour to kind of go through those topics and see if there are any clarifying questions or very brief comments. We'll stick to those 10 topics because it's a lot of topics and there's only

an hour. It'll be pretty challenging probably just to manage that. It's at least a chance to get a little bit of feedback on some of the updates if you all want it.

Then, you'll all get some sleep and hopefully have a nice meal and then get up early tomorrow morning and join us at 9:00 for the second half-day session. What we'll be doing on Friday morning is leading off with the 21st century toxicology workgroup, get a report out from that workgroup, as well as some summaries from some other toxicology 21 activities that are ongoing in the program.

In addition, one of the topics will be some efforts we've been undertaking with Canada under the North American Free Trade Agreement, in particular, development of QSAR guidance that we'll be using on both sides of the border. Mary Manibusan, who is the division director in the Office of Policy across the river, will give that presentation.

After that presentation, Mary will also give you an update on the endocrine disruptor screening program which is hitting some key milestones just recently and going into the next year. We thought it

would be important for you all to hear the status of the program.

Then, we'll wrap up with an update from Don Brady who is from the Environmental Fate and Effects Division, get an update on where we are in the endangered species program. Then, Rick Keigwin will given an update on where we are with some changes and some new approaches in our registration review efforts.

Then we'll wrap it up and think about the future, think about what our next meeting is going to be all about. Then, Margie is also going to spend a little time explaining how we're now -- it seems like it was just yesterday -- in a cycle where we have to re-up members of the PPDC. So, we're going through a nomination process so that next time we meet there will be some new faces around the table. So, Margie will just make sure that everybody understands what that process is all about.

So, I think that should keep us pretty busy over the next day and a half. I'll try to do my best to keep us on schedule. So, I think we've all worked out a pretty good process over the last couple years in sort of

managing the class. I appreciate you all keeping track of what you heard. If there's a new point to bring up, certainly bring it out, but if you've heard a comment that's very similar to what you've been saying, use your judgment in terms of sort of watching that clock like I'll be watching it as we go through the agenda.

So, we'll quickly go around the room and introduce ourselves. I want to point out that there are some members of the committee who are participating by phone for the day and a half. Eric from the Coeur d'Alene Tribe is on the phone, as well as Harry Daw who is from our Region 3 office. Region 3 out of Philadelphia is now the lead region for the pesticide program. So, sometimes folks from Region 3 might be here. Sometimes they'll be calling in when we have our meeting.

Also, Sue Crescenzi who is representing Allison Starmann from the American Chemistry Council is also on the phone today. There are also members from the public that are calling in, as well as members from public in the room.

Everybody that's on the phone, please be sure

that you put your phone on mute so we don't hear you, which would make it really hard for the meeting to go forward. Every member of the committee, after you're done speaking, be sure you turn off your mike. Otherwise, we get feedback which makes it hard for everything to work through.

So, with that, why don't I turn it over to Mark and we'll start with Mark and introduce ourselves.

DR. WHALON: Well, this is a first for me ever being first in this thing. Mark Whalon, Michigan State University. Thanks.

MS. SMITH: Cindy Baker-Smith with AMVAC. You're stuck with me, Steve, for two days. I don't have that Arizona Powerball winning ticket. One was in Arizona, but it wasn't me.

DR. KEIFER: Matt Keifer from the Marshfield National Farm Medicine Center.

MR. HANKS: Doug Hanks from the National Potato Council, Idaho.

MR. VUKICH: Good morning, Jake Vukich from DuPont Crop Protection.

MR. WEGMEYER: Tyler Wegmeyer, American Farm

Bureau, sitting in for Ken Nye.

MR. BUHLER: Wayne Buhler from North Carolina State University.

MS. LUDWIG: Gabriele Ludwig, Almond Board of California.

DR. CARLOS: Marylou Verder-Carlos, California Department of Pesticide Regulation.

MR. JACKAI: Louis Jackai, North Carolina A&T State University.

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

DR. GILDEN: Robyn Gilden, University of Maryland School of Nursing.

MR. SMITH: Steve Smith, SC Johnson.

MR. SANCHEZ: Valentin Sanchez, community worker with the Oregon Law Center.

DR. WILLETT: Mike Willett, Northwest Horticultural Council in Yakima, Washington.

MS. PALMER: Cynthia Palmer, American Bird Conservancy.

MR. MCALLISTER: Ray McAllister, CropLife

America.

DR. CLEVELAND: Cheryl Cleveland, Dow AgroSciences from Indianapolis.

DR. LAME: Marc Lame, Indiana University School of Public and Environmental Affairs.

MS. LAW: Beth Law, Consumer Specialty Products Association.

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

DR. FERENC: Sue Ferenc, Council of Producers and Distributors of Agrotechnology.

MR. COX: Darren Cox representing the US bee industry.

MS. SULLIVAN: Kristie Sullivan, Physicians Committee for Responsible Medicine.

MR. SHEEHAN: Pieter Sheehan, County of Fairfax, Commonwealth of Virginia.

MS. HERRERO: Maria Herrero, Biopesticide Industry Alliance.

MR. KUNKEL: Hi, Dan Kunkel, Associate Director, IR-4 program, sitting in for Jerry Baron.

MS. COX: Caroline Cox, Center for

Environmental Health.

MR. SCHERTZ: Scott Schertz, Schertz Aerial Service, member of NAAA.

MS. RUIZ: Virginia Ruiz, Farmworker Justice.

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

DR. KEGLEY: Susan Kegley, Pesticide Research Institute, representing Pesticide Action Network.

COLONEL GORDON: Scott Gordon, Armed Forces Pest Management Board.

MR. KASHTOCK: Mike Kashtock, Food and Drug Administration, Office of Food Safety.

DR. CALVERT: Good morning, I'm Geoff Calvert with the Centers for Disease Control and Prevention.

MS. KUNICKIS: I'm Sheryl Kunickis, USDA.

MR. JORDAN: I'm Bill Jordan, Deputy Director in the Office of Pesticide Programs.

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

MS. WISE: Louise Wise. I'm a deputy assistant administrator for OCSDP, Chemical Safety and Pollution Prevention.

MR. BRADBURY: Once again, welcome everyone, and thanks for traveling and joining us for this day and a half, and members of the public.

With that, I'm going to turn it over to Marty Monell to take on our first topic of the agenda.

MS. MONELL: Great. Behind me and on the wall there you should see slides. There's also a set in your books, if it's easier for you to make notes. As I recall, last spring we did a more comprehensive presentation on the state of the pesticide program budget. We felt it appropriate because we had endured some pretty significant cuts in 2012 budget that had been unanticipated and really came about when the budget was passed in January, which was a full quarter into the fiscal year.

So, we had to do some scrambling in order to meet our commitments, both statutory, regulatory, and areas that we felt were important priorities. But we did it. We were able to adjust, economize, and figure out ways of implementing various cost-saving initiatives so that we were able to get through the year and then fund all of our priorities.

So, this is essentially an update for you from that presentation. The first slide basically shows you for the past, for '11, '12, and thus far in '13, what the overall pesticide program budget looks like. This includes the amounts of money that we give out for the state and tribes -- that's the stag portion of the budget -- as well as the support we receive from the AA's office and so forth. It does not contain the regional components because that is not included in what we consider to be the pesticide budget. This forms the baseline for the minimum amount of appropriations that is contained in PRIA.

So, the next slide depicts actual amounts that are available to the pesticide program. You'll see the decrease that I made reference to earlier in 2012. There was about an $8.5, $9 million decrease that we needed to absorb. It was done, as I said before, through various means of -- fortunately, we always front-load contracts into the first quarter so that our core work will be funded while congress is debating budget.

Our experience has been we normally have a continuing resolution for at least the first quarter of

the fiscal year. So, it's important that we get known work funded in advance so that we're not caught short. So, through that vehicle and other exercises, there was some painful decisions about funding. There's no doubt about that. But we were able to get, as I said, the statutory work done, the high priority regulatory work done, and our payroll made.

You'll see the last bar on this graph shows what we have received thus far on the continuing resolution for 2013. If you recall, well prior to the election, congress decided that it was not going to entertain a 2013 budget battle during all of the other things that were being deliberated. So, they funded us at 50 percent of the 2012 fiscal year. So, this figure represents what we have available on the baseline.

Going forward, of course, we have no idea what it will look like. My understanding is there currently is active debating as to what the baseline ought to be for 2013. So, there's more to come, but at least we have some assurance, and have had some assurance since the beginning of the fiscal year, of where we stand for six months. So, we're able to make decisions with regard to

our extramural needs -- that's the non-payroll needs -- for the six-month period.

We're doing some planning, obviously, for the full fiscal year, but that is always subject to change at the last minute, depending upon congressional action. So, it's sort of a difficult planning process, as you might imagine, not knowing exactly what you're going to have for the full fiscal year. But we're doing the best we can and certainly going forward and funding that work which we know is mandatory that we're going to have to do regardless of the budget situation. So, that's been our approach thus far.

The next slide depicts our fee collections. Obviously, our fee -- and I'm going to talk more about PRIA, but the fee scheme is really a very important piece now for our resource picture because we have a pretty good idea what we can depend on for the fiscal year. PRIA fees obviously depend upon the number and the type of actions that are submitted to us at any given point.

But, as you will see, we've got a picture. We've got some history which can help guide us and predict what we're likely to receive in fees going

forward. So, thus far, we've only received $2 million in 2013. That's not unusual for this time in the fiscal year, number one.

Number two, because of the uncertainty of PRIA, a lot of companies decided to put their submissions in early, before the end of the fiscal year, before the potential end of PRIA, so that they would be covered by a time line. So, we received, as you can see, a big bump up in 2012 in terms of the PRIA fees. In large part, that came about as a result of uncertainty as to whether PRIA 3 would be passed. So, we had a very busy September in terms of activity.

So, we look forward to another productive year of PRIA collections. As you know, PRIA also has a component that provides for maintenance fees which help support our old chemical program. That's the review of chemicals that are already on the market.

The maintenance fees, you can see our history. By law, we have been authorized for the past five years to collect $22 million. We're pretty close for each of the previous five years. Then, with PRIA 3, we expect to be able to collect $27.8. In case you're wondering, the

bills are in the mail as of today.

So, obviously, being able to count on this amount of collections is a huge comfort to us because it enables us to plan with a little bit more certainty than we've been able to do in terms of long term with the appropriated dollars, especially for this fiscal year.

So, speaking of PRIA 3, as you know, the Pesticide Registration Improvement Extension Act of 2012, or PRIA 3 as we finally call it, was passed by the senate and the house by unanimous consent. The senate passed it on September 13th, the house passed it on September 14th, and the president signed it on September 28th, which was the Friday before the drop-dead date of October 1st. So, we really were hanging in the balance, so to speak, wondering whether or not this was going to actually get passed in a congress that was definitely an unknown entity.

The resulting legislation was because of a lot of very hard work by stakeholders, a very diverse group of stakeholders. We had industry, obviously, growers, environmentalists, and farmworker advocates that all agreed upon an appropriate piece of legislation to not

only continue PRIA but to improve upon it. As you hear some of the components, I think you will agree that we have vastly improved upon the PRIA concept.

The role of the agency in this is basically to give technical advice. We started about a year ago in the pesticide program meeting in groups to give advice to the coalition as to how we thought PRIA could be improved. You'll hear the results of that kind of work.

PRIA 3 is another five-year extension. The original act was passed in 2004. So, we're now in our third iteration. We've learned a lot. I think that kudos should be given to the pesticide program, not myself but the folks that are actually doing the work, because clearly, if we had not measured up to the intent of PRIA in terms of meeting time frames and providing good quality scientific review, et cetera, nobody would have had the interest and the desire to move this to re-enactment. So, I think that's probably our most important role, is to actually implement in a way that you all have directed us to do.

PRIA 3 expands the number of categories. Every time we go through this reauthorization, we seem to find

more types of work that ought to be covered by a time frame and a fee. So, we started with 90 in the original PRIA. We've bumped that up to 140 under PRIA 2. Now we're at 189. And that's not even all of the different types of work that this program does with regard to new registration actions.

So, it's a lot to get your arms around, number one, but it's also a lot to track. So, when you hear Oscar Morales this afternoon talking about IT enhancements, a huge piece of what we do is tracking it, is having the ability to figure out what's coming in, where does it need to go, and how can we most efficiently get the work done. So, you'll hear more about that this afternoon. But clearly, every time we have a 50-category bump up, the implications are more than just the work involved. It's how do you keep track of everything and make sure that it's running smoothly.

New to PRIA 3, some of the new categories are for inert ingredient approvals. Previously, we only had a small portion of those covered by PRIA categories. The other types of inert activities were not covered by a category; therefore, it didn't have time frames. So, we

did a lot of work with the coalition to come up with some appropriate ways of addressing the work around inert ingredients.

The SAP review, the Scientific Advisory Panel review, and the Human Subject Review panels also involves a lot of work by the pesticide program. So, we have actions that need that type of review also covered by PRIA categories. The (inaudible) petition, Gold Field Letters, those things that you rely upon so much, especially for international work, are now covered by a fee so that you can be guaranteed of when you're going to get it. It's a nominal fee, but it does at least recognize that there's work involved by the pesticide program to provide you with that.

The existing set-asides that have existed since the original PRIA and then were expanded upon in PRIA 2 are still in existence. They remain the same. There's worker protection set-asides, there's a set-aside for the applicator training for restricted use pesticides. There's a set-aside for partnership (inaudible). So, all of those types of set-aside activities remain funded.

PRIA 3 also requires an additional $5.8 million

collection in maintenance fees. This was two-fold. First, the $5 million bump up is to acknowledge the fact that all of the activities surrounding the registration review program really are quite costly. When we met with the coalition in conjunction with sort of talking about what would be an appropriate amount for maintenance fees, we updated our cost analysis of this work.

So, we had a full-day session basically walking through not only the increases in cost for our registration program, the big ticket items, new AIs and new uses, but also the increase in cost for the registration review program, in part because of implementation of the Endangered Species Act. But, just the overall programmatic costs were significant. We are on a time line under PRIA to get the first round of this review completed by 2022. So, in order to have a chance of meeting that deadline, we definitely needed to have more resources.

The $800,000 of the $5.8 is for IT set-asides. In this arena, it was recognized that since the very beginning of PRIA, there have been some enhancements to our IT abilities that have been sought by both the

registrant community and the environmentalist community. The two big ones are the ability for the registrant to be able to find out the status of their application without having to call a staff person, sort of the UPS-type approach that you could go online and figure out what the status is of your application. So, we just don't have the resources to invest in getting this done.

The same thing with conditional registrations. Our systems just aren't as well enhanced as they could be to track conditional registrations, and there is a great deal of interest in being able to do so. Find out what are the conditions of these registration actions that are taken, and what's the status of the meeting of the conditions, and so forth and so on.

So, again, we just have not had the resources to really focus on this type of work. So, the agreement was that we would do that with these enhancements. So, those first two items will be the first two that will be major activities once we start receiving the maintenance fees. As I mentioned, these particular enhancements are to be paid for out of the maintenance fees.

So, the other areas where we decided to have

some investment for ITs are the electronic submission and review of labels. This is something that this group has talked about many times, about how important it is that you be able to submit to us electronically a proposed label and that we be able to review it electronically and so forth. So, with this investment, we'll be able to move that forward in a very significant way.

We're also working with our partners in Canada, PMRA, on electronic submission of CSFs. This is important because many of you submit -- the confidential statement of formula. I'm sorry I'm so acronymed -- has to be submitted with most actions to both Canada and ourselves, as well as other countries. But, for right now, we're partnering with Canada. They have developed some technology that we're going to be able to leverage so that both countries will be able to receive the same information in the same format, agreed upon, electronically. So, we'll be using some of the IT set-aside to enable us to work on that.

Lastly, we already have an endangered species database of sorts, which we populate with species location information as we get it. The ideal is to

enhance this database and then share it more broadly across the federal government so that there is a repository of information that all of us in the federal government that have an interest and need for this information will have access to. I would assume more broadly, further down the line, this would be a web application where the public would have access as well. But, for starters, to enable us to do our work as efficiently as possible, we will be enhancing our internal database.

The other thing on the maintenance fees that I wanted to point out is that over the years, there have been some complaints that the way the maintenance fee taps a structure really wasn't fair to the small business, medium/small business community. Quite honestly, there really hadn't been an adjustment to the caps in many years. So, one of the things that we focused on -- and, apparently, the coalition in working with congressional staff was encouraged to work on -- was making it a more equitable distribution across all of the various industries so that the caps would capture a fair distribution, especially of the increase.

So, the caps for large businesses were increased. What I mean by a tap is the maximum amount of fees that a company would have to pay for their product. So, if you pay $3,500 per -- I'm just making that number up -- $3,500 per product and you had 100 products, well, there is a cap at which you would have to pay no more. The same for medium-sized businesses and small businesses. So, we adjusted them so that we would be able to collect the appropriate amount of fees, the $27.8 million, but that the caps would be adjusted such that it wouldn't impose an unfair burden on smaller businesses.

There was also an additional cap, if you will, imposed. This was also worked out between congressional folks and the coalition that provided for relief for the first product of a very, very small -- ultra small it's called in the legislation -- business that only has less than five products, less than 500 employees, and $10 million or less in gross sales. That means from all of their sales, not just pesticide sales. So, this was an effort to provide a 25 percent first product discount for those types of small businesses.

We also have new authority now to ensure that

we get clean labels. This will be a huge help to the registrant community because they will be able to go to states for their state registrations and provide a clean label which will improve that whole process, rather than the current situation which is you might get a label with comments and then you have to come back to the agency and get that situation straightened out before state will allow you to get that registration.

So, what we do now is we haven't extended the total time frame. What we've done is allow for a period of time towards the end of the time frame during which there will be a negotiation of what the final language will look like. So, say, two months before the PRIA due date, the registrant can expect to be contacted by a registering division. This, in particular, impacts the antimicrobial division and the registration division for conventionals. It doesn't really impact the biopesticide division because they already require clean labels.

So, about two weeks before, there will be a contact made saying this is what your label needs to look like. If the registrant is happy with it, we're done and you can proceed to registration. If the registrant says,

well, I'd like to talk about that a little bit or otherwise work on it, there's a 10-business day opportunity to negotiate the label language so that by the PRIA date it is done. If it's not done, then there's a discussion about whether or not it's appropriate to have a renegotiation. But the idea behind it is we want clean labels. We don't want to have to keep going back and forth with messy unclear labels. So, that's contained in the legislation.

We also have new authority for the agency to conduct a preliminary technical deficiency screen. Right now we have the statutory authority within the first 21 days to conduct a screen, but it's only to make sure that the application is complete. So, are the right forms there? Is it formatted properly? That type of screen. Quite frankly, we're able to fix most of those problems as they come in within the 21-day period. So, I think in the eight, nine years of the PRIA experience, we've probably rejected two because the application couldn't be fixed in terms of formatting.

The big issue that has come up, though, is that once the matter goes into review, it's determined that

you claim that this is substantially similar to another application. In fact, it's not even remotely. So, then a company might come back and say, well, let's try this one. No, that doesn't work either. Let's try that one. There was no sense of a beginning or an end.

That's just one example of the issues that we came up with and that led us to say, okay, we've analyzed our renegotiation situation with regard to causes behind our need to request renegotiations or, in the industry's case, your need to request us to renegotiate a date. A large part of it are problems with product chemistry, with this failure to be substantially similar, the me-too kind of situation.

We thought well, gee, if we could have for a short term action 45 days to really sort of get into the matter and determine what the deficiency might be, we could work it out and then put it into review without having to renegotiate. I mean, that's the ultimate goal here. For the longer term actions, if we could have 90 days, we could again look at it, make sure the right data is there.

I mean, oftentimes we might get a submission.

If there hasn't been a discussion with the divisional ombudsmen, then the inappropriate data or lack of data could arise. So, we wanted the ability to take a look and make sure that the right data is there, that, again, product chemistry issues were diminished, and so forth. So, we have that provision now. We have 45 days for actions that are less than six months in duration and then 90 days for actions up to a year.

The hope is that we will come up with a process that works for everyone. We don't want to have to keep negotiating due dates because that wastes everybody's time and you don't get the predictability or the registrants don't get the predictability of getting a product to market, and we waste time on inappropriate actions. So, that's the ultimate goal.

We're working with the stakeholder community, with the coalition, on criteria. Obviously, given that the bill was signed into law on September 28th to be implemented October 1st, meant that we had to put something out there how we were going to proceed. So, we've identified six areas that we believe are worthy of our looking at within that technical screen time frame.

We're working with the coalition now to sort of flesh it out. We'll be having a meeting in January, after the holidays, to sort through all this and talk about what makes sense. We've received some suggestions, actually, from some registrant groups, and we'll be working that. But this is really a big deal for us because it makes no sense for anybody to waste time on packages that are just not appropriate, that we're not able to work on and, therefore, you're not able to rely on a specific date.

So, that was a big deal for us. We also have authority now to collect data on small businesses. When the coalition was up on the Hill working with congress on this reauthorization of PRIA, we were often asked questions about well, how many businesses will be impacted if we do a tap this way, and how many businesses will be impacted if we reduce certain fees for ultra small businesses, for example? We didn't have that data. We didn't have the statutory authority to collect that data and certainly didn't have time to put an ICR out there.

So, realizing our dilemma, congress obviously

added a clause into PRIA that authorizes us to collect information about businesses, their status of small businesses, their status of ultra small businesses, the number of employees, and so forth. So, this will help everyone get a better handle on what the registrant community looks like in terms of their overall status vis-a-vis the taps and percentages for maintenance fee payments.

We have additions to our report language. As you know, now we must provide an annual report to congress and to the public on our web that provides a status of how we've implemented PRIA from year to year. Since the first year of PRIA in 2004, moving forward, it has become quite an expansive encyclopedia of the registration work. I have the honor of reading every word of it before it gets posted to the web. I start in December. They give me pieces and so forth. It's really very illuminating all of the work that is done in the course of a year by this program in terms of both the registration work and the registration review work.

So, in addition to those basic provisions of the PRIA and the annual report that's required, we now

are tasked with reporting on other areas. Obviously, we're tasked with reporting on the progress of the IT investments for which there's the $800,000 a year set-aside. So, that's a new area for us. The reports are also to include the number of applications that are rejected under this new preliminary technical screen authority that we're given, the number of applications that are rejected and the reasons therefore.

So, we'll be tracking this. We would be tracking this anyway for our internal use and for the benefit of the stakeholder community that proposed doing it this way. But now the public and congress will also have access to that information.

The environmentalist community was very interested in our increasing the openness and ability of our tracking systems vis-a-vis incident reporting. So, because our incident reporting upgrades to our system -- it's the incident data system. You may be familiar with it. It's where the 6A2 data gets reported and tracked. We've invested, I would say minimally, in upgrading that system so that it's a little bit more friendly for us to internally utilize and manipulate to get trend data,

because that's basically what you get from 6A2 reports.

You don't get a lot of very detailed information at this point. This group has been reported to before on our hopes for improving the whole incident reporting and tracking status in our program. It's not on our regulatory scheme right now. I think you're going to be hearing a little bit more about it during the course of this meeting. In any event, the agreement was that we would provide a report in the annual report on our progress towards updating the system and, as the administrator deems appropriate, our ability to make data available to the public.

Obviously, this is something that's going to require a lot of work both from the technical side and from the regulatory side. So, I think that's why they ultimately decided that the appropriate mention of the issue was to keep track of it vis-a-vis the reporting mechanism in PRIA.

The last area that we're to report on is an assessment of the public availability of summary pesticide usage data. You, I believe, have an update in your folder on sort of what we use for usage data, how we

use it, and various sources of our usage data. The interest here was to the extent possible to get usage data available to the public as well. So, we are to be just reporting on our progress, if any, in that. A lot of this data is proprietary so we don't have control over it. But some of it is available through public means. It's more limited, but it is available to the public, and we will be reporting out on that.

So, that concludes my formal presentation. Are there questions, either budget, PRIA 3?

MR. BRADBURY: Cindy, Matt?

MS. BAKER: Thanks very much, Marty. I just did kind of quick calculations to see the percentage that OPP is getting out of the total dollars. It's declined a little bit. It's not dramatic, but it's declined a little bit out of the total dollars. So, what's the implication for you guys in terms of FTE and work?

We've seen what happened with PMRA in Canada with their reductions. I think it has had some significant impacts on one, how they look at their workload and two, just the fundamental number of people who are available to do the work. What thoughts have you

guys had about potential impacts in terms of that as a result of these numbers?

MS. MONELL: Well, two things come to mind. One is that the decrease from 11 to 12 also reflects the fact that the Stag account was held harmless. That's the amount that goes to the states and tribes. That's recognizing that the states really have been very hard hit during this recession and the desire by congress and the federal government not to impose further burdens by reducing that. So, headquarters more or less had to absorb the cut. So, it's not specifically reflected there, but that was a piece of it.

The other piece is that our starting premise has been that since the pesticide program is done primarily out of headquarters -- in other words, we are the decision-making entity -- that we needed to do everything we could to protect our people, protect our payroll. So, that was sort of our threshold starting point.

Then, the next down was, well, what are we required to do by statute, by regulation, by litigation, by whatever means that were something over which we had

no discretion. So, then we covered that, if you will. And then, that which is discretionary, how can we manage it so that our highest priority discretionary work is funded, if not from previous funding, maintaining that, or through new funding to the extent it's available.

So, while we have slowed down the backfill of positions, it's not because we have made a conscious decision that payroll isn't important; it's recognizing that payroll is a significant portion of our budget. So, we've had to adjust. Yes, we have slowed down hiring, and that's essentially mandated by the agency because of this issue.

But also, we've done it in a way that recognizes that we have to get the work done and the work is done here. We can't in any way decrease the scientific approach that we use in doing our work. Nothing gets slipshod that we have to do it with the same rigor that we would if we were (inaudible). So, we manage the fee accounts in that way as well.

MS. BAKER: You don't have to do it in this meeting, but is there a site or someplace we can go to see what are the FTE impacts? I mean, you had this many

FTE in 2011 in the division and now you're projecting this.

MS. MONELL: Sure. I've got some slides from last May that we can update, sure. I'd be happy to.

MS. BAKER: Thank you.

MR. BRADBURY: Just real quick, Matt, to follow up a little bit on what Marty was talking about. Last time we met, we were sort of letting you know what was in play. We talked about a lot of activities going on in the program, not to reorganize the program but to rethink sort of how the business model works and how the staff works.

There's been five groups working on everything from information technology advancements to how do we do our science most efficiently and our risk management decision making, to how do we ensure training for the staff and when we can recruit, recruiting people that have the ability to do lots of things, and how we're working across our division to maximize our capabilities.

So, getting back to your question of how many FTEs per division, that's very important. People need to have their branch chief and their supervisor and all

those things that have to happen, but realizing that as we move forward, it's going to be a more fluid and dynamic organization where we'll be looking at what's the problem that needs to be solved and where across the organization is the best match of people, and how to ensure that our people are learning more -- everybody, me too -- learning more things so that we're better able to take on more tasks.

We may have gotten our Ph.D. in this area or our Masters degree in this area, but we're going to be learning constantly so that we can do more in any given period of time and try to smooth out the FTE utilization across the organization, managing of FTEs and increasing skill sets within everybody in the organization.

Matt.

DR. KEIFER: My question pertains to your comments about 6A2 and what you described as sort of minimal effort to improve 6A2. The biomarkers group who have been trying to increase our thinking about how we make diagnoses, how we do epidemiological research on the impact of pesticides on human health of course is focused on the tools necessary to make the diagnosis to follow

the population. That's been our effort. The receiving end of that is either 6A2 or some other form of human health surveillance system, which at the present time is extremely weak in the United States.

The closest thing we have to it is Geoff Calvert's project which is the NIASH sensor project. It doesn't cover all of the states. It probably misses a fair bit. Between 6A2 and the censor support that NIASH gets, that is effectively our surveillance system for pesticide illness in the United States.

It seems to me if we're going to realize the true promise of the 21st century toxicology model, which includes, as you recall, that outer ring which catches the illness that is induced in the general population, we have to do something about reinforcing that capability.

I just want to make it clear that I think we really need to start thinking about that, whether it's 6A2 or enhancing the system that Geoff depends upon or Geoff uses for the censor reports, it's got to be one or the other. We've just got to know that information.

MR. BRADBURY: Point well taken.

Ray and then Mark.

MR. MCALLISTER: I have several questions. I didn't understand the difference between your slides 2 and 3, one showing the LCSVP budget. Those are numbers I thought we'd heard previously as levels of funding for OPP.

MS. MONELL: Excuse me, no. Page 2 are the levels of funding for pesticide program work throughout OSCPP.

MR. MCALLISTER: And the OPP budget numbers are?

MS. MONELL: Just what this building receives.

MR. MCALLISTER: But they're considerably less than the floor level protected by PRIA.

MS. MONELL: Correct, but if you recall, Ray, in PRIA, when it describes what the minimal appropriation is, it specifically refers to the budget categories, which are included in number two.

MR. MCALLISTER: Okay. One other question regarding the ESA database you mentioned with the species location information, I assume that being shared across the federal government means that the services would be (inaudible)?

MS. MONELL: Or something like it. We're developing databases. Services already have a certain amount of databases. The goal ultimately is to share this information in one place or have access to it by everyone. But, for right now, our focus is on as we get location information, habitat information, that we would be able to store it so that we would have it for future use so we don't have to reinvent the wheel every time we have an issue.

MR. MCALLISTER: So, you're talking about receiving information in the context of registration action?

MR. BRADBURY: Ray, what we're talking about, first of all, as Marty was indicating your question is getting at, we are working towards a federal government repository of species location information, habitat location information, the characteristics of the species and the habitats. While that planning process is ongoing, we still have information in the building, so to speak, and we need to do risk assessments every day. It's starting to get better and better at taking a look at endangered species information.

So, the funds that Marty is talking about will at least ensure that the information we currently have you can get access to at our fingertips quickly so we can use the information that's currently available through the services. That will definitely be a stepping stone to a broader federal government approach to how we go forward. We're certainly not trying to recreate or redo what the services are doing, but at least be able to manage the information we currently have efficiently. That will be a stepping stone to a broader federal effort.

Mark and then Caroline.

MARK: My question also centers around the wholly issue of the use of the data that you're collecting and will now be able to collect. I'm very interested in it from a couple of points. Certainly, the endangered species part of it is critical, but also some of the use and adoption issues, particularly as it relates to IPM, for example, biopesticides and their uptake and how they're being used (inaudible). That data would be really useful in the context of prospering and growing IPM across the US, especially in specialty crops

which are so hit by maximum residue limits and export issues and things like that.

So, I wonder is there going to be a streamlining to get that data into the hands of the people who can use it and really utilize it in the context of further implementation?

MS. MONELL: Well, I don't see anyone here from BEAD. Oh, Susan is back there. Actually, Mark, if you don't mind, this question probably would be more appropriately addressed when we talk about the -- there's a fact sheet in your book about the usage data. I'm just suggesting that you just hold that thought because it's going to be an opportunity for a more robust discussion about usage data needs and appropriate ways of collecting it.

I mean, I certainly hear what you're saying, but that is not what -- I mean, it is envisioned in the reporting mechanism. What is not envisioned in PRIA is that this data will be collected.

MARK: That's what I was really afraid of.

MS. MONELL: So, it just means that you'll have to use -- we will collectively have to think about other

ways of collecting the information.

MR. BRADBURY: Caroline and then Cheryl and then we'll wrap up this session.

MS. COX: When the fees, the PRIA fees are set, is there some calculation that they're supposed to cover some percent of the cost of registering a pesticide? What's the sort of conceptual framework behind it?

MS. MONELL: The conceptual framework by the founding fathers and mothers, me being one of them, was that the cost of registering a pesticide should not exceed -- the pesticide fee should not exceed 40 percent of the cost of registering a pesticide. This was at the insistence of a lot of the NGO community in the initial PRIA discussions because there was concern, obviously, that, appearance-wise, if registrants were paying for the full cost, then there might be some expectation that they would receive some sort of a deal or whatever.

Since this statute was primarily based on the prescription drug user fee statute, PDUFA (phonetic) they call it, where I believe it's in the 90 percent range of the cost of registering a pharmaceutical or getting a pharmaceutical to the market is paid for by their user

fees, there's been a lot of criticism about that.

So, one of the sort of understandings, basic foundations of PRIA, was that the fees would not exceed 40 percent of the cost of doing the work. As it turns out, it has not come close to that. Fees pay for about a high 20 percent of the cost of the registration work.

MR. BRADBURY: Cheryl.

DR. CLEVELAND: I'm way in the corner this time. You mentioned a number of things that are a priority from an IT perspective. I see them as a bit unequal in terms of how legally binding they are. One of the things you didn't mention was the update about the web distributed labeling project that we have in our packet. What caught my eye here is that this was designed to obtain online legally valid labeling information.

So, my question is, if that's the design of this web-distributed piece, you're going to have to have some extreme attention and funding and long term support to keep this database viable and really useful. How are you setting the priorities for your IT pieces here? You've got ESA, you've got risk assessment, you've got

things that really depend on final decisions. You've also got status of application, which actually it's nice but it's not legally binding. So, how are you balancing all of this?

MS. MONELL: I obviously wasn't clear. The set-asides that are identified in PRIA with those which were decided upon by the coalition and acted upon by congress, they don't necessarily reflect the highest priorities of pesticide programs. They're certainly things that we didn't object to and believe that we can accommodate.

So, the way it worked, actually for the whole process of PRIA 3, was there were probably six workgroups identified to tackle areas around PRIA 3 that might need some attention. On these workgroups were members of all of the eight trade associations, and then, the NGO community was invited as interested, if you will. So, for instance, the group that was looking at conditional registration issues, obviously the NGO community was very interested in that.

So, when that topic came up at the IT group, they were present and certainly weighed in very heavily

on that. The result was that that's an area for IT expansion and investment of this additional PRIA funds. Those five areas again are not -- they're very important, obviously, to the overall program implementation, but they don't necessarily reflect the pesticide program's highest IT priorities.

DR. CLEVELAND: Okay, that helps. The last question is very broad. Can you explain what sequestration is going to do in terms of the budget? It's not very clear. It's in the news. I don't understand it.

MS. MONELL: Well, you know about as much as I do. Congress is wrestling with this issue. Just continue to read the paper. I mean, that's what we do. We don't have any insights. Our opinions are not asked. By law, by the sequestration law, I forgot what the act was called, but nonetheless, by law, OMB had to provide a report that basically told congress what the impacts would be on the various federal departments and agencies.

EPA was told -- this was told as an agency -- that our number is 8.2 percent. It's a public piece of information. But what we don't know and what was unclear

is, does the agency have discretion to apportion that 8.2 percent cut? What was the baseline for arriving at that percentage for EPA and other percentages, I'm sure, for other federal agencies? We don't know. I don't believe it's been agreed upon.

I think that that's sort of the threshold issue that congress is wrestling with right now. So, there's so much unknown that we're just not allowing ourselves the luxury of speculating. We're planning with what we know.

MR. BRADBURY: Okay, thanks, Marty. Why don't we take our break now. We've got a 15-minute break scheduled. So, on the clock in the room, we'll reconvene a little less than 15 minutes. At 25 minutes to the hour, we'll reconvene. Thanks, everybody.

(A brief recess was taken.)

MR. BRADBURY: Okay, folks, why don't we grab your seats. We're going to begin the next session. Our next session is a report out from the pollinator protection workgroup. Rick Keigwin and Don Brady have been helping to work with the workgroup on their efforts. So, I'm going to turn it over to Rick. Don Brady is

under the weather. I think the stress of working on this project probably put him down.

So, Rick, I'll turn it over to you to start the session. Thanks.

MR. KEIGWIN: Thanks, Steve. Just to remind everybody of the work of the pollinator group, we were formed at a PPDC about a year and a half ago. We began meeting as a workgroup back in September of 2011. I think at this point the workgroup is actually larger than the PPDC. We're upwards of 65 members. Mary Clark West (phonetic) has been doing a great job of organizing us and corralling us and getting us to the point that we're at today.

As you'll recall, the workgroup is organized around four themes, those being labeling, best management practices, communication, education, and training, and then, finally, enforcement. What you're going to hear today are some recommendations for you all to consider in terms of providing advice back to the agency in each of those four areas.

I think you'll find that there is a great bit of overlap between the four groups and the

recommendations that are coming forward. As part of these recommendations, you'll also hear from each of the presenters relative priority, understanding that some of the higher priority items still need a considerable bit more work. But there's a lot of energy from the meetings that we have been having of moving forward in each of these areas.

So, on labeling, Dave Epstein (phonetic) from USDA will be making the presentation. On best management practices, Brett Adi (phonetic) will be giving that presentation. On communication, education, and training, Wayne Buhler will be giving that. He also will be demo'ing for you a web site that he has put together that may be a way for us to communicate on many of the best management practices. Then finally, on enforcement, Darren Cox will give the report out from that group. So, let me first turn things over to Dave.

MR. EPSTEIN: All right, thank you, Rick. I was asked to speak on behalf of the labeling subgroup, which we have a couple of dozen people on this workgroup from all aspects of the stakeholder community. We've got the state lead agencies, the beekeepers, the registrants,

the commodity groups, and government personnel as well. We've had a number of conference calls. We have come to some consensus. There are things that we have largely agreed on that we have not come to consensus on. There is still, as Rick says, a whole lot of work left to do.

In terms of the labels, you can see up here our first bullet point is a need for clearer label language. That's pretty broad. What we've spoken about largely is the need to strike a balance between protecting bees and protecting crops. In terms of bees, we are working along the same lines as the EPA with their white paper in terms of using honeybees as a surrogate for all bees.

We've heard loud and clear from our commodity groups, our applicators, the beekeepers, that bee language needs to be prominent and uniform on the labels. In terms of clarifying language, there are terms that need to be defined and used consistently or they're not enforceable. We heard from the folks on our workgroup with the state lead agencies that say that currently they are often moved to use state standards where they have to make interpretations about label language.

So, what are some of the things we're talking

about there? Language such as toxic or highly toxic to honeybees. It doesn't make any difference to the applicator or the beekeeper whether it's toxic or highly toxic, but it does have meaning in terms of relation adrift with highly toxic having restrictions in terms of drift language. But it's not very clear to those who have to enforce these rules what that means.

Such things as apply early in the morning. To anybody who has ever raised a teenager knows that the meaning of morning can have many meanings, starting at noon for some. So, you can't have things on the label that are not very specific to things that can be well defined.

Actively foraging versus foraging or visiting versus actively visiting, this is some of the examples of language that is already on labels. The group is in agreement that there has to be a uniform language that is used that is consistent. Such a thing as the actively foraging question, we wrestled quite a bit with that. How do you measure that?

We talked about using crop phonology, but there are issues with that such as the glooming weeds that may

be in that crop. How do you account for that, or questions about crops that may have indeterminate bloom? So, we've come to the consensus that we need to review these terms and come up with consistent definitions.

To that extent, one of our members, Eric Johanssen (phonetic), who is with the Washington Department of Ag Pesticide Registration, went through and reviewed all of the commentary that was on the EPA web site regarding this issue. The group has come to a consensus on a number of these terms, but there's still a lot of work to go.

The second point that you see up there is the information on residual toxicity, RT25, which represents 25 percent immortality based on the SB population exposed to the formulated product that's been applied to foliage, and then the bees are exposed to it.

We have not reached consensus on how this should be on the label. There's been a lot of discussion on this. There are questions from the registrant community about it being a level playing field where data is or is not available, and how the data may be different depending on environmental conditions or geographic

regions. So, we're in agreement that we need to work on this, but we don't have the answer of how it's going to be represented on the label as of yet.

We also referred to best management practices, which you're going to hear a lot more from the best management practices workgroup. But in terms of best management practices on the label, we've had a lot of discussion about the need to talk with EPA about how we can make references in the label language to potential web sites or something that will have much more in-depth information on local best management practices, crop specific possibly, just local sources of information and how do we tie into that.

We had a lot of discussion about commercially pollinated versus noncommercially pollinated crops. Best management practices really become very important in the crops where we do not have commercially pollinated. So, those are, in very brief form, what the labeling group has talked about that's condensed from about probably 30 hours of discussion to five minutes.

MR. KEIGWIN: Thanks, Dave. What we're going to do is take questions at the end because of the

interrelated nature of the recommendations.

So, Brett will give the report out on the best management practices.

MR. ADI: Like the labeling group, we had a number of phone calls throughout the year. We developed a priority list. Best management practices are probably the fastest thing to (inaudible) to get results. Maybe one of the harder things is because it's voluntary. So, with that, we came up with a couple ideas.

First, we started (inaudible) and a lot of the land grants and the Department of Ag have done a lot of research in the best management practices -- available electronically. Some are still paper documents, but when we looked at all of the material available, we decided there's a need to have some type of national coordination to pull all this together and get it to a format where it's readily accessible.

Wayne has talked about putting together the web site with North Carolina and a database for all electronic formats. But it's still almost overwhelming all the amount of good research that's been done. Some of the research shows a benefit in the autopollinated

plants for having bees there. This is one of the things we came up with. We need to continue that research.

You'll see it's on our point number two, a subpoint, but this would probably be more directed at communication and the Department of Agriculture and EPA working together, but to bring up this overdata and make sure it's still correct and do field studies to see what the relationship is to a lot of the autopollinated plants.

For instance, there's corn. No benefit there. Soybeans, they say there's no benefit, but if you look at the old studies, 0 to 40 percent gain, sunflowers gained, canola gained, (inaudible) gained, cotton gained. We could document what the gains are by keeping the bees healthy there for that pollinated crop or autopollinated crop. BMPs are much more readily adaptive because there's a direct economic interest for the (inaudible) where the bees are usually (inaudible).

That was one of the things we came up with, that we need to have a national database and somebody to keep that up. We need to continue research on what the BMPs are and their effects and their financial returns to

the growers that don't think the bees directly benefit them.

Secondly, it's becoming a smaller and smaller world the way the bees work. They're becoming more concentrated and more mobile. So, everybody is everybody's neighbor. So, it becomes a stewardship issue to engage in the BMPs because you're keeping them for not only your neighbor but for the future yourself so you're not locked into producing one or two crops.

You may have the alternative to go and (inaudible). So, this becomes a communications and extension effort. I see the two agencies, the Department of Agriculture working hand in hand with the EPA, farm industry, and the bee industry to bring these BMPs (inaudible).

We talked about the BMPs. We have some that are just rock simple and then there are more complicated ones that are local. The rock simple ones, we can adapt these right away, but just good communication on the stewardship and keep them available as a national resource.

We've outlined I think five or six of them

here. I kind of recategorized them just a little bit. But the simplest is apply pesticides when bees are not foraging. I mean, that's the very simplest right there. The second would be avoid applying compounds where extended residue toxicity will overlap (inaudible) bloom. Very simple.

Third, and it goes right into what we're talking about in the labeling group, the RT25 is needed to be a known component there so those decisions can be made properly. Avoid drift. That's pretty obvious. Provide clean water for bees. Maybe look at it another way, do not contaminate the water. That's a real obvious simple thing we need to work towards.

Then, the last one here, and this I want to direct to everybody here, develop resistant management strategies (inaudible). We are very limited to the industry what we have available. We would encourage the USDA, the ARS to go full throttle in working on varoacides.

We would encourage the registrants, even though, by definition, the bee market is probably micro micro market, to look at the combined market, look at

what the value is without the bees being healthy. You don't have the almond crop, you don't have the apple crop, you don't have the blueberry crops. Look at the combined market as a registrant for developing varoacides. Don't look at just the bee market, but look at your full product line and combined markets.

We desperately need good compounds to keep the bees healthy. We need the EPA's help when the registrants come up with these programs to fast track them and the USDA, if it's an IR-4 program or whatever other tools you may have available, to bring that product to the market so we can have a good rotational basis to keep the bees healthy.

I think that kind of highlights my BMPs.

MR. KEIGWIN: Thanks, Brett.

Next up is Wayne Buhler. He's actually going to come up because he's going to demonstrate for us pesticideinformation.org that Wayne has been working on for quite some time now.

MR. BUHLER: Yes, thank you, Rick. I'm hoping that I can go on record as being the first free-standing presentation at a PPDC meeting, especially since this is

probably my last one.

Actually, I'm with the extension service, so I speak much better standing. I wanted to give you kind of an idea of what we're doing before I get to the web site. There's been a lot of discussion, as Paul and Brett have pointed out. This has been many hours telephonically speaking to try to come to some sort of consensus as to what we're up against or what may work best in terms of communication and education.

I remember 14 years ago when I first started my job at NC State, I attended an AAPCO meeting, American Association of Pesticide Control Officials. I was only two weeks on the job. I was completely lost in acronym speech, Marty, so I know where you all come from.

While swooning out in the lobby, I met one of my colleagues from Louisiana State University, Mary Grodner (phonetic). Mary unfortunately died just a couple months ago, so maybe as a memorial or honor of her, it's great to be able to speak about being able to bring a lot of information together for maybe one consistent message.

Mary told me this, she said, Wayne, you know

there's 50 states out there and there's 50 different ways of doing pesticide safety training. That's so true. I mean, each of us have our own programs. Each of us have probably apiculturalists that we work with at the land grant universities. So, we're not always speaking off of the same song book.

In fact, I brought with me from North Carolina a lot of the evidences, I guess you could say, of information and fact sheets and PDF files of how we are communicating to our audiences. Mostly it is a state by state kind of thing, but there are a lot of great messages that are out there. So, consolidating that may be the greatest challenge, meeting up with both what Paul and Brett have said, to have that consistent message is something that we would like to see.

In fact, I probably heard it best from one of the members of our group, that maybe we should act more like NHL referees and let these other groups duke it out, fight to the finish, and then come up with a good set of terms that everybody agrees with so that those are the ones that we can communicate most effectively.

There are some unifying messages, and there are

some ways that we do training that is consistent across the states. A lot of that is due to the work from EPA to create pre-certification types of materials, those that the pesticide applicators, whether they be a private applicator or a commercial applicator, will use to prepare for a certification exam.

Unfortunately, there's a lot of stuff to teach a person who is going to become certified as a pesticide applicator, as you can imagine. In fact, I think there's over 170 different core competency areas. So, this is just one of those 170. Unfortunately, we just have a half a page in the core manual that's designated for pollinator protection.

So, amongst other issues, I think it is important that we do provide training in this. But, more than likely, it's going to come across through continuing education or re-certification opportunities, as many states have structured their programs.

I think what we'll do is show the web site. What I'd like to do is just talk a little bit about some of the features of this site that I've been involved in creating. Fortunately, I guess I was in the right place

at the right time, because there was money that came through the Center for Integrated Pest Management, which is located on the campus of NC State University. So I was fortunate to be able to get some grant funds to start up this web site as the national coordinator.

But it is a site that is really regional in our outreach. I work closely with my colleagues from the northeast at Cornell. I've worked with colleagues at South Dakota State, Perdue, Nebraska, and in the northwest in Washington and California. So, it's really kind of a combined national effort, and I think of it kind of as a national repository or portal, if you will, to all things pesticides safety related.

I guess, Mary, you can probably come over here and tweak this a little bit. I'm going to go back to the home page for the pesticidestewardship.org site. So, those of you that are listening in at home or at your office, you can just type that in as pesticidestewardship.org.

You can see our navigation is primarily with this left frame sidebar. We've covered a lot of hot button stewardship-type issues. Of course, the most

important thing that I do, 95 percent of my time is how to teach people how to read the label. We've covered issues like calibration, disposal, drift management, handling containers.

There's one particular site for homeowners, integrated pest management, PPE, and then we get down in the Ps here with pollinator protection. We could go on with recordkeeping, resistance management, spills (trouble with audio).

So, in essence, what we've done is try to create the best of the best that is out there by putting together programs with permission from people that have already provided material. This one on protecting pollinators is actually designed from a (inaudible) publication in California. As you can see, there's many subtopics that we are addressing, which are designated by these orange squares.

The pesticide may be toxic to pollinators, so we'll describe terms like toxicity there, understanding pollinator habits, using an IPM approach, minimizing drift, cooperation and communication. There we're talking about basically how the farmer can cooperate or

communicate best with the beekeeper. We even provide contract examples from the University of Georgia and Florida, symptoms of accidental exposure, and then, lastly, resources and suggested reading.

Here is really a compilation of material that I have found to be really helpful for me, for my extension agents, or for an applicator that will call and ask for material. So, I've basically try to cobble it all together into one site, if you will. So, we have NAPSI and their fact sheets, which are excellent, Project APHIS-M, another good repository or portal to information for both beekeepers and orchardists, including BMPs for managing bees. The ZERCI society is very active, of course.

Here is the pollinator protection EPA portal for reporting bee incidences and bee kills, curists, USDA, and then, more or less, a kind of regionalization of different state fact sheets dealing again with protecting honeybees from pesticides. So, you can kind of see how that stratified from south and northeast, midwest, so on and so forth. So, again, a lot of great materials. This is just pointing to them.

Maybe the thing to do is to tease them apart and look for ways that we could actually present this so that people aren't having to thumb or read through a lot of information but really just go to this place as a one-stop shop and a portal for more information. In fact, there is more information on beehive management.

So, we do link to e-extension within the USDA, and there we have a community of practice for the pesticide environmental stewardship group, as well as one for honeybee health. So, if you'd like to learn more about just managing or husbandry of bees, then you could actually click and go into the e-extension and find a huge community of practices, apiculturalists mostly with the land grant system, that have designed and produced, I guess, a really robust web site on that.

Let me just say that this web site is just an offer. I do have long-term commitment and support for it. We also have quite a few contributors as well as editors, reviewers, supporting organizations that provide both financial support and editorial oversight. So, we think of this as being a site that would be vetted by experts and providing the best information possible while

also directing people to resources that would be helpful in this area.

MR. KEIGWIN: Thanks, Wayne.

Then, Darren is going to present recommendations coming from the enforcement subgroup.

MR. COX: Well, enforcement is an exciting topic to be able to end with. We got together and worked on this and it's kind of difficult because we're not a policing agency, but we did come up with a lot of good ideas on how we could advance risk management through enforcement strategies.

So, one, we identified there was a need for improved standardized and traceable reporting for bee kill instances. Many of the states we found out have different ways of doing things. It is an option for states to be able to forward that information up the food chain to identify traceability and corrective measures. So, that was something that came out really, really quick.

Then, portions of the subgroups recognized that EPA is currently engaged in certain activities to update or improve enforcement, some specific to bees. However,

there still remains the need for improvement in both the mechanisms for reporting -- also, what is reporting? Some states you may get more reporting than a different state. So, it's good to be able to separate that and be able to identify it.

The workgroup noted that not all states collection the same information or in the same manner. The workgroups also notes that while OPP has made efforts along these lines, there remains a lack of clear understanding of what to report and how to report the incidences.

We explored ways to get public input into FIFRA in enforcement manual and guidance development. The workgroup discussed the respect of the ongoing efforts by EPA's Office of Enforcement and Compliance Assurance. While these are good, more access by affected stakeholders would be good.

The workgroup discussed that enforcement may have rules, business, than, say, a program office like OPP. Many of the workgroup noted that knowledge that could benefit efforts by OECA is being foregone. The workgroup believes that more stakeholder input would

benefit those efforts. Then, grant guidance, making pollinator protection a priority in the EPA cooperative grant process with states.

Finally, we believe that the workgroup believes that there should be a greater support by OPP to make pollinator protection a priority for all states. One means to do this would be to include pollinator protection more directly into the grant process between EPA and states.

Before I came down here, I had a little piece of paper I found in my truck and had a good quote from Henry Swartz (phonetic). It says, whether you think you can or can't, you're right. This is kind of how we've got to approach this problem collectively on dealing with these state-lead agencies. So, we're looking forward to seeing how this progresses over the next year and a half.

MR. KEIGWIN: Thanks, Darren.

So, to wrap things up and then to begin to get your input, we wanted to just summarize where we think we are. I think you heard across pretty much all four workgroups that improving communication and getting similarity and consistency and how we community

information is critically important.

We thought one of the areas that we could first start on was BMPs because we thought we had some really good examples that were out there now. As Brett presented, we had some fairly simple things that we thought could part of some of the initial BMP information that could be made available.

Secondly is the issue about providing information regarding residual toxicity. Considerable discussion in yesterday's meeting in particular about the high value of this information but some concerns about how that information could be conveyed both in the short term and the long term. In particular, the need to put that residual toxicity information into some type of a context.

The discussion led to maybe we start in the short term to having that on a web site so that contextual aspects could be presented in a clearer manner, could bring in some discussions about influences of climate and other meteorological issues that might influence residual toxicity, leading, perhaps in the longer term, to putting that on labels once we have some

experience of how to convey that information through labeling.

Clearly, working with a variety of stakeholders was also quite important. We identified a number of groups that if we were using similar information on the BMPs, it's not just only governments, but it would be cooperative extension states through industry stewardship programs and work through NGO organizations. Darren was just presenting looking for opportunities to continue to improve EPA's guidance on pollinator protection issues and opportunities to bring public input into the formation of that policy.

Some of the longer term things would be working towards clearer label language. So, maybe we'll take somebody up on their suggestion from yesterday of letting folks duke things out like the NHL referees do and try to come up with some clear terms that everyone can understand that we can move toward putting on labels.

As I mentioned earlier, looking for opportunities once we have some experience with putting residual toxicity information on labels. Then, the group also wants to tackle not only -- now that we've

identified that, we need to have better reporting and traceability in terms of investigations, how we might go about doing that, and what are the elements that everyone should be reporting, and how do you set up a traceable system as part of an investigation.

We think that many of these activities, the four workgroups that we have operating right now, can help us achieve those goals and recommendations. We also thought that some of the recommendations that came forward today perhaps are outside of our scope or aren't necessarily recommendations solely for EPA. Clearly, that area of research, research on repellants, research on additional best management practices, probably isn't an EPA issue, per se. We would participate, but it likely would not be an EPA lead.

We also identified that while we had great participation from USDA, there may be other federal partners that we might want to include as we continue to work on these issues.

So, Steve, with that, I think I'll turn it back to you.

MR. BRADBURY: We'll go around. I'm not going

to try to go through workgroups subgroup by subgroup because, as you all mentioned, a lot of it is intertwined. But let's all be listening for tasks that we might be able to take on sooner rather than later. We can work as a group to see where it goes.

So, what we want to do now is make sure the full committee can get some clarification on some of the things you've heard about, for sure, but it's also, over the course of almost the next hour, to start to get a sense from the full committee where you think the biggest return on investment could be for specific items, realizing some are short term, some are medium term, some are longer term.

So, it's probably going to be a combination of getting some clarification. We'll be listening for that, as well as listening to emerging concepts which seem to be resonating. I'll try to synthesize as we go with my colleagues up here and then talk back and speak what I think I'm hearing back to the full group as we get near noon and see if we can start to target some specific tasks we can take on, the idea of implementing some things, though I think some things are sooner, some

things are longer.

But I want to move beyond some ideas that we could take on to starting to identify these that will start to happen and start to make some things go. So, with that, I was talking and not watching, so I may not have everybody in the right order.

Jennifer.

DR. SASS: Well, first of all, this is a really good report. I just want to say that it shows how much work was being done by the working group and all the sub-working groups. This is a hard issue and it's really a nicely written report. So, just a few comments.

You could use a little definitions in here. So, I'll just tell you what I picked up quickly from reading it. Notice 2000-X comes up on page 1, I think. It would be good maybe to have a footnote to that so that people could get a link to read it.

The honeybees, managed bees, non-Apis bees, it would be nice to have a little footnote also defining how those are understood.

The residual toxicity was a new concept for me, but it wasn't defined anywhere, including what RT25 was.

So, the presentation did it just now, but mentioning that it's 25 percent bee mortality associated with that level of residual toxicity, I believe. So, whatever the definition is, put it in, because it's not there now. That would be very helpful.

Then, the residual toxicity also, I had a question. Does it include systemics? So, I'll put that out. I have a few more things, so I'll just have that question there. Is that part of residual toxicity? I couldn't tell.

Then, I like the part where you guys were looking at reducing dust drift and you were thinking about the seed dressing. So, I wondered if there was another comment you wanted to make on that to flush that out. But anyway, I liked that you were looking at that because that's important.

Then, also I like that you were thinking about reserve land, making sure that it's not treated with pesticides. I think that's all my comments. Thank you very much. Good work.

MR. BRADBURY: Thanks, Jennifer.

Marc Lame and then Mark Whalon.

DR. LAME: A couple of general questions. One has to do with an assumption and the other one with a suggestion, but they're both questions.

First of all, I assume, based on what I've heard and in talking with folks and reading, that there are differences in state-lead agencies with regard to education and enforcement when it comes to incidents. So, I was wondering how that might be addressed.

The second question is, has the agency put on a PREP, which is a pesticide regulator education program, for the state-lead agencies with regard to pollinator protection?

UNIDENTIFIED MALE: So, regarding the first part, our EPA office in region 5 in Chicago has actually been taking the lead on developing some investigation guidance that is in development now. The plan would be that that would then become national guidance for all regions and all states to use as part of a bee kill investigation. That was what we were alluding to in terms of some of the guidance that's under development.

Regarding the PREP courses, it's interesting that you bring that up because that also came up during

our workgroup meetings yesterday. In fact, as part of two of the PREP courses that are planned for 2013, there are pollinator protection components. For one of them, I think it's one day and for the second one I think it's a two-day of a five-day session that will be devoted to training state regulatory staff on pollinator protection.

DR. SASS: I forgot PREP isn't defined as well in here, and BMPs aren't defined, the best management practices. It's used in the title of that section but it's not used where the acronym is used. So, I couldn't find it. I was really searching for it when I was reading it.

MR. BRADBURY: Mark Whalon and then Cindy Baker.

DR. WHALON: I sat in on this meeting yesterday and have done some background work earlier for a talk I gave to this group, to the bee keeping group. It struck me that perhaps a tool had been overlooked in this process. That is the whole area of system science or system analysis.

You have a multifaceted mortality and survivability process going on with bees in the

complexity of a background that's changing very rapidly in terms of pesticide makeup of agriculture and speciality crops, in particular.

I think about all the viruses, the verroa issues, those pesticides and their changes, the movement and management of bees, the queen longevity, and some of the problems associated with that, IPM and its changing that are interactive effects of site by site insecticide, fungicide interactions, the genetics and the history of genetics in bees and integression of wild genes, et cetera, for some bee producers. I think about our investment in USDA and bee labs and research. Yet, I don't see any systems approach to this issue.

I think it's a real significant oversight that we can't come together in a systems model to try to understand all of these factors and focus on where that may lead us in terms of where we ought to invest first and fastest in order to do something for bees and beekeepers as vital as they are to all of this nation and the food in general.

So, I would encourage some kind of outcome out of this process that would look in that direction and

that would specifically develop resources to take that on, because this is too complex to do it piecemeal.

MR. BRADBURY: Cindy and then Caroline.

MS. BAKER: Thanks, Steve. I would just like to build a little bit on Jennifer's opening comment about the success of this workgroup. I've sat on a number of PPDC workgroups and I think that this workgroup has been extraordinarily successful. I think it's really because people have put in a ton of time.

We've had calls and people calling from vacation, EPA people included. Really, I think people have rolled up their sleeves and tried to come to some solutions. So, I think that's why you see some real specific things about we think we can go forward with some things there.

I just had a couple of comments that I don't think have been made by anybody yet. On the best management practices side, I think we need to solicit some more engagement from some other commodity groups to get in and be engaged in this. I think we have basic principles that were laid out today that I think are generally very supported.

But people like corn growers and soybeans and some of the other crops that don't think they're affected but are affected I think really need to get involved as we work through these best management practice plans. Plans will only be successful if people buy into them and use them. They're more apt to buy into them and use them, I think, if they're involved in the development of them. So, I think that we should broaden the outreach a little bit as we try to get the content right on those best management plans.

I think some other specific recommendations is I think SFYREG should form a workgroup to deal with this. I think that SFYREG is meeting in early December. I think having input from those state-lead agencies and active involvement with them and the other stakeholders is really critical because the states play a huge role in this particular issue.

So, EPA laying out some good guidance and working through a week is good, but the states need to get bought into this and raise where are their limitations in terms of resources or training materials or whatever so that they can be addressed.

We had someone representing OECA on our workgroup meeting yesterday. I think to the extent they can, I think if you guys can weigh in with your counterparts there about opening up that process to get stakeholder input, what comes out will be a lot better. Right now, the beekeepers have not been engaged in that discussion, and I think there's a lot of valuable input from them and other stakeholders that could make that process a lot better.

Then, lastly, the work that region 5 is doing, I would put the same information into that. To the extent that they can start engaging with this workgroup or the SFYREG workgroup or others to get some input, I think that would be really good. A lot of thought has been put into what would be successful, and I think they would benefit from that information.

MR. BRADBURY: Thanks, Cindy.

Caroline and then Virginia.

MS. COX: I am not part of this workgroup, but, like everybody else, I'm really impressed by the amount of work and the quality of the work and all that. It is amazing to see a group that big make this much progress.

But I do have one concern that I wanted to share.

It seems like the focus -- well, I guess I have two concerns, actually. The first one is that it seems that the focus of the workgroup has been on bee kills, which are very important and I understand why you're focusing on that. But I think there also needs to be some discussion about more chronic effects on bees. Maybe you guys have talked about that and it's just not reflected in this report, but I would really encourage the workgroup to take that up really seriously.

Then, the other thing is, I was thinking about the incident reporting and the guidance for how to do an investigation of a bee kill. It strikes me that we need that not just for bees but, hey, people, and frogs, and everything else. I think it's really important to have it for bees. It's probably most important to have it for people. But I don't know if those guidances can be generalized. But certainly the reporting systems could be generally for incidents and illnesses, not just bee kills.

MR. BRADBURY: Thanks.

Virginia and then Cheryl.

MS. RUIZ: Following on that note, can you talk a little bit about what the current system is for incident reporting?

UNIDENTIFIED MALE: There are a couple of different vehicles that we have. There is an ability on the EPA pesticides web site right now where people can click on a link and it will allow people to submit information that way. There's also an ability to submit information through NPIC (phonetic) and there's a portal on NPIC to submit information. Then, we know people have been calling us directly and then will complete the information.

I think part of the discussion that the workgroup started to have yesterday is, are we collecting the right information as part of that. There's probably some standardization that could occur across those and some enhancements that could be done. There's probably some better, for lack of a better term, marketing that we could do about how to submit that information. I think there's still some confusion on how to actually submit the information.

So, those are two of the areas that I think the

workgroup will start to focus on.

MS. RUIZ: As a follow up, is there any sort of mandatory reporting or anything like that in the states?

UNIDENTIFIED MALE: Obviously, 6A2 related information would need to be submitted. Then, at a state level, states have different requirements. Different states, I know, have bee rules. But there is some differences across states on what's required to be reported at a state level.

MR. BRADBURY: Cheryl and then Darren.

DR. CLEVELAND: So, listening to some of the workgroup discussions yesterday, it's very clear that there's still a lot of concern about the way that the RT25 is going to be interpreted. That comes down to the fact that it's a true screening assessment. It's hazard versus putting it into context. It's hazard putting it into context with risk assessment.

So, I wonder if this -- I guess it falls under the labeling group -- if there is an effort to go forward and hash out how the details of this are going to be handled, maybe a subteam, a working group. I don't quite understand how that's going to go, but that was one piece

that I picked up that's not really completely resolved.

The other thing has to do with enforcement. It's good that we've gotten as far as we have, but there's a lot of issues still here. One of the things that I would say is there needs to be continued input. I would reiterate Cindy's comment, let some transparency into the enforcement.

Mainly, you heard a number of stakeholders yesterday react that they'd like to have some input in that process. Registrants, in particular, have some expertise in investigative processes. We have a vested interest in understanding when there is a bee kill, we're probably the last to be invited to the table when you think about that. You're thinking state agencies and growers, but there is a place for registrants to be engaged as well. So, I'd like to make that comment.

MR. BRADBURY: Thanks.

Darren and then Scott.

MR. COX: I'd like to add that the bee industry and the registrants have really been able to come out of their corners and work good as a collaborative effort to address this. I'd like to thank everybody involved with

that.

One good example is the cedars with (inaudible) planting the seeds. We identified a quick way to jump on that as a solution and get it fixed. It's already being implemented. I would suggest as we go along this route and we find things that can be quickly assessed and remedied, let's work on it. As we get into the drift reduction technologies and we find something that can mitigate the risk, have an avenue to where it can be streamlined to where it hits (inaudible) the farmer and the beekeeper to where it can have an affect this year instead of five years from now.

There's other technologies. As we start going down this road and we identify how to do enforcement, there's going to be a lot of pushback from applicators that say, geez, we can't do everything at night. It's almost to the point where we need to be looking at ideas on how we can advance the science and to advance risk management through improving these technologies and saying, okay, what can be changed or put a think tank involved in it.

There's emerging GPS technologies that could

aid in facilitating that. So, I guess we've got to start trying to think outside of the box on it. Integrated (inaudible) management strategies, that's another thing that the bee industry has looked at. We know we're not the cattle industry, the sheep industry, and our bees don't eat grass, but there's got to be some place for pollinator habitat to be able to grow and flourish in the United States. Thank you.

MR. BRADBURY: Thanks, Darren.

Scott and Luis.

MR. SCHERTZ: To reinforce a few of the comments. One, probably the biggest one, is many of the subjects around this table we come back to enforcement. I think realistically the state-lead agencies have a very full plate and typically declining budgets, et cetera, so we do have to be somewhat realistic on that. I don't think that's a silver bullet, but obviously improvements can be made.

Also, this focus has been on pesticides, but there are definitely other issues, particularly habitat and beekeeper responsibilities that probably enter back into -- I believe it was Mark's comments as far as a

systems approach. There probably are big opportunities with the movements on cover crops. That's a definite place for collaboration with the SBA and NRS, et cetera.

Also, there is a real need to protect crops even during pollination. We have to have that available. Like Cindy's comments, there really has probably been a lack of engagement by many of the major commodity groups because they haven't thought that they were potentially effective.

So, those are just a few comments to around this out.

MR. BRADBURY: Luis and then Cynthia.

MR. JACKAI: Yes, I'd like to add my voice to everyone who thinks that this is a (inaudible) because it is, in particular the (inaudible) web site. Wayne has worked on it. I've used it a number of times, and it's extremely useful and helpful.

I had a concern with the incident reporting. We probably need some clarification on whether it's self reporting or (inaudible), because that needs to be clarified. The other point is, if it's not self reporting, what is in place to enforce some kind of --

well, if somebody does a self report, what happens and how do you do that?

In the same way, the RT25, I've been thinking how easy it would be to enforce that. If you consider a case where a grower is using a chemical because that's the best for his crop, but it doesn't really meet the RT25 requirement, so actually the bees are going to be exposed to it.

On the one hand, he's using it in compliance with the requirements for his crop. On the other hand, it's violating another set of requirements. How is that going to be enforced? So, enforcement is going to be a little tricky. I would like to hear your comment on that.

UNIDENTIFIED MALE: I'll start and then others may want to chime in. On the reporting piece, registrants, when they get information about incidents, have an obligation under FIFRA section 682, the adverse effects of reporting provisions of FIFRA, to submit that information to EPA. So, that's the mandatory piece of it.

What we've made available, both through the

pesticides web site and working with our partners at NPIC, are voluntary reporting systems for others to submit information to us about incidents occurring. So, the workgroup is really going to be more focused, I think, on the mechanisms for the voluntary reporting. There is a broader group that's working on incident reporting generally, and we could probably link up with them for the pollinator specific issues.

Regarding the RT25, one concept that we have discussed, because of the very complex issue that you raised, was until we sort of figure out how to best convey the information and put it on labels and perhaps make it a mandatory provision on labels, is to just make that information available.

So, one concept that we have been discussing is having a web site on the pesticide page similar to the aquatic life benchmarks that we've made available or the human health benchmarks for pesticides that we in the Office of Groundwater and Drinking Water launched in the past year that are essentially advisory levels to make people aware of -- so, to the extent to which they are going to make a decision on which type of product to use

based upon its residual toxicity, they would have that information available in all one place.

There was a great bit of concern discussed during yesterday's workgroup meeting about putting that information on labels today, in part because of some of the diversity of data that's available or not available and some level playing field issues that some labels might have it and some might not.

There was a timing of implementation issue expressed in that in the short term while we're figuring out how to best convey this information, if the RT25 information across a broader set of active ingredients and products was available on a single web site, that might be an easier mechanism for conveying the information.

What you raised were some of the very issues that the workgroup was struggling with even yesterday. So, thank you.

MS. PALMER: Cynthia Palmer, American Bird Conversancy. I would second the feeling that this group has made a tremendous effort in the workgroup. As Caroline Cox was mentioning, I think that we do need an

expanded view of protecting pollinators, pollinators including birds, including bats, including other organisms.

The American Bird Conservancy is particularly concerned about the red flags raised by some of the products that are being used in terms of their persistence, their systemic application, their quasi-permanent findings to cholinergic receptors. We are undertaking a major assessment of aquatic toxicity, looking at invertebrates, also, of course, looking at the effects on birds.

So, this is just a placeholder to say stay tuned for the next meeting. We should have more results, hopefully, by January.

MR. BRADBURY: Go ahead, Douglas.

MR. HANKS: Just as a producer point of view, I hope that the risk of bees versus agricultural is always taken into relevancy. I'd hate to say that Al Gore was right, we are seeing warmer weather in the Pacific Northwest. Mites are being a problem. So, we're having to control them also more.

Second, be in tune with NRCS for each

opportunities for the bees. Then, enforcement, I think that there should be a definition in the bee kill of are they honey pollinators, are they wild bees that are being killed. Is that a definition in the enforcement process?

UNIDENTIFIED MALE: Doug, I would hope it's never a case of bees versus agriculture. We view ourselves as an integrated part of agriculture, so we don't want it to be bees versus agriculture. We're agriculture's partner here. We're here to serve agriculture. I just want to make that point clear. We don't want to be bees versus agriculture. We are agriculture.

MR. BRADBURY: I've got a question for the labeling group. It seems simple, but then it gets hard. Foraging versus aquaforaging, things like that. It seems like the group may have started -- I wasn't sure. At one point it seemed like in the conversation that maybe there was some consensus revolving around certain phrases. Then, I also heard the National Hockey League analogy as well.

So, if could you expand a little bit on sort of was the universe getting in shape or there are some

things that seem easier than others?

UNIDENTIFIED MALE: Well, I'll make an attempt at this and then others who are on that workgroup can chime in as well. I would say yes, we can make significant progress on this. We've been trying to boil big issues down to little issues that can be addressed directly. When it comes to terminology, I tried to kind of give some examples, like with the foraging and the various parameters that have to be looked at to determine what that means.

I think that these are questions that consensus can be developed on, but we haven't gotten to the point where we are directly addressing the individual terms yet.

Marylou, do you want to take a shot at that?

MS. VERDER: I agree with Dave. We had actually discussed some very specific ones like visiting and actively visiting. Then, there's all other factors that the other stakeholders had brought in that we didn't think about at that point.

So, my proposition would be that when we have our next meeting, to have very specific agenda items.

Okay, Dave will discuss visiting and actively visiting and what are we going to (inaudible) these circumstances on. I think that's the halfway that yesterday we had reached that we are going to continue to talk about the labeling issues because otherwise it's very vague. So, we're going to have more specific items to think about.

UNIDENTIFIED MALE: I think that this FACA gives direction to us on where we should focus. I think we can get it done.

MR. BRADBURY: Cindy.

MS. BAKER: I would just add one further comment to that, Steve. I think the fast consensus that we could come to in the labeling subgroups are what are the phrases that need more explanation. The challenge was as we started digging into each one of those, there's such a heavy component of other stakeholders and the enforcement overshadowing piece that isn't completely worked out that we keep getting bogged down there.

So, the workgroup I think would be able to make more progress, as Marylou said, if it was more narrowly focused on just doing that.

MR. BRADBURY: Jennifer and then Susan.

DR. SASS: I just wonder again about the systemics. Are they included in the residual toxicity?

MR. BRADBURY: I'll make sure that my answer is correct after lunch, but I believe the answer is no. It's based on surface contact, a lot of exposure in toxicity.

UNIDENTIFIED FEMALE: I just picked up the guideline for that study; it's a spray.

SUSAN: I just wanted to add that not that the spray drift notice should be a model for efficiency, but at least --

MR. BRADBURY: Well, to be fair, you all were pretty darn good (inaudible).

SUSAN: So, the really great thing about what happened with that was that there was a guidance that went along with it that explained what you meant by where it might be a problem or other things. So, this is where you might be able to expand on what the label language means in the absence of actually being able to change it quickly.

So, I'm kind of interested in seeing something happen before all the bees actually die. That may be a

way forward that describes what's meant, what EPA means by those label words.

MR. BRADBURY: So, I'm going to kind of do the part where I'm trying to synthesize and then share what my brain is trying to put together, and then see if generally the committee is on board. I think I'm picking up from what Marylou was describing and Dave was describing and Cindy where that group is starting to see the next step. So, hopefully, this is pretty logical.

Picking up a little bit of what Susan said is part of the task at hand, which would be -- I don't think the full committee has to do it but trust the workgroup -- find that universe of phrases that you think are the most critical to get on with first, as you look across the label. Start to work towards, as best you can, consensus is great or different variations, if you can't reach a consensus, on how to stabilize the meaning behind the words you're seeing right now on the label. Active foraging versus foraging is one example.

I think Susan's observation may be helpful as part of that process to see where maybe there is a suite of words that work by understanding what was meant behind

foraging versus active foraging and things like that.

So, without getting too refined to give the workgroup the freedom to fine tune what their next steps would be, but it would be to have this workgroup to find that universe of phrases that isn't so big that you can't get anything done but a small enough set that seem to be critical words that could really make a difference.

Try to document the intent behind those words as best you can. Folks from EPA and up can help that history. Then, see if you can start to propose clarity. It may be the first thing to do is something Susan suggested, maybe just get a document together and describe what's intended by the words and then maybe actually coming up with a proposal to what those new words should be.

I think if you can come up with a small enough list so when we meet six months from now, I would like to see, to the extent possible, maybe there's a list of five phrases and we didn't get to all five, but for the first two, here's our recommendations to the full committee on how to resolve the first two sets of phrases.

If there isn't consensus, that's okay, too. At

least give us sort of what the range of options are in terms of those first two phrases or all five. Again, two and five, don't take me literally, but I do think if you give more than five, you're not going to get anything done. With two or three, you might make some progress.

With that attempt to try to synthesize one aspect of the conversation, I don't need everybody to put up your name, but if some folks think that's a really dumb idea, let's hear about that. Otherwise, I'm going to assume the group thinks that's a reasonable task for the workgroup to take on.

UNIDENTIFIED FEMALE: No, don't do it.

MR. BRADBURY: Marylou and Dave, you should speak up as well. I'm asking for feedback. It was more like feedback that was in the realm of no, don't do it versus feedback -- I'm just looking at the first workgroup with the labeling workgroup so that we can define a more narrow task for the labeling group. We'll go to the other workgroups in a second.

UNIDENTIFIED MALE: I think it's a good idea. I think we can accomplish it and within a defined time frame here of half a year, no problem.

MR. BRADBURY: Jennifer, I just meant that first workgroup to try to come up with a specific task for that first group.

So, that will be one task, that we get more specific for six months from now.

BMPs, while they came back to Mark's system ecology, clearly these four groups are intertwined. I am trying to bite off half. We can start the half and then we've got to work for synergy and integration.

So, one question I had on BMPs, I think the group did a nice job of describing what's good out there. There's lots of information, and there's different entities like North Carolina State that are providing ways to get at it. But this does seem like a hyperspace in terms of organizations that have information and different kinds of groups that might want to get at the information.

The part that was still fuzzy to me is to what extent can EPA to advice from the PPDC help try to gain focus to the resources that are being invested? I don't think I'm saying it the right way, but a thousand flowers are blooming and that's good, but are there some flowers

and some prairies that we should be concentrating on? That was a part I was trying to hear, but I'm not sure if I've heard it.

Go ahead, Gabriele.

MS. LUDWIG: That's probably going to be a surprise, but one thing that did get talked about and I didn't think it really came out in the comments here was the DSAR or the idea that you really need someone to help coordinate all of this. So, the question is, we don't really know where that belongs, but you need someone who works with the grower groups to get the MPs into whatever the cumulative site is. You need someone who can help reach out to groups to say this information is available.

So, if you're asking point blank, that's what we would say, is we need actually a human resource somehow to help make all of this happen.

MR. BRADBURY: Cindy.

MS. BAKER: I would say, Steve, in my mind there's two steps here. One is could we finalize some content that could be shared through multiple vehicles today that would help improve things that are going on in the way of best management practices.

Second is more to Gabriele's point. As multiple agencies get involved, and that's what that red circle, I think, was intended to show, around the areas of habitat, around the areas of what commodity groups and applicators and registrants and state regulators can do, I think that's the second bigger effort where you could put probably more ideas into best management practices with the involvement and interaction and support in resources from some other agencies.

UNIDENTIFIED MALE: One suggestion might be on the best management practices and enforcement fact sheets is you have EPA regional directors that can help disseminate and educate states and universities and all that. That might be a suggestion also.

UNIDENTIFIED MALE: About a month ago, Dr. Epstein, Cheryl, USDA, held an industry workgroup for bees, researchers, and this same thing came up. We do have a lot of good information. We just need a way of communicating out to the grower groups. So, I see an underlying theme. I just encourage both USDA and EPA to work on this.

I know the funding is short, but we do really

need, for lack of a better term, a national bee extension person to go out to the grower groups and keep them current. Everybody has a whole plate full of stuff when they're dealing with their own specific commodity. We need to keep bees in their mindset, the importance of them.

So, I would encourage both agencies to work towards a type of extension position that's proactive that goes out to different grower groups.

MR. BRADBURY: Let me try to do a synthesis here. One activity that will happen is EPA pesticide program will make a commitment today to work with USDA as the two most significant parts of this right now in terms of the federal government in terms of what I think is the person or the entity that's got to start to figure out how do we come up with a strategic plan and a way to bring the information together and then get it out to multiple portals.

So, we'll make a commitment working with Cheryl and colleagues of USDA to identify that node that can start to help make this happen through the land grants, through extensions, things we probably don't even know

about that USDA knows about so we get that clarity.

Then, I think the second task at hand would be the workgroup feels like it has the right spread of expertise or can tap into additional expertises to start, if you haven't already, to identify these are BMPs that we think are nationally applicable or regionally applicable, but to what extent do we start to really make sure it's not just doing a Google search and getting all sorts of stuff up, but you're getting pointed to the things that may be most apropos to the situation that we're dealing with.

I think if the workgroups could report out in six months sort of where that focus needs to be. At the same time, before that six months is over, we'll make sure there's a federal point of contact, an organization within the federal family that can start to help in that dialogue to get to that point. Is that making sense, that latter part?

What's the strategy for helping people get to where this node is going to be? I think that's a good next step. But I think in the next six months, if we can have established in the federal government where's the

entity that's going to help make this happen and starting to get clarity on the information that we think is really high priority first in getting organized and sorted out, then I think we'll be ready to start the process of how can we advance our outreach.

If you guys can get all that done in three months, then you've got three months of sitting around. You can start working on the strategy of how to get the outreach going. So, the first two tasks and then I think Bill has got a good point, it has to happen. But I don't want that to get in front of the information (inaudible).

I had one other thought on the BMPs. There have been discussions today and prior to today about how -- a colleague this morning, before the meeting started, talked about how a corn grower or soybean grower is actually the neighbor of the almond grower because those bees are associated with the corn and soybean fields in the midwest at a certain part of the year and then those same bees are going to the almond growers to help with the pollination of the almond growers. So, in fact, the quality of the environment for those bees while they're in the midwest is very highly connected to the

productivity of those bees when they're in the almond groves or other places in the country.

I think Cindy and others mentioned the importance of getting some of the other commodity groups to be at the table. If some of the BMPs are designed to ensure good pollinator services, then one part of the country and part of that hinges on best management practices in a different part of the country. If the folks aren't talking together, then we're like trains passing in the night and not get the impact that we want.

So, definitely be working with the USDA in reaching out to other commodity groups. But there are members of the PPDC that I think can probably help us doing that, the Farm Bureau, others that -- I'm kind of looking to you all in the northwest to help us reach across the various commodity groups so that we've got that kind of input.

Gabriele.

MS. LUDWIG: I just want to say that to some extent some of us have been trying to do that. With all the range of issues, especially with farm bill, you're not going to get the time of day from some of those

groups. So, until that's resolved --

I think the other thing to put in there in that mix -- and I don't know enough about this -- but the beekeepers have been raising the issue that we do have pest management on nonagricultural land that's having an impact. Bringing in some flares from that arena for that discussion on best management practices would be useful.

MR. BRADBURY: Okay, thanks. So, we've got the first two tasks. Part of it is the federal government to help define that node in the federal government to help the workgroups starting to hone in on the first suite of consistent messages that can be in the system. Spend some time, if there's time, to start thinking about the outreach strategy.

Then, EPA and USDA probably reaching out to some members of the PPDC to figure out how to get to commodity or other land management entities to bring them around the table. I appreciate everybody has got too much to do, but I think it's really important that we reach out some more.

MS. LUDWIG: And I just realized that could be someone like from Aphis or BLM might be a starting point

for that.

MR. BRADBURY: Can help to get the connections, right.

DR. CLEVELAND: One idea is we did this with resistence. We had what's called the Federal IPM Coordinating Committee. As an extension of that, we invited all of the federal agencies that had resistence or pest management responsibility. We had a meeting, I believe it was last May, here in Washington. We've got a meeting coming up on December 12th. We haven't got our agenda complete.

We can have the issue of pollinators brought up at this meeting. It would be, I think, a really good starting point, same with resistence, all of the different agencies. These could be non-ag agencies. A lot of my colleagues at the table here are part of that federal IPM coordinating committee, but certainly we can bring the issue of pollinators and how they're working to protect them at this meeting in December.

MR. BRADBURY: Thanks, Cheryl. So, the BMP communication, we've sort of got to focus there. I want to turn to the enforcement area. Again, try to

synthesize and get feedback so we can go forward.

During the report out, I think it became clear there are things going on in region 5 with them sort of taking a leadership role with the states in region 5 to start working on some enforcement guidance. That hasn't necessarily been plugged in to some other work that we're doing here at PPDC. I mean, it hasn't been completely divorced, but it's probably not formally hooked up.

There's clearly been discussions with SFYREG, generally on pollinator protection and issues that need to go, but it hasn't necessarily been a real formal plug-in. Mark brought up, or I think somebody brought up, funding in terms of the state grants in the out years. That conversation actually is going on in terms of state guidance as we do our two year out fiscal planning.

So, on the one hand, it seems to be the pieces are there. It's making sure they get plugged in the right way. In particular, how do you get stakeholder input into some of these evolving enforcement guidance manuals or some of the tracking systems that could evolve.

So, what I'd like to propose on that one is that we in EPA will take the responsibility to make sure that the different parts of EPA that are in play on this are getting their act together in terms of getting something bigger than the sum of the parts. Then, with that, be able to reach back out to this workgroup as our node to make sure everybody knows when key events are happening, in process, so that we can get some of the diverse stakeholder engagement going on.

So, the workgroup is starting to think about what would be the first two, three, four messages you think are really important to get into, say, the first draft version of the enforcement guidance or new ideas about how to develop a better tracking system, for instance, so that once we sort of get a venue set up where this dialogue can happen, you're ready to provide some of the input, even if it's lots of different input, because there's going to have to be consensus, but it's just organized so we can be efficient and move forward with that input.

We'll figure out ways to make sure the workgroup isn't running off without the full pieces.

We'll figure out ways to keep everybody informed that the timing is such that things can happen sooner rather than later. Maybe if there's a meeting happening in a couple of months and there's six months until we meet, we can at least make sure that group knows we're starting to consolidate.

In the future, you're going to be hearing some ideas from the PPDC to help on some of that feedback so that the entities are getting across -- at least get them on notice that that's coming down the line. Some of these things are happening. I don't want to stop them from happening, but I want to make sure when they get to the right stage, we can get the input into these groups before the things get cooked, so to speak.

UNIDENTIFIED FEMALE: I think our impression yesterday was that OECA wasn't soliciting input but they would take it if we gave it to them. There were things that they needed to do that we don't have any way to control.

MR. BRADBURY: So, what I'm saying is that the pesticide program will take the responsibility to organize the EPA family to help ensure that appropriate

connections are getting made to the processes that are evolving.

UNIDENTIFIED FEMALE: Can you just go back over the list of exactly what you want us to detail on the enforcement side?

MR. BRADBURY: Well, I don't know. All I know is that the workgroup reported out that it's really important that a diverse range of stakeholders have the ability to provide some thoughts to the people drafting these enforcement guidance and education tools from registrants, to beekeepers, to commodity groups.

I don't know what it is that you guys are all thinking about, but to the extent that you've already got them written down, then just have them ready to go so that once we can find the first time to have some dialogue, we won't pitch it as the full PPDC's recommendation, but at least we can pitch it as some ideas that are emerging as the PPDC starts to get their head around it. So, it's mostly just a workgroup to the extent you've already consolidated your top three and then your next three and then your next three, you're done.

If you still need to talk that through, start doing that so that once we can get the venue set up, we can start sharing with them, at least conceptually, the issue that we think are really important to focus on. I don't know what they are. I'm not going to judge what they are. I'm asking the group to do that part.

I'm the fault now for not keeping on the clock, but there was one last piece of this one that EPA could use some advice on. It's the incident reporting. I realize there's some different aspects to that phrase. Some of it could be an incident reporting system that's helping enforcement people track what's the status of an incident that's being evaluated and what did you learn and how do you make sure others, if they run into that scenario, can learn from that and not reinvent the wheel.

Also, the incident reporting not in the context of the 6A2 but of beekeeper or grower or anybody observing something that that doesn't seem right, and how do you get the information into EPA so that we can take a look at it and figure out what to do with it.

We've got Oregon State portal, we've got an EPA

portal, but this isn't the first time I've heard in meetings with folks that nobody knows this exists. People don't know how to use it. Maybe people don't trust it. There's a whole variety of things. So, what I could use and the program could use is some feedback from the workgroup on what is the barrier or barriers that are keeping people from knowing those portals exist?

Is it that people know the portal exists but it's God awful complicated to put information in so they just tune out and they don't bother to do it? Or, they're afraid that the information could be used in a certain way, so, therefore, they're adverse to providing information. We need some input as to why is it that people either don't know about these sites or can't use the sites or don't want to use the sites so we can work on that so that something can happen.

I don't think building a third web portal is a solution. I think it's trying to figure out why is it that these portals aren't trusted or are too hard to use or maybe nobody knows about them. What do we need to do so that people know about them? I'm not trying to prejudge what the problem is, but we need better problem

definitions so we can try to solve that problem.

Darren.

MR. COX: I would say right off the bat there needs to be a level of trust rebuilt between your state-lead agencies and your beekeeping communities. I mean, beekeepers have operated under a fear of retaliation in many cases for reporting. So, historically, they will just absorb the loss when they can and then they shift to California and they don't get the bees to the almonds so they absorb the loss.

So, if we could get better interaction right down to the individual counties to work with the beekeepers to report -- because many of the beekeepers don't have GPS coordinate sites. It's the bee yard that got sprayed over behind the barn five miles away from their shop. I mean, they have no idea what pesticide it was that was used. In many cases, it goes back to it being extremely problematic with your state-lead agencies because they have no idea who sprayed what where when and why if you don't have proper usage reporting.

So, it's almost like you need to put together an effort with California where they do have some form of

traceability for usage reporting. I'm not trying to push usage reporting here, but somehow to be able to educate the beekeeper for calling in to somebody to assist them with how to explain filling it out.

Most beekeepers, they're not going to be able to pull out a laptop, even though some of us are proficient with that, that we don't carry iPhones. I know beekeepers who don't even have cell phones. So, it's trying to advance old school technologies and reporting in new school technologies. We really need assistance of your land grant universities and your extensions and your state-lead agencies to facilitate that information.

MR. BRADBURY: That was very helpful. It will be that kind of work in the workgroup. Maybe Darren's idea is, bam, that's it, but it would be helpful to have that workgroup spend a little time building on that introduction that Darren just provided so we can then start to figure out what do we need to do to enhance the ability of people to get information. That would be the other task I'd like the enforcement group to take on. Unless somebody thinks it's a really bad idea, that will

be sort of the domain of that group to take on, the enforcement group.

I know Rick has been taking notes. I've been trying to take notes. We'll make sure tomorrow when we sort of summarize everything, that we've captured the tasks at hand. I think if the workgroups feel like they're up to it, I think we've narrowed specific tasks within each workgroup with the idea of getting action, things happening within the next six months, which I think is really critical.

The only reason we're in that position is because of the hard work that everybody has been doing to figure out what's the problem, what are some options for solving the problem, building the partnerships, the teams that are bringing in these different ideas. So, we couldn't get to where we are today without all the hard work you all have been doing to get up to this point. So, I want to thank everybody in the workgroups for all the hard work and the chairs of those workgroups as well.

Okay, so let's take our lunch break. We're scheduled to be back at 1:15. We'll start at 1:15 to

give ourselves a little bit of a break. So, I'll see you all at 1:15. Thanks, again.

(A luncheon recess was taken.)

AFTERNOON SESSION

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MR. BRADBURY: If everybody could grab your spot around the table, we'll get going on the afternoon session. So, thanks. The Tox 21 workgroup works until 1:30, so some of our colleagues will be coming in a little bit later, but we've also got to keep track of this agenda so I don't keep you all until 6:00 or 6:30.

So, we want to get rolling into the afternoon session. Our first session is integrated pest management. We will get outputs from the workgroup. So, I'm going to turn it over to Keith Matthews who is chairing this session.

MR. MATTHEWS: Good afternoon, everyone. I hope everyone had a good lunch. Yes, we are back once again for a session on school IPM. What we're going to do, the way this session is going to be structured is that I'm going to ask Frank Ellis to give a brief update on activities in the Biopesticides Pollution Prevention Division on school IPM.

We actually are making a lot of progress since the last time that the PPDC met. We've had a number of

different activities that have occurred, and a lot of progress is being made on this initiative. We're moving forward on this.

Once Frank gives that update, then we're going to have reports out from the two subgroups of the workgroup that are helping us out on school IPM. So, we're going to have Mike Page and Dave Tamayo speak to that. Then we'll be able to segue immediately from those reports into a discussion by the full PPDC.

So, if we can, just to get things started, Frank, will you go ahead and give us a brief update of what's been going on?

MR. ELLIS: Sure. Thanks, Keith, and good afternoon, everybody. I'm Frank Ellis. I'm the Chief of the Environmental Stewardship Branch in the Biopesticides and Pollution Prevention Division. It's a big title for our group which does a lot of the stewardship and outreach work within the pesticides program. A lot of the work that we do is around IPM promotion, specifically school IPM.

So, I'll give you an update on a few school specific things and mention a few others. I apologize

for those who were in our workgroup meeting yesterday. Some of this will be a little bit repeat for you.

We are making some significant progress, as Keith said, on school IPM. Just last week, we were able to announce our strategic and implementation plan for school IPM. That was released and has been picked up quite broadly and been fairly well received among the school IPM community and the larger children's health community as a whole.

As expected, we're getting some feedback about folks who may not share our philosophy about the benefits of IPM or that as an approach, so we're working to address those. But overall, we're getting very positive feedback on the plan. Related to that, the regional offices, as well as our headquarters group, has put together work plans for FY 13. So, those fall into alignment very well with strategic and implementation plan as a whole.

Regarding our center of expertise for school IPM, we are in the process of staffing that center. It's going to be located in EPA region 6 in Dallas, Texas, but those folks will work for me here at headquarters. We

had three positions that we announced at three different staffing levels. Those positions have closed. We've started some of the interview process and are waiting for the list of qualified applicants for the other positions. So, we are moving forward with that process.

Timing is somewhat dependent on when we can conduct these interviews and get the information from our human resources group. So, we'd like to have these folks on board as soon as possible because we have a large list of things for them to do as soon as they hit the ground.

Our cooperative agreements and grants that we issued last year are underway and seem to be going along well. We've set up quarterly conference calls with the representatives from all of these grants. Included in those calls are our 10 regional school IPM coordinators and a lot of the staff here at headquarters that deal with school IPM issues.

So, what we're doing is sharing information on the progress of the projects and hopefully lessons learned in areas where we can work together more effectively as these grants go along. These are two-year projects. We're just in the process now, I think, of

getting the second quarterly reports into the office. So, we've very happy with how those are going for us.

I did want to mention a few other non-school related efforts that we have going on. Our group also works with IPM in lots of different areas. One of the areas that we're working with now is IPM for tick borne diseases. Candy Pissard (phonetic), who is in our Environmental Stewardship Branch, is working with most of the other federal agencies who have an interest in tick borne IPM.

We're planning a conference this spring to bring together representatives from all these agencies, as we're working on a white paper that kind of assesses and inventories what each of these agencies is doing, what resources we're putting towards these efforts, and where there may be gaps in our overall approach. So, we'll all get together this spring. Part of it is going to be a federal only meeting.

Then, the next day we're going to have a public meeting and bring in six experts from around the country to talk about what's going well for tick IPM, where there are resources needed, where there are research gaps, and

hopefully make some significant progress in that area.

We also are doing some work, fairly recently -- one of our staffers, Lee Tanner (phonetic) has worked very hard to have a relationship with a northeast IPM center with the National Pest Management Association and with some pest management providers and some building service groups to do a study of IPM in class A buildings. These class A buildings are, for the most part, green buildings or lead certified green buildings.

So, we're going to do a comparative study in two different areas, one in New York and one in LA, that looks at IPM in a conventional pest management program in one building pared with an IPM program in the other and seeing how the delivery of information and the pest management that's provided through that plays out. Hopefully, we're going to see some very useful information in that it's going to be meaningful as far as being able to sell IPM within the green building community.

We've also got work going on on the international front with the OECD, the Organization for Economic Cooperation and Development. That group has an

IPM workgroup on which we participate. They're actually having a conference. They had one earlier this week in Australia to look at metrics and uptake measures around IPM.

This group is working towards looking at IPM measures more on a global scale, a country-wide scale. We are watching that. Tom Green, who couldn't be here at this meeting, was able to go and present on behalf of several of us in the US here who weren't able to attend. So, we're working that issue as well.

So, that's kind of the IPM's update in brief for you all. I think we'll go ahead and turn it back over to Keith at this point.

MR. MATTHEWS: Okay, thank you very much, Frank. As you can see, there's a lot of really good work going on in the Environmental Stewardship Branch related to IPM, in addition to the work going on with the schools.

So, at this point, we're going to turn to a report out from the two subgroups of our workgroup. Just to summarize for you, we have two subgroups. Subgroup one, the charge is to advise EPA on the development of

metrics to assess the effectiveness of the agency school IPM initiative. So, we've asked the experts who are assisting us to help us develop positive deterministic metrics that we can use to assess the effectiveness and the benefits of this particular program for this initiative.

Subgroup two is going to discuss appropriate ways to assess quantitatively the benefits of IPM, not only in school settings but also in agriculture and public heath settings. From the very beginning, we thought that this would be a very useful topic because, to my understanding -- and I've talked to a lot of people about this, and I think it's their understanding is well, there is a dearth of knowledge out there in terms of the actual quantitative benefits of IPM.

Everyone knows that IPM is good, but in terms of quantifying just how good it is, there's not a lot that's been done. So, we've asked this subgroup to help us to determine appropriate ways in which quantitative measurements of the benefits of IPM could be developed.

So, without further ado, I'm going to turn this first session over to Mike Page.

MR. PAGE: Thanks, Keith. As Keith mentioned, my name is Mike Page. I'm from the (inaudible) Department of Agriculture and Consumer Services. I'm also a member of the subworking group of the IPM working group, or committee. I'm also representing the Association of Structural Pest Control Regulatory Officials, a.k.a. ASPCRO, who has a keen interest in promoting IPM at the state level.

Briefly, I just wanted to kind of cover a couple of points in an introduction to kind of set the stage for this discussion. Back in December of 2010, EPA announced an initiative to promote and expand the use of IPM in schools as a way to improve children's health. The subsequent 2011 PPDC, this committee, formed an IPM working group to address the needs pertaining to school IPM.

As Keith has said, there were two subgroups that were formed. One was to develop metrics to assess the effectiveness of implementation efforts. The second was to delineate ways to assess quantitatively the benefits of IPM in agriculture, public health settings, and in schools.

So, this presentation will summarize the efforts of the first charge, and that is developing the metrics to assess effectiveness. Dave Tamayo will also be covering the group two (inaudible).

As part of this presentation, we were asked to do a couple of things, one of which was to provide a couple of deliverables. This presentation is one of those and serves to summarize a formal list of the recommended metrics that we want the agency to adopt.

We are also delivering a written document containing an expanded explanation of those metrics. That document will be entitled “Evaluating the Success of US EPA School IPM Initiatives.” In the document, we will make recommendations on how to judge impacts, how to go about measuring the success of IPM implementation. There’s some information sources that are in that document. We will also talk about the rationale for the metrics that have been chosen.

The working group used kind of a two-step approach to developing the metrics that we’re recommending and proposing. These metrics essentially precipitated from a comprehensive review of three items.

The first was a really comprehensive list of performance measures that were developed by the National IPM Evaluation Group.

The second were a list of metrics that are commonly used by IPM experts today. These metrics were found in the pest management strategic plan entitled "School IPM 2015." Those two documents can be located at the web sites that are indicated on the slides.

The third thing we reviewed and considered were commitments made by the agency in its recent released strategic plan that Frank has discussed already and the deliverables that were included in the grant awards that will be used essentially to test drive the fitness of implementation procedures in different regions of the country.

I think it was mentioned that the strategic plan was issued subsequent to the grant that was issued, but the plan actually does emphasize some key things, such as the formation of partnership with other federal/state agencies, extension, and nongovernment organizations to leverage resources toward accomplishing the goal of implementing IPM in schools nationwide.

You'll probably see this as a general theme in the metrics that we're going to be showing in the slides to come.

One thing that is clear is the agency has a very good working relationship with FLAs and extensions, but probably could leverage the more resources through their forming partnerships with other federal agencies that deal specifically with children's health.

This slide essentially represents a compilation of grant metrics that are associated with the deliverables in those six grants that I spoke of earlier. Grants were awarded in six states and include different aspects of IMP implementation strategies. If you take a quick look at the list, you can see there's a little bit of overlap in these grant metrics.

There's some interrelated activities that represent some level of coordination. There probably is room for improvement in the level of coordination should EPA have funding for future grant awards that will assist with this initiative.

It's also important to note that these grants highlight the agency's commitment to empirically measure

what is working and what does not work. The group also wanted to make a strong recommendation to have this committee charge the agency with reverse engineering these list of grant metrics into the agency's strategic plan. As I said before, the strategic plan came out subsequent to the issuance of these grant awards. We feel strongly that it would be more beneficial to tie those two things together.

Lastly, and although it's not listed on this slide, the group strongly recommends the agency publish annual standardized reports that consistently track the ongoing successes and failures of these grant metrics. In doing so, the agency can preemptively address criticisms that have occurred with past agency initiatives such as the strategic ag initiative.

The second step or second phase of our committee's work essentially was to select low cost, high impact measures and triage the list of metrics that were derived from the first step. In other words, the list of metrics that were found in the national IPM evaluation group and the school IPM 25th team document.

We wanted to make sure that there was a concise

list of cost effective and reasonable metrics that could provide meaningful measures at the intermediate level of behavioral change and at the long term conditional changes that are predicted to occur when adoption of IPM philosophies have taken root. There's a need to also mention that most of the metrics proposed in this presentation and our document will measure overall progress toward IPM adoption.

Finally, we did not list any kind of short term knowledge impacts because they really don't provide meaningful information which lead to actual improvements in children's health.

The next couple of slides are going to be representative of ongoing measures on the intermediate behavioral level. There are two essentially intermediate levels that we're looking at, on the state level and on the school district level.

This slide focuses on state level measures. These measures are listed in slides that were part of the survey conducted in 2008 and 2012. There are some slides at the end of the presentation which show graphically some of the questions that were presented as part of

these surveys, and some of the data that we're getting back as a result of those surveys.

These measures are essentially a way to help establish a base line by which improvements can be tracked. Survey questions were also the same in both survey years, and there are plans to repeat the same survey in a few years, probably, say, 2015. I do need to mention that these results will be published in the future as well and made available to the agency, or this committee, as needed.

This particular slide essentially indicates school district measures. As you can tell, they're more focused on verifiable IPM, which was defined as part of the agency's strategic plan. Perhaps we should go through a few of these, the biology and behavior. Understanding the biology behavior of pests is certainly a beneficial thing in trying to control pests without the use of pesticides, knowing when to take action against key pests, or essentially establishing threshold levels where actions should be taken. Monitoring of pest populations is a key part of any IPM program.

And then, of course, moving those conditions

that are conducive to infestation, declutter, and so forth. Using one or more effective pest control methods, such as sanitation, structural maintenance, and nonchemical methods in place of or in conjunction with the use of pesticides, are part of the agency's definition of verifiable IPM.

I think these are very important to be measured, although they're much more difficult to measure. It measures, essentially -- like the one monitoring pests, for example, will help to ensure that IPM program is achieving its intended goal by reducing pest populations. After all, that is the central tenet of any IPM program.

So, as I mentioned, measuring (inaudible) is kind of difficult, but it's not impossible. There are a couple of ways that we go about doing that. This particular slide indicates how IPM is measured. Basically, it's through self-assessment surveys, one of which is being conducted now by the National School IPM working group. They are currently surveying districts in more than 40 different states. These are combination online surveys and phone follow up. These kinds of

measures are very cost effective and easily done.

The use of on-site assessment tools, however, is a little bit more costly, but it does give a measure of greater accuracy in identifying the conditions and status of an IPM program's implementation. These tools, such as IPM Star, I-Pest Manager, and the IPM calculator created by Texas, are really excellent tools. They do offer, like I said, a much more accurate way of identifying key stages of IPM implementation.

Some of the long term conditional measurements, again, utilize surveys and/or on-site evaluation inspections, if you will, of school districts. We should note that a number of these metrics listed are part of the grant deliverables that were discussed earlier.

The metrics represent areas the agency should consider for future RFPs, perhaps on a small scale, which would include on-site evaluations by experts that sample schools that are currently under IPM projects and schools that are not in order to compare and contrast the benefits of IPM implementation.

Other more challenging metrics have also been measured but are definitely more costly. These

particular things that are listed here relate to human or public health conditions, such as asthma, that are really important in trying to get an indication of how well an IPM program is actually working, the goal of which is to reduce pests which are known to have triggered asthma events. But these three things are, again, very difficult to measure, very costly to measure.

So, we're making some recommendation that the agency track the results of the research that pertains to these measures. As the need arises, the agency should consider supporting research efforts to track these measures on a limited basis under grant-funded research for implementation projects.

This particular slide was kind of a late entry, but it addresses the focus on children's health measures. The group felt very strongly that this committee should charge the agency with building upon the partnerships with sister agencies, that they should draw upon the expertise of children's public health partners in a way that is useful and effective to their initiative, and collaborate on a workgroup basis between EPA and partners to develop initial measures during the first year of its

three-year plan. Of course, those measures should be revised in subsequent years.

As I mentioned earlier, I have a couple of slides here that essentially illustrate the types of surveys that are being conducted by the IPM working groups. These are the results, essentially, of data from eight states. Of course, more states are being surveyed at this point. But it gives you an idea, essentially, of the types of questions, types of metrics that are being measured by these questions. I'm just putting them up there briefly to kind of let you guys see the things that are being looked at.

I also measured the surveys that were conducted in 2008 and 2012. Just a brief look at this particular slide will indicate that in the four areas that are measured, there's a pretty notable improvement in the activity levels of IPM in states across the nation.

Again, tracking state funding levels is also an important feature of monitoring IPM implementation. Again, this shows a rather marked improvement in funding IPM initiatives, probably because of the leverage of funds provided to the US EPA, USDA, the IPM centers, and

even CBC. The green box there kind of gives you an idea of the impacts that these demonstrations are having on this particular issue.

Before I leave, though, I didn't get a chance to put a summary slide in, but I would like to make and summarize a few critical points, leave the committee with at least three issues that I think you should address.

We think that the PPDC should charge the agency with reverse engineering the metrics in those six grants and putting them into the strategic plan for IPM implementation. The second thing is to require the agency to publish annually a standardized report of the progress being made on these grant metrics. Thirdly, work to form and strengthen its partnerships with sister federal agencies to leverage resources toward this initiative, specifically in the area of children's health.

With that, I'll conclude the presentation.

MR. MATTHEWS: Thank you, Mike. I would like to say that this was a somewhat brief summary, but it reflects an awful lot of work that the subgroup has put into this. I'd like to express my appreciation for all

the work that has gone into both the work on this particular charge question, as well as the charge question on the quantitative benefits.

So, the way we've structured this session is for the two subgroups to report out, and then we will go in and have a discussion by the full PPDC on both of these report outs. So, if there's no objection to that, I'm going to ask Dave Tamayo to take over and to talk about some of the work that's come from the quantitative benefits subgroup.

MR. TAMAYO: I'm taking over, so don't touch your dials. We're sort of at the opposite end of the spectrum of where the other subgroup is in that we've really just kind of started the discussion on appropriate ways to quantitatively assess the benefits of IPM. So, I was asked, actually, to sort of jump start that conversation and try and get us to a starting point.

So, I want to emphasize that what I'm putting out here is really more of a status report of kind of what we started talking about. Even though some things may be phrased as recommendations, these are not yet ready to be the clear recommendations of the workgroup,

because we haven't talked out all the issues.

I wanted to start out with the charge. The charge that we were given is discuss appropriate ways to assess quantitatively the benefits of IPM in agriculture, public health settings, and schools. I wanted to make a couple of comments on that.

One is that the genesis of that came from Keith expressing, I guess, not quite a frustration but the situation of him asking around, well, what are the quantitative benefits. It's very difficult for people to point directly to the body of research. I think that there is a characterization that he made in addition to that in that not a lot of work had been done. I don't think that we necessarily, as a group, agree with that at this point.

I think that we want to look -- one of our recommendations, and you'll see it wrapped up throughout here. We're not sure which sectors there's been a lot of work done and where there hasn't been enough work done. I think our emphasis is on finding out what's been done and increasing access to that.

Then, there was also concern about the second

half of that, about looking at an agriculture, public health settings and schools. I think that there's a feeling that we may be asking to not have those specific things called out for in the charge, because nobody could really remember why those things in particular -- certainly schools have an emphasis, but we'd like there to be -- we may come up with a recommendation to please amend the charge somewhat. I think that will be sort of based on further discussion.

So, I'll go to the rest of this. I think kind of where we're headed is that we do have an initial sort of outline of the types of data that should be used. We're thinking about trying to make some recommendations to EPA. Once you have access to these quantitative assessments, this is how they ought to be used.

I actually started out with developing an example for a flyer that might be used using quantitative assessment of benefits for promoting IPM in schools. I have a little bit of a draft of that. Then, there's sort of a draft effort or recommendation to conduct a comprehensive literature review on what is out there and seeing if that's a utility, but that's not a

recommendation yet. We may be headed in that direction, but we'll have to discuss whether that's a worthwhile thing to do.

So, switching to the actual data types, comparisons of pest management effectiveness and emphasizing direct measurements of pest pressure. So, how much damage is there, what are the populations of the pests, in relation to what's really a problem. Then, is there some sort of an increase in the yield?

Looking at measurements for how to reduce risk and/or exposure and going beyond just looking at well, we reduced the amount of pesticide that was applied. We want to sort of focus on studies that really look at did the changes actually result in a reduced risk situation.

Looking at demonstrated improvements in health outcomes. Asthma may be one of those things. Measurable benefits to the environment, so using systems like IPM Prime which the IPM Institute developed for certain -- they've got a pretty good system now for certain crops. But looking at ways to look at the different types of potential environmental endpoints and are there ways to measure how IPM made improvements or changes in

environmental endpoints.

Are there some long term cost savings associated with, in particular, reduced pest management costs? I think you could probably also extend that to some of the other things I already mentioned, like increased yield. That's not a cost savings, but that's a balance of the other side of that coin.

So, the next slide -- and remember, these are not final recommendations. Just trying to give you a flavor for where we're headed. We're considering asking EPA to use these quantitative assessments to create some materials to promote IPM. That would necessarily be in cases where EPA has identified a need for it to take a leadership role.

Look for ways to increase accessibility to existing studies. That's kind of based on even just starting to figure out what are we going to talk about. It is difficult to find these things. So, even though there's a lot of claims that IPM has these benefits -- and certainly, I know there are some examples in schools where there are some studies done.

I'm sure a lot of you know of many cases in

agriculture where there's a lot of research that has been done to promote or to show the benefits of IPM. You can find out how to do the IPM and what the specific recommendations are, but it's a little less accessible to get to the actual studies. So, the citations aren't necessarily there. So, I think EPA can take a role in that.

Promoting more generation of quantitative assessments and maybe working with some of the partners that are identified, and even in its own granting programs, looking for ways to spur that.

This one will probably take a lot of conversation. There's good quantitative assessments for IPM alternative, incorporating that or really using that in some of the risk management decisions that are done in the pesticide regulatory arena. How you would actually do that, I'm not really sure. So, that's a potential thing that we might be recommending to EPA. Then, always be on the look out for other types of quantitative assessment methods that we may have overlooked going along.

I did mention the potential literature review

for quantitative assessments in schools. These might apply to any other sector. It's almost self evident that it would be beneficial to have comprehensive documentation of what's been done out there, whether good, bad, or indifferent, but really know what the literature says.

It would help identify data gaps in direct future studies. I think it would be very helpful for EPA to have that in hand. I think Keith articulated that very well. We just don't know what that information is. So, I think it would really help EPA to promote an integrated pest manager to have that as a resource. Then, I think also it would be very useful for people out in the school community who need that sort of information to back up their advocacy of instituting IPM in their community.

So, obviously, there are some limitations to this. Of course, we would want there to be specific citations of credible studies and not just sort of vague assertions. So, we want there to be studies that can be pointed at, that can be evaluated. Certainly, it will be found that there are some systems that need additional

study to have a robust set of data.

I've already mentioned a number of times that there may be a lot of stuff that's in the literature, but it's not readily accessible. Some of the measurements may be very cite specific or operator specific. Then, it's a moving target, too, because the pests and human systems are changing all the time.

It should be recognized in developing these that you can't necessarily expect all the benefits to accrue in all the different situations. It's just a set of information that you can use as to how good this system is. Even if something is not being achieved in that particular situation, that isn't necessarily the defining factor.

Finally, a lot of these quantitative assessments, the ones that we've identified so far, those are all measurements of relative advantages. They don't necessarily capture all of the good reasons that there may be for implementing IPM. So, there may be other things other than quantitative assessments that would be worth looking into.

So, I want to give just a very brief example of

how this might play out in schools -- or, not how it plays out but just sort of a cursory look at how this might be used for schools as a case example, so improved pest management.

There are studies that show that IPM just prevented problems from occurring in the first place where there had been significant problems in the past by applying a rigorous IPM program. It just kind of made it so these just aren't occurring anymore. It was very helpful to have the actual on-the-ground studies of that to be able to point to. Obviously, that's an example of more effective pest control, but there are other examples for, like, controlling cockroaches in North Carolina.

You can go a little bit deeper and look at actual health endpoints, where in North Carolina it was shown that there was a reduction of cockroach allergens. Now, that's not measuring the population itself, but the reduction of cockroach allergens was very significant.

Then, on that final bullet is getting to the idea that you can reduce pesticide risk by changing to lower exposure methods. This is an example of where it would be -- I don't have a specific citation. I believe

that there's some out there, but it wasn't readily accessible to plug in there. So, that's an example of how it would be useful to have a more robust literature review.

Another direction we might be headed once we have a really good set of quantitative assessments, take what had been provided as a draft -- you can see there's just like a little Word document -- and turn it into kind of a nice document from the EPA that EPA could use to go out to the school community and say, here are the quantitative assessments of IPM benefits in your school community, and making a case for that. I think it would be useful to have that. So, we'll see if we can work through a more specific document to bring to you hopefully by the next meeting.

Then, finally, we sort of got started on quantitative benefits of IPM and didn't get even as far as the other beginnings. But ag is a much bigger animal. It's much more diverse. You can think of schools as being roughly equivalent to a particular crop. Obviously, there are hundreds of crops. So, the quantification of benefits of IPM for agricultural

situations is going to vary by the crop.

Fortunately, the way that IPM is looked at in agriculture situations, there's certain measurements that are much -- the whole thought process of that is much further developed. The economic benefits are much more directly measured. At least some of the economic benefits are much more directly measured through the balance of crop yield and pest management costs. I think a lot of you are familiar with the idea of economic threshold. I mean, that's the whole basis of it there. So, there's an advantage of ag.

But there's a disadvantage. You can get out there and you can find that there's a lot of IPM systems that are promoted by universities and other sources, but you see what the formulas are. You see the implementation of it. But you don't have ready access to the research behind it. It would be advantageous to have more ready access.

So, what is the actual research behind there? Presumably, I'm going under the assumption that the universities wouldn't be promoting these things, wouldn't have these definite things, if they didn't have the

research behind it. It's just that needs to be brought more to the forefront. Maybe there will be some instances where that's not the case, but hopefully not very many.

Then, similar to the school situation, it would be helpful to have studies that show improvements and health outcomes for, like, workers or neighbors or the farmers themselves. Advantageously, IPM Prime is already developed for use in agricultural systems. It's pretty robust for the ones that it's done. I think that it's pretty clear that EPA's role should be complementary to USDA.

I know I keep talking about this as if these are specific recommendations. These are actually more recommendations to this subgroup. So, thank you.

MR. MATTHEWS: Thank you, Dave. I appreciate that. I do want to emphasize the points that Dave has been making. This is actually a really major problem here. It's not a problem, but it's a major effort that's going to be required to kind of address this particular charge.

So, it's completely understandable that there's

not necessarily recommendations coming out of this subgroup at this time. As I said before, there's an awful lot of work that has gone into it, but there's an awful lot of work that has to be done with respect to this particular charge to the subgroup.

So, I guess maybe the best way to handle this would be to open up this second charge for any discussion from the PPDC, any comments that the committee may have. I know Mike had specific recommendations, so we want to make sure that we get to those and see what the full committee thinks about those specific recommendations with respect to the metrics.

MR. BRADBURY: Scott.

SCOTT: Well, first off, my apology in that I am technically on this group and, honestly, I got side tracked more than a little bit on the pollinator one. But what I would suggest, if ag is going to be a real focus of this, we do need to broaden the membership or the participation to include more ag people on it. I know in the early meetings that I was a part of it, it was pretty weak on the ag representation.

MR. BRADBURY: Jennifer and then Mark Whalon.

JENNIFER: Thank you. So, I haven't participated in this work group, but I think it's a really important work group. So, thank you guys for taking this on.

A couple comments and thoughts. One is, when you say schools, are you including or should you maybe write that you're including daycares and childcare facilities? I think you should. So, if you haven't talked about it, that's my recommendation.

Then, the other thing is, IPM, integrated pest management, is the idea that you first try to use nonchemical or nontoxic treatments, and then you have like all these other tools in the toolbox and you sort of move down the line from no risk to little risk to increasing risk to deal with the problem that you need to deal with. So, you're responding with appropriate force to the problem with least amount of risk possible.

So, in that vain, I wonder if the IPM workgroup would consider making the recommendation to cancel or have EPA cancel all cosmetic uses of pesticides on schools and childcare facilities? It's not a very radical thought. I was just looking it up. I think

there's something like 50-some municipalities in the US that have already done that. I don't actually know the exactly number, but it's definitely double digits, that have passed those kinds of things.

DC is working on that as well. I've testified to support that. In Canada, 171 municipalities have already restricted lawn uses, including all of Quebec, Ontario, and New Brunswick. Quebec and Ontario are huge provinces. Actually, those cosmetic restrictions on lawn care pesticides actually represent -- 79 percent of the entire population of Canada fall under those restrictions. They seem to be doing okay.

Also, medical groups support it. Environmental groups support it. The bans or restrictions were made because of the environmental and health concerns. Ontario has a total ban on all lawn pesticides in the whole province, which is a good double digit chunk of the population of Canada. BC and Saskatchewan are going in that direction as well. The majority of the provinces voted in support of it.

So, it's not a very radical idea. I think that it does fall into IPM because it's the first step to not

have toxic chemicals being used. I think this group could make a recommendation that EPA cancel those uses. But, if not, this group could at least make a recommendation that we would support those kinds of -- we would recommend that schools, daycares, and child facilities not use any cosmetic use of pesticides on lawns and gardens.

MR. BRADBURY: Before we go to Tom, we definitely have captured Jennifer's suggestions. What I'd like to do, though, is manage the time and the topics first to focus on the specific charge to the workgroup, which had to do with the metric stuff. We can come back to Jennifer's thoughts with the full group. So, those of you that put your cards up, I'd like you to put them down if you wanted to respond to what Jennifer said. We'll come back to it.

What I'd like to do first is get feedback on the specifics around workgroup 2, which was, in one part, should we kind of shrink our scope a bit. Scott sort of touched on that. If we're going to keep ag in that workgroup, we need some more umph. But I think Dave was sort of indicating maybe one thought for the full PPDC of

trying school first and then get that done and maybe move on to another sector.

So, those would be the kind of things I'd like to get some feedback from this whole PPDC now and then we can see how the clock is going and see if we can come back to some of the points that Jennifer raised.

So, Mark and then Tom.

DR. WHALON: One thing that relates to that a lot, Steve, is the origin of IPM itself. Actually, going back to the very beginning of when IPM became popular and even identified EPA had a lot to do with that process, USDA almost secondarily, but then it became an operating process within USDA.

So, when I look at what's happened with IPM in schools, again, IPM in that arena, historically, EPA leads out. If you look at what happened to IPM or what is happening to IPM and agriculture today, it's struggling a lot for a lot of different reasons. Part of it is the public sector's support of development of new arenas and areas.

It's really interesting how this same concept, which is a quantitative evaluation concept of how one

assesses a pest management process, could be applied directly and with what I'm advocating as a systems approach to pollinators, for example. So, the next step may be okay, take the prime money and put it into pollinators, I don't know.

The thing that I'm saying is that historically, if you look at IPM, the progenitor of IPM, at least on the ground initially, has historically always been EPA. Then, EPA, those monies dry up in EPA. For whatever reason, USDA steps in, does a process. Now, USDA has got an immense challenge of getting an IPM into all of the agricultural sector processes. The resources probably aren't sufficient to get it in all of them.

So, I commend EPA for its position. Again, in this case, in IPM in schools, I know that you're going to run with that banner. You're going to get a lot of press for that process. You're saving kids, all that. That's great. Meanwhile, I think IPM on the landscape is largely floundering in many instances, dying out in the public sector because of the lack of resources.

MR. BRADBURY: Thanks, Mark.

Tom and then Joe.

TOM: While this addresses at least one thing that Jennifer said, I think it's important because I'm on the committee. The first two committee meetings we had, we, of course, had to start with what is the definition of IPM. We agreed that as a group and went forward based on the decision that we were going to use the FIFRA definition of IPM. So, that's the definition that we're working on, and the results of the outcomes are based on that definition.

Then, the other thing of the charge, which, you know, we had some problems with just even listing public health to what was the definition of public health. Were we addressing mosquito control in hospitals or whatever that definition itself could be (inaudible). As we mentioned, we didn't have enough resources of people on the committee for agriculture.

One of the other areas of which I kind of represent, the green industry, it's a lot more complicated, IPM in the green industry, because we have to deal with a customer base. That's why people hire us to do certain things on the property, or whatever. Sometimes it causes more problems to deal with integrated

pest management or whatever to satisfy customer demands, since if we don't perform, we lose the business. So, that makes it somewhat more difficult while we practice IPM and we can add some things in. It makes it more difficult for our sector to follow the same procedures that are used possibly in school IPM.

MR. BRADBURY: Thanks, Tom.

Susan.

SUSAN: Well, Tom just sort of got to where I started out with where I was going and clarified that you're starting out with a base point of the FIFRA definition of IPM. Having come from sort of the ag side and animal health side, IPM means different things to different sectors. FIFRA or school IPM may be very risk oriented, reduce (inaudible) maintaining the healthcare levels that you need.

When you get into agriculture and livestock production, IPM may simply be can I use another tool that costs less. It's more cost effective than necessarily risk reducing. That doesn't mean they can't work together and in concert, but if you go back and look at some of the things that have been done for IPM, a lot of

it is pest resistence.

Your IPM, your toolbox, as Jennifer said, has a lot of different things in it, rotating pastures before you give an antibiotic, and then only using ones that you did last year. So, I think there are a lot of decisions that go into an IPM approach in every sector. But if your baseline is FIFRA -- and I admit I haven't read it -- but if there's a FIFRA definition for what IPM is, there's probably a different definition for IPM and a lot of people out in the ag sector that -- and are they consistent with each other?

You can't track down quantifying the benefits and risks because that's not how they're looked at in every sector. They're measured differently. They're done for different reasons sometimes than a singular approach of reducing pesticide use and risk. That's my only caution, having this group have such a broad, broad goal.

If you're going to limit it to public health settings and in agriculture on a FIFRA definition of what IPM is, I don't know what you can find in some of those cases, rather than saying, but IPM has different things

for different people. So, that's my only caution. It sort of echos a little bit about well, maybe we need to have ag people if you're going to look at ag.

Who else you bring in for the public health settings, they probably have a different set of criteria as well for what's a benefit to IPM, different thing at risk. So, it was only just a note that that's a lot of work for this group. It's a big charge.

MR. BRADBURY: Mark.

MARK: Appropriate just to this -- we're not going to the first presentation but to the second presentation and what we're discussing on measures. Actually, in my experience, going into extension in 1980 and all the way up until now, I've read many, many, many reports, mostly in the Journal of Economic Entomology quantifying the benefits of IPM in all kinds of different crops and public health situations, whether it be the benefits are financial or they have to do with resistence or other things like that.

So, that said, I do agree with what Keith brought up, which is that we haven't done a good job of late compiling them into an understandable document. So,

I think a lot of the discussion that I've just heard is probably a little bit preliminary until we do this literature review, which, truthfully, won't be that hard. I mean, just have a grad student search Journal of Economic Entomology for the last 40 years, and they'll probably come up with something. So, I think we'll have to see what happens from there.

MR. BRADBURY: Okay, thanks.

Robin.

ROBIN: I'd just like to echo what Jennifer had suggested, that yes, I would like to include nursery schools and daycare centers. I think that counts as schools. And yes, the healthcare community does use FIFRA as a base. Then, we also have a little bit more public health protective definition that we would consider. The literature is there for both daycares and healthcare facilities to be found. There's lots of literature.

MR. BRADBURY: Okay, let me try what I tried this morning. So, for the second breakout group of the IPM group, here's what I'm synthesizing as an idea to get back to that workgroup for the next steps.

I think I'm hearing that trying to do schools and ag and public health at the same time is too much to do and probably has more leveraging to do in terms of USDA, CBC, and who knows who else in terms of some of those latter things.

So, I'd be proposing to not take those two off the table but change the sequence and timing. First try to concentrate efforts on the school environment and tackle with the topics that are in this subgroup in schools, not say we're never going to come back around to ag or public health, but we may do it in a different context. Maybe think about that in the background.

Take the recommendation coming from workgroup two, which was to get the tighter focus and accept that recommendation from the workgroup, and then you guys continue working on how you want to recommend the (inaudible) aspects but in the school context.

The other thing I was going to point out is right now the school IPM strategic plan and implementation plan, and what with Steve Owens we started in 2010, is for school. It doesn't have daycare and that component in the EPA plan right now. So again, it

doesn't mean that we couldn't take on daycare centers, for instance, but I would like, given the agency's first cut at this, to stay focused on the scope that's in our plan.

If the workgroup can see that it's very easy to say, and, by the way, the same logic would apply to a daycare center or something, I think that's great. Sweep it up. But I want to make sure that we get the school part done because that's in the plan. That's what the million dollars of grants are focusing on.

I want to make sure we get that connection as efficiently as we can before we start expanding what we're trying to take on, given where we started. So, I'm not saying no, not ever, but just making sure it's an efficient process as we go forward.

Robin, go ahead.

ROBIN: Can I clarify now how the two subgroups are different? What's the difference between the two subgroups if they're both focusing on schools?

MR. BRADBURY: It's my understanding that the first workgroup is trying to get a handle on how do you measure the implementation of, in this case, school IPM

happening. The second subgroup is trying to come up with ways to say not only are more, for example, schools taking it on, in the context of taking it on, those schools have been able to consider resources to educate more kids in certain ways or to maximize their ability to teach kids because they've been so efficient in managing their pests.

Things like that is what I see a difference between the two. The first one is how do you measure, is it happening, and the second group is trying to help provide the information to show what you gain by taking on a school IPM approach.

Mark, I may have messed that up.

MARK: First of all, I pretty much agree with where you're going, Steve, on this. I will say, though, that in order to quantify the benefits of IPM in schools, we'll look at cost, we'll look at people who find pests a nuisance, but we also need, of course, to look at children's health.

So, that is obviously going to spill over into the public health aspect that would, of course, then spill over into childcare, hospitals, elderly care. So,

we're not going to leave that too far behind, or we shouldn't leave that too far behind. There's already lots of good work being done on that.

MR. BRADBURY: The connections are all there. It's just sort of where is your focal point and then look for the branching. Use the same approach as the pollinators, if there's some passionate disagreement with this general approach. Seeing none, then people are taking good notes, I hope.

So, that will be sort of the feedback, Dave, to that group that you reported out to. School is your focal point. Now start thinking about your recommendations of things to take on to make that happen in that context. We're not shoving the other ones off forever and ever, but we're just going to sequence things. That's going to be our approach.

Okay, let's flip around to the first workgroup, which had three very clear recommendations to the full group. If you all think those make sense, then they'll come back to us at EPA and we start to work them out. So, if I captured the notes, the three recommendations were first, we should try to reverse engineer the metrics

from the grants back into the strategic plan and the implementation plan. The second recommendation is with these metrics -- and they'll probably evolve with the years -- but to provide a yearly report on using some set of metrics (inaudible) in time how we're doing. Then, the third recommendation was to make sure we're really advancing the partnership with other federal entities or state entities in terms of children's health advancement, which gets back to some of the comments we just had.

Did I capture those, the recommendations, accurately? Anybody on the full -- this is kind of an awkward thing to do to people, but should I sense that the full PPDC agrees with those three recommendations for the agency? Any reason for the agency not to take those recommendations? Now, how we'll actually do it is something we'll have to work on, but to take those three recommendations and start working how to make it happen.

Cheryl.

CHERYL: Well, I'm confused by the actual recommendations. You've got metrics used all over the place, and there's pages of potential metrics. So, the overarching recommendations that you back engineer these

into the strategic plan I think are the grant metrics specifically. But then, you've got this proposal for a public health report based on metrics. Is it all of these metrics, some of these metrics? I'm confused as to what is actually being proposed.

The other question would be, I'm going to have a reaction to page 5 when you talk about the simplistic reduction in applications if you're not going to talk about substitution agreement of pesticides, if you're not going to talk about reduced exposure and baits and things like that.

UNIDENTIFIED MALE: I think that's an important point. I apologize if there was some confusion on part of the list of metrics that were presented in the presentation. The focus, though, on this particular recommendation was on those metrics that were listed in the fourth slide of that, they all were derived from the six grants that the agency has issued and awarded. Those grants were actually awarded prior to the finalization of the strategic plan.

What we're asking is that the work being done on those grants is also part of the strategic plan.

We're essentially test driving those particular measurements. We feel strongly that those should be kind of part of the strategic plan to kind of be more cohesive and link together those efforts on the initiatives, if that helps.

MR. TAMAYO: So, Cheryl, in part, answering your question, Mike did a good job. Also, in the strategic plan, as Mike said, you want to have the measurements of how schools are going to succeed with integrated pest management.

But, furthermore, by putting those metrics into the strategic plan, one of the things it allows the agency to do is to reach one of their objectives in the strategic plan, which is to have better regional coordination and standardization of IPM in schools, with, of course, the understanding that pests and even pest management changes are region to region. The metrics, in my experience, can be the same. So, that's answer one.

The other one to what you brought up towards the end regarding your concern that looking at the percent of pesticide application reduction is too simplistic -- this is me speaking from my experience --

is that I try to stay away from toxicity and toxic arguments in many ways.

But if you can leave that stuff aside, pesticide applications are usually -- not always, but most of the time an indicator of effective pest management. So, whether it's boric acid or using some kind of fumigant, I don't know, nuking them, the fact that you've had to resort to a pesticide application, organic or otherwise, is an indicator of the effectiveness of the pest management that you've led up to that point. So, that's why it's important just to even look at the number of applications.

UNIDENTIFIED MALE: I'd like to get in on that point because if you are able to reduce the number of pesticide applications, it is implicit that you are doing something to take its place, either good monitoring practices or you're substituting with greener products. In fact, that's what's happening. The trend now is for more organic pesticides to be used to replace, to substitute, the more toxic products.

So, I think in the long run, what we're really interested in is to see that as a result of pesticide

reduction, the pest problem is also reduced. Now, we can go into great detail to find out how that has come to be, but it's important that we keep that in mind. There's some substitution of (inaudible); otherwise, the pest problems are not going to go away even if the pesticide, toxic pesticide use is reduced.

UNIDENTIFIED MALE: May I respond to that? Actually, this goes back to the argument of what we call bait substitution. The baits the industry brought up are typically very effective and very safe, at least from what we know right now. So, they've done a great job, and that's all well and good. But the fact that they have to use baits also can indicate, and usually does indicate, that they are not doing the other things to manage their pests that they could.

So, if you talk about substituting a method -- so, sanitation versus chemical control -- I agree with you. But if you talk about substituting a green compound for something that might be more toxic, from my point of view, you haven't addressed those other things first.

MR. BRADBURY: Okay. Cynthia, if you want to get into a debate on this, I'm probably going to cut it

off, because what I'm getting out of it, I think what we're talking about is the fact that you're going to use a suite of metrics and you're going to interpret these metrics as a whole. You probably don't look at one in isolation of other information that you're getting. You can get a richness of information based on the (inaudible) of the metrics and how you integrate the interpretation.

What I wanted to try to do is I've got to start watching the clock and wrap this one up. So, keep your card up, Cynthia, but if you want to get in that debate, you can. But here's what the agency is going to do. The agency is going to take the three recommendations from that first workgroup. We're going to work them in the agency like we do whenever the PPDC gives us a recommendation.

There's usually, for lack of a better word, an implementation phase to the recommendation. Sometimes recommendations are very sweeping and you can't do it all at once, so there's different options within the recommendations that we need to take a look at. Keith's group will work on those recommendations, come up with

some approaches to make them so.

They'll work with the IPM workgroup to be the first piece of PPDC to get some feedback. Are we hearing what you wanted? What do you think about this way to start to implement those recommendations? We can do that over the course of the next few months so that at a minimum, when we come back and meet in six months, you'll hear, with some help from that workgroup, how we're going to take those recommendations and start to make it happen. So, that's what we're going to do.

But, Cynthia, go ahead.

(The recording ended.)

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MARILYNN H. McNULTY

Transcriptionist

UNITED STATES

ENVIRONMENTAL PROTECTION AGENCY

# PESTICIDE PROGRAM DIALOGUE COMMITTEE MEETING

November 29-30, 2012

Conference Center - Lobby Level
2777 Crystal Drive
One Potomac Yard South
Arlington, VA 22202

P R O C E E D I N G S

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MR. BRADBURY: Good morning, everyone. Let's get the Friday meeting started. We've got just a few more folks getting through security, but I think our timing is pretty good. So, for those on the phone, just another reminder to make sure you keep your phone on mute. With that, why don't we get started.

Again, I want to thank everybody for all the contributions and excellent discussion yesterday. I think we got a lot done, identified some key action items to take on in the areas we discussed yesterday. And at the end of the morning session, we'll recap those action items.

So, this morning we're going to take some time, about an hour, to go over a number of activities in the area of 21st century toxicology, both activities that the workgroups have been taking on, as well as some of the related activities going on in OPP and OCSPP.

And then we'll talk a bit about the endocrine disruptor screening program, and then have an update on the Endangered Species Act implementation efforts we're

undertaking, as well as an update on registration review.

Then we'll wrap up with itemizing tasks, activities, goals for the next meeting, as well as Margie spending a little time describing how some turnover in the membership of the committee plays out over the next few months.

So, with that recap of the agenda, I'll turn it over to Jennifer McLain and Vicki Dellarco to kick of the 21st century toxicology discussion.

DR. MCLAIN: Good morning. I'm Jennifer McLain. I'm the deputy director of the antimicrobial division. I'm one of the chairs of the 21st century toxicology integrated testing strategies workgroup. As you know, this has been a fairly longstanding workgroup at this point. We were established in 2008. The group objective is to focus on communication and transition issues that EPA faces in new 21st century tools, methods, and policies.

This is the diagram from the NRC report, the toxicity testing in 21st century. We wanted to put this up here as a group because it gives the background for where we've come from and where we're going and what

we're focusing on, both in terms of the toxicity pathways but also the population and exposure monitoring that feeds back into looking at those toxicity pathways. It's something that as a workgroup we keep in mind to make sure that we're appropriately focusing in the right direction.

Here are some of the workshops that we've done in the past. This is one of the major things that the workgroup has accomplished over the past few years. We started out in 2010 with a -- just know that what you see on the screen is going to be different than what you see on the paper. Don't worry, we'll just keep going. Your paper version is the more updated version. This one is just a little bit shorter than the paper version. So, just pay attention to what's in front of you.

So, the workshops that we did in the past, the first one was focusing on our strategic vision, basically to introduce our vision to a broader stakeholder group and talk about where we see the office going, how we plan on transitioning, our policies over the years. Then, we followed that with a workshop in 2011 that was focused on the outer ring I just mentioned in terms of surveillance

monitoring. We had a workshop on diagnostic tools and biomarkers in pesticide medical management, exposure surveillance, and epidemiologic research.

So, what came out of that workshop, if you remember, we've had a couple conversations with you since that workshop, one immediately after and then one in this past spring. After this past spring, when the workgroup came to you and talked about a couple of project proposals that they had developed of an outcome of the workshop, the workgroup received a charge to follow through on those projects. This is some of the activities that we're currently working on.

We have two larger charges that we're working on. The first one is to develop a priority list of candidate pesticides for the purposes of research, biomonitoring research. To do that, the charge was to put together an expert group, to agree on criteria, and to develop that list. The second charge would be to create a pesticide use case to further encourage funding for research on the rapid diagnostic methods.

We were also asked after the workshop to put together some better definitions surrounding the area of

biomarkers because there was some confusion in the discussion about biomarkers when we were here. So, the request was, can you put together some better definitions and put them up on your web site so that when you're talking about the work that you're doing, we have a resource to go to.

So, our progress right now with respect to these charges is we have a subgroup that's headed by Jimmy Roberts. We're going forward with this group to first get together a set of experts. These are scientists and public health professionals from industry, and NGOs, and academia, and the medical community, other government organizations, EPA.

That group is charged with getting together some criteria and making recommendations for pesticides that fit those criteria so again, we can have this set of pesticides that would be a priority for future research on biomarkers for pesticides.

So, at this point, we have convened the expert group in terms of getting folks to agree that they would like to be a part of it. We are planning on trying to have a first meeting in December if we can arrange it or

early next year if we can't.

The other thing that we have completed is putting together the biomarker definitions that were requested. So, in OPP we worked with the Office of Research and Development and put together some definitions. We have them ready to upload onto our website. They'll be there probably in a few weeks. So, we're going to have definitions of what is a biomarker of exposure, a biomarker of the facts, and a biomarker of susceptibility.

So, those are some of the things that are ongoing and where we've been. We're going to spend the next couple of minute talking about some of the other things we have going on. I'm going to turn it over to Eric Janice (phonetic) and he's going to talk about a proposal that we have for you for a third workshop.

MR. JANICE: Thanks, Jennifer. Good morning, everybody. I am Eric Janice. I've been serving on this workgroup since 2008. I led a small group of folks, a small subgroup of folks to help develop the concept and agenda for this workshop that we're hoping to do next spring.

Really, what it is -- and I'm glad that you showed us the diagram earlier, because, really, what it's meant to do is to dig into the guts of the inside of that ring diagram that you saw and explore the current 21st century tox tools that are currently being used by EPA, discuss the regulatory application of these tools.

It's meant to be just a one day, mostly non-technical workshop. It's really meant as sort of a service to the members around the table and other interested stakeholders just to continue the education process that the workgroup has been undergoing for the last several years in this area.

Really, what we want to do, just to quickly go over this, the proposed agenda is we want to essentially define what an adverse outcome pathway is. If you don't know what that is, maybe you want to come to the meeting and define other common terms that are used in this area.

We want to be able to understand the use of adverse outcome pathway as a framework to not only organize information but to help inform decisionmaking here. To do this, we're going to explore the development of AOPs in a number of areas by inviting subject matter

experts and “downstream users” to present case studies on the development and application of these tools in a number of areas, human health, environmental, ecotoxicity, for example.

Then, later in the day, we want to present a series of case studies and implementation of adverse outcome pathways and other tools. We’re going to mainly focus on adverse outcome pathways, but there are other tools such as quantitative structure, activity relationships, and other things that are currently being used by the agency.

We want to look at again a series of case studies and how these are implemented from a number of different perspectives to try to explore the benefits of using the tox 21 toolbox and the challenges to using the tox 21 toolbox, essentially. We’re hoping to invite folks from possibly the Farma (phonetic) area, possibly from other industrial partnerships where they have used computational tools to do screening and to do other activities that EPA is interested in.

Then, finally, we want to wrap up with a panel discussion that will involve all of the folks that we’ve

invited to the meeting thus far and probably some folks from the agency and start really digging into what are the barriers to implementation here, what are the barriers to greater use of these tools by the agency and by the registrant community, how do we build confidence in these tools, how do we think about even measuring success in terms of implementation.

So, that's the concept. We would like to recommend that we do this in conjunction with the spring PPDC meeting in 2013.

DR. MCLAIN: One more project that we want to talk about, and Kristie Sullivan is going to talk about the subgroup that she's heading.

MS. SULLIVAN: Thanks, Jennifer. So, this workgroup has been going on for quite a while. We had a metric subgroup pretty active in trying to decide and determine some metrics that the agency could use to measure the benefits of 21st century tools a couple years ago. A couple of us started talking about resurrecting that subgroup in order to look specifically at acute toxicity tasks that we're talking here about, the sort of six pack, as it's known, of tests.

We basically are, as it says, looking to establish metrics for progress on using in vitro tools and other alternative approaches instead of animals for those tests, and trying to use those metrics to help the agency set goals for reducing (inaudible) and reducing the use of animals for those tasks.

There are some sample metrics that I can give you just verbally. We're still really working through exactly what the metrics should be, what are the most helpful metrics, and what are the ones that we can actually easily measure, and also working through the goals.

We're thinking along the lines of the number of tools or approaches that are used per year. In fact, we can measure those just looking at the (inaudible) to the agency and what test companies used in their submission, and then also looking at the number of animals used for acute testing per year. Obviously, hopefully, hope to see over time a decrease in that.

So, we had a small subgroup working on this, but there's (inaudible) from the larger workgroups for setting goals and making progress in this area, of

course. One of the things we're trying to do is to be more specific about where in development and approval some of these alternative tests are, in vitro tests or QSAR tests approaches and sort of the timelines that you can see for when they would be able to replace or reduce the acute tests and what we can do to move them along as a group.

So, one snag that we're kind of hitting is that it is, of course, possible to count what tests were submitted, whether you're talking about the bovine (inaudible) test which is the BCOP for eye irritation. You can see that someone has submitted that in place of a rabbit test, but there are other alternative approaches that you can use, sort of weight of evidence and things like that, that aren't really reflective. You just wouldn't see that test. So, we're trying to work through how we can measure progress for those alternative approaches.

DR. MCLAIN: So, we'll just open it up to folks, anyone who has questions on the activities that the workgroup is doing right now or feedback on the proposals that Eric presented.

MR. BRADBURY: Susan.

SUSAN: I just have one request. When you set the time for the workshop, would it be possible to not set it on top of other workgroup meetings? That happened last time. I think it ended up being when there were working group meetings. I know it's tough because a lot of people work on different groups. Having a workshop, I like to be able to attend.

DR. MCLAIN: Yes, that's a good suggestion. Our plan is -- and I'm not even sure if a date has been set, but our plan is to have the workshop on the day before the PPDC meeting because we need to take advantage of the travel of you all to come to the workshop. But we can talk internally about what to do with all the workgroup meetings. We'll find a way to make it work.

MR. BRADBURY: Robin.

ROBIN: On the biomarker definition slide, are you working with the public health laboratories on developing those definitions?

DR. MCLAIN: The folks that we worked with are in our Office of Research and Development, our exposure laboratory. They're not definitions that are set in

stone, so if we -- when they go up, if you see things that you think should be either added or changed, please just send us a note.

ROBIN: I would recommend working with the public health laboratories once you've gotten what you think are your -- because I know that they're also working on biomarkers very heavily. So, that would be a good collaboration once you take it outside of the walls of EPA.

DR. MCLAIN: Right, right.

MR. BRADBURY: Mark and then Dave.

MARK: Given the kind of euphoria that surrounded the century 21 release in the news and in science and in other journal articles that came along, and given where you're at right now, are you surprised by the kind of time frame that it's taking actually to transition and move towards and in vitro system?

DR. MCLAIN: I don't think we're surprised by the progress that we've made or the amount of time that things have taken. I think at the outset, and as recognized in the report, it's a long term vision. When you get to the point that you're talking about, where

you're talking about are things in vitro and in silico and everything happening in a non-animal system, that's a very long term vision.

We've always planned for it to be an incremental approach and a changeover time and a slow adoption and change as we move forward.

MARK: Well, one of the things that I would suggest in the context of that is, given some of the things I've heard out in the field and some of the scientific organizations, it might be good to release sort of an interim thing, well, this is where we're at and this is how long -- we're looking at a long term future. I think that would really help the PR that's out there and the landscape right now.

UNIDENTIFIED FEMALE: Just to add to that comment, as part of my endocrine update today, this morning, I'll be talking about our movement with 21st century toxicology and that incremental progression that you've articulated and what we've articulated, this agency, and moving forward in a step by step fashion to increase confidence. I think the timing will be demonstrated through the SAP that is scheduled for the

end of January in terms of moving from vision to implementation. It's a very good comment.

UNIDENTIFIED FEMALE: So, Mark, that's a good comment because a couple years ago we put up a web site about our 21st century vision. Part of that web site had the tool thing developed and it had milestones and when we were predicting things to go into peer review or where we would look at it. We need to go through and probably update that web site.

UNIDENTIFIED MALE: From my perspective in the university and in the teaching community, as well as the research community, and not a very faithful member of the 21st century tox group, the kind of stuff I hear among colleagues is what's happening. I'm thinking about it from the academic science end of it.

MR. BRADBURY: Dave and then Matt.

MR. TAMAYO: I'm kind of channeling Susan here. Jennifer, your response, it sounded like the plan was to have it the day before PPDC. I think that's exactly the wrong time to avoid conflict with the workgroups. I think, really, I don't want you to go too far along that line because I'm on some other workgroups as well.

DR. MCLAIN: We will talk and work it out so that you don't have lots of conflicts on those days. We'll try to figure something out. I understand the concern. We would like you to be able to come to the workshop and learn. So, we'll think about that.

MR. BRADBURY: Matt and then Ray.

DR. KEIFER: I just wanted to voice support for Eric's idea about adverse outcome pathway workshop. I think it's a great idea. It gives us insight into a lot of things that we otherwise might overlook.

MR. BRADBURY: Ray and then Kristie.

MR. MCALLISTER: Several questions about the biomonitoring workshop and the next steps. You mentioned an expert group for development of priority pesticide lists. The members of the group, are they posted and known or are you still recruiting?

DR. MCLAIN: Right now we're just in the stage of getting some final responses from folks who are agreeing that they would be interested in joining the group. But we will post the group up on the web site for the workgroup so everyone knows who is working on that. I think that we can probably do that -- I think we

actually might have just had our final response come in this past week. So, that's something that we can do really soon.

MR. MCALLISTER: Is this to be a workgroup of PPDC or something independent?

DR. MCLAIN: This is a subgroup of our workgroup that is charged with working with this expert group. So, the expert group is basically working with our subgroup to provide us with recommendations. Then, what we will do is come back to the PPDC when we meet again and talk to you about the recommendations we receive from the experts, both in terms of the criteria for prioritizing the pesticides and a recommended list of pesticides.

MARK: The web site, is that linked under the PPDC web site or is it somewhere else?

DR. MCLAIN: Yes, it is. If you go to the PPDC web site, you'll see, I think, on the right hand side there's a list of all of the workgroups. Each one of the workgroups has a separate page. We'll make sure that it's in an easy place on the page for you to find.

MARK: These definitions and examples, they're

not exclusive to pesticides are they?

DR. MCLAIN: No, they're not.

MARK: They look like broader --

DR. MCLAIN: Right.

MARK: Is this inquiry coming from the direction of PPDC? Is that a primary purpose for establishing these definitions or is there some other initiative involved here?

DR. MCLAIN: No, the definitions were really in response to a request from folks here at the table, that they just wanted to have a resource of some simpler definition to look at. So, that was our goal in putting them together, just to provide some information.

MARK: Okay, thank you.

MR. BRADBURY: Kristie and then Mike.

MS. SULLIVAN: I just actually wanted to respond to Mark's comments about your colleagues. So, one of our charges as a workgroup is to advise on communication with stakeholders. So, I'm just curious about what do you think is the best way to reach your colleagues? How would they like to get information about what's going on?

ERIC: Well, another article in science would help, probably. That kind of thing really splashes. But I think short of that, historically, the EPA has really done some nice documents on various areas, not just toxicology but IPM and what they're doing in school IPM now, kinds of modes of communicating. Those are the kinds of things that some of us in the field who are connected with you through this process or other processes can use to educate people in the field. So, that's what I'm thinking about, more like that.

Certainly, getting a splash as big as century 21 tox did initially isn't probably going to happen now. That's going to be very hard to manufacture. But the steady education process probably ought to go on because I think that will not only help you recruit in the future for input but also keep the people who are interested in that abreast. So, that's more like I was thinking, more like an extension scientist.

MS. SULLIVAN: So, maybe having a published report of the workshop would be helpful, some kind of written minutes or something that people can look at if they're not able to come to the workshop.

The other thing we actually talked about a couple years ago was having like a presentation, like an elevator speech or something, some sort of presentation where you have a few slides. Is that something that would be helpful if people had a few slides they could show your colleagues?

ERIC: I could really use that, yes. I would use it in my grad and undergrad class.

MS. SULLIVAN: Okay.

ERIC: Right now there's a place for it. I already used the NRC's century 21 thing in my grad class. That's pretty -- it looks great. Then there's the reality. So, that's where I'm coming from.

MS. SULLIVAN: I think this workshop -- a lot of people haven't heard what AOPs are yet, but it's really a continuation of toxicity pathways in the original report. A lot of people have latched onto it as really a helpful way to visualize how you use these tools. So, I think the workshops can be really helpful for a lot of people.

MR. BRADBURY: Louis.

MR. JACKAI: I think all of the above avenues

that you've mentioned are going to be very useful, particularly the slides that you talked about. Another opportunity would be to take advantage of the professional meetings or workshops that take place every now and then. You reach a lot more people that way. You can have a question and answer session to clarify any doubts that might exist. But all of this would be useful in getting to the university community.

MR. BRADBURY: Okay, let me just wrap up this segment. I know there's another presentation on some other activities. As far as the workgroup recommendations, we'll proceed with the planning for the biomonitoring workshop, realizing we're going to have to work on some scheduling options. We'll see how much money Marty has got in the checkbook and see if we can stretch out some travel for some folks. But we'll figure something out.

Then, the metrics activity in terms of trying to keep track of what tool they're starting to use and how that is playing out. One thought I have in addition to looking at reduced number of animals, I can also imagine reduced number of dollars or time frames maybe to

make the decision.

But if there's some way to capture the quality of the decision making, which I know that's kind of harder to get your head around, but we've always talked about how it's not only trying to increase efficiency and throughput, but it's as much confidence or even more confidence in the overall decision making. So, if the workgroup can think -- that's hard, but I think it's important to try to keep wrestling that concept as well.

Then, the whole workgroup, maybe out of the metrics group or out of other activities, be thinking about other ways to get the word out in terms of what we're doing. Maybe it's like a progress report or enhancing some information that's on the slide already to sort of help punch home where we are and where we're going. It could be a number of venues, but the workgroup keep thinking on ways to get the word out.

Okay, Dickie or Jennifer.

DR. MCLAIN: Okay, before we leave this, I want to just thank the workgroup for all the work they've done. It really is a working workgroup. We do, as you can see, a number of projects that are quite varied from

each other. A lot of people put a significant amount of time into those projects. We really appreciate the work that you do to help us in this area.

I also want to give a thanks to one of our OPP staff, Rebecca Vandenhagen (phonetic) who is our executive secretariat. She has been invaluable in keeping all of these subgroups and workgroups coordinated and moving forward. So, thank you, Rebecca.

So, now we're going to move on to some of the things -- Mark, you gave a good transition to this -- that are going on in OPP in terms of where we're going with 21 century activities.

So, you're all familiar with our vision and our goal to move our science into 21st century. We want to move our assessments in a place where they are more integrative and hypothesis driven so that we're focusing our resources on the chemicals and the end points where they'll have the biggest impact to those of greatest concern.

So, our strategy for doing this is to ensure that we have a very strong science foundation and policy foundation and really work together with you, our

stakeholders, and with the research community, other government organizations, and the international community in moving the science forward and the application and the implementation of that science forward.

So, as we were discussing earlier, this is really an incremental move that we see as an evolution of where we are as a program moving forward. So, what I'm going to do is present a few of the things that our office has recently completed or we're very close to completing. Then, Mary is going to follow with one of our major projects in terms of the QSAR guidance that's just come out.

The first of these is our genetic toxicology policy which we put up on our website a couple months ago. This policy acknowledges the advances and gene tox science, the new methods that have come out that we're always open to receiving. But, more importantly, it allows the testing to be integrated with existing standard tox studies rather than having a separate independent study. So, of course, this reduces the animals that are used. That's one of the things, as an office, that we are committed to finding ways to make

that happen.

This next one is an alternative approach for doing eye irritation testing for hazard labeling and for antimicrobial products that have cleaning claims. This is something that we started in 2009 by establishing a voluntary pilot program. It was based on an ICFAM (phonetic) review of a comparison of in vitro and in vivo data on antimicrobial cleaning products.

The purpose of our pilot was to try to ensure that we could apply the test that ICFAM had come up with in their review to our labeling process in house to ensure that we were making decisions and appropriate hazard labeling for the product. The test that came out of ICFAM uses three different protocols. That's to cover the range of the toxicity categories that the products might fall in. There's no restriction on the toxicity categories with respect to the pilot. It's open to any of the antimicrobial cleaning products.

It's been going on for a few years. We feel that we have received a sufficient number of studies to be able to make some determinations, that we are able to successfully make our labeling decisions that we need to

make with the in vitro tests. Our staff has been trained through this pilot process, and we are now working toward establishing the approach as an OPP policy. You can be looking for that in the future, not too far from now.

The next slide is on our guidance that we put out earlier this year on waiving or bridging acute toxicity tests. There's actually nothing new in this guidance, but we understood from a number of stakeholders that what we had out there was confusing because there were so many different documents that had come out over the years about different components of bridging or waiving.

The request was to please just consolidate them so that there's a single source of information, to really encourage the bridging and the waiving of studies where we have other information that we can use to make our decisions. The guidance covers all pesticides, so there's specifics in there for biochemical and microbial pesticides, to antimicrobials and conventionals.

Kind of building on that theme that one of our goals is to use knowledge and promote the use of existing knowledge when we're doing assessments. We've also put

together guidance for our staff to assist them in evaluating the open literature and looking at the studies that are out there right now to help us make decisions about the studies that we need to further our risk assessments.

So, there are two separate guidance documents that are specific to the ecological and the human health risk assessment. This is for our staff, but it is also for you so that you understand the process that we go through when we're searching the literature, how we evaluate the quality and the utility of studies and the open literature and make decisions about whether or not they're useful for the risk assessment in either a qualitative or quantitative sense.

The principles that are in these documents aren't a deviation from where we are as an agency. They're really built upon some of our existing policy in terms of our guidelines for ensuring the maximum quality and utility, integrity of scientific information, and our risk characterization policy that really is based upon a philosophy of transparency and consistency and reasonableness.

So, those are a few of the activities that have happened over the past year. I'm going to turn it over to Mary because she's going to talk about one of our major accomplishments of the year.

MS. MANIBUSAN: Okay, good morning, everybody. I'm Mary Manibusan. I'm coming to you today from the Office of Science Coordination Policy, but nine months ago I was with the Office of Pesticide Programs. I was also the grand chief of the Toxicology and Epidemiology Branch in the Health Effects Division. That's where really I had the privilege to be a part of this project that I'm so pleased to be presenting to you this morning, and that is the completion of the NAFTA Quantitative Activity Relationship guidance document.

Up on the cover slide is my name along with my partner from the Pesticide Management Regulatory Agency, Jill Patterson (phonetic) who co-led this huge effort with me in terms of its production, its writing, and its evolution. Again, this is one of the projects that really peaks at tox 21 vision as we just talked about this morning and carries it forward into the implementation phase.

So, for this morning's presentation, what I'd like to do is just give you some background on the NAFTA project, talk to you a little bit about why we're focusing on QSAR as one of the IATA tools, among many, and then spend a little bit more time just giving you some general concepts of the framework that's in the guidance document, talk to you about the scientific peer review process, as well as the vision in terms of moving forward with QSAR with respect to the adverse outcome pathway, and then, of course, the implementation plans and next steps.

The NAFTA project was actually formalized in December of 2009. Of course, a lot of work had begun already in terms of thinking about QSAR, using QSAR in many of our day-to-day evaluations. IATA includes many technologies, and we recognize that. It includes molecular, cellular, and computational toxicology.

We're looking to again refine our need for specific testing requirements for pesticides, targeting our testing to only the data that we need to make decisions in human health and ecological risk assessments.

As a NAFTA project, it's really signaling our movements collectively as North American countries in this direction, moving towards utilization of these computational tox schools and how do we do that consistently and align our programs to such a degree that a presentation of this type of data in Canada or Mexico is no different than what we receive here in the U.S.

So, QSAR is a very, very old tool, if you think about it, but it's being used consistently. This is nothing more than looking at a chemical structure and some of the inherent chemical properties and drawing upon it to establish what you would need to understand for a chemical that's not yet tested. So, this is moving in the direction of reducing animals. In fact, perhaps in some situations, not needing any animal testing. That is the future. That is the aim. Where we are today is what this guidance document speaks to.

In terms of its longer history, we know some examples already in terms of quantitative structure activities. We use it for our carcinogenicity predictions. We know that when we have an electrophilic compound or a cleaner compound that can (inaudible) DNA,

we can anticipate its toxicity. That's not necessarily true for all endpoints and not necessarily true for all chemical domain structures. So, I'll talk to you a little bit about that.

That really tries to capture what we use QSAR today in terms of (inaudible) endpoint predictions for regulatory applications. But it also has a segment that speaks to how we look to using QSAR in the future in terms of key events and precursor events in the adverse outcome pathway.

So, what is the QSAR guidance document and, more importantly, what it is not? The purpose of the QSAR document is really to articulate and lay down in one single document what we already know and what type of experience we've already gained. We've been using QSAR in our residue of concerned determination, looking at metabolites and (inaudible) of concern for inclusion in our risk assessment as well as in our tolerance expression.

We've not been doing that according to guidance, perhaps, but we were doing that using expert judgment. We're doing that within different programs

within even the pesticide program. So, this document is really to gather up all the intelligence, all the experience that we have to date and put that in a framework that we can share and ensure a systematic and consistent process.

The targeted audience here is for pesticide evaluators. It is not for the QSAR modelers, it's not for experts who know how to integrate information, like (inaudible). It's really for the day-to-day reviewers. How do you evaluate a QSAR document alongside with your other empirical data?

The functionality of this document, it is a flexible framework. It is not an SOP. It will not take you step by step through the process of evaluation. It gives you a conceptual design in terms of how you should think about QSAR as you progress forward in your assessment.

I want to highlight again that this document is not just a human health (inaudible) piece. It also speaks to how we use QSAR in our environmental risk assessments, and emphasizing that QSAR is only one of the many components as you conduct our weight of evidence

analysis.

Here is a flowchart diagram that's embedded in the guidance document. Here it really speaks to the three central components of the document. The first component is just an introduction background. It tells you what QSAR is, what kinds of methods are available to you. It talks a little bit about our history in terms of how we've used it across our agency.

The center body of the document really speaks to how a reviewer would consider a QSAR piece of information in our risk assessment, starting from the problem formulation asking a question of, what are you looking to use this QSAR to answer, what is its purpose, what are you trying to do in terms of decision making, and moving into determining the adequacy of the QSAR prediction, again looking at its relevance, its reliability, and using some of the OECD QSAR validation principles that have been already articulated, and then integrating that piece of information alongside with what you have in pesticide submission information and asking the question, does it make sense, is it biologically plausible.

There's also a section that speaks to an event where you might have multiple QSAR predictions, and how will you think about combining those sets of data. Again, conclusions really going forward, how do we think about QSAR in the AOP concept as well as thinking about peer review and the need for expert judgment.

So, I want to spend a little bit of time in the centerpiece of the document just to give you a look and feel about what this guidance document really lays out for you. Again, probably the most important piece in this guidance document is the problem formulation piece.

Again, asking the question, what it is you're trying to do. For example, if you're trying to replace a reproductive (inaudible) if you've got a QSAR report that gives you information on (inaudible) endpoint, you're done. It's not adequate. You cannot make a decision. You move forward.

But if you have information on QSARs that is relevant to the decision making that you're looking to make, then you can proceed forward and looking at the adequacy of the QSAR prediction. Again, here you're looking at the validity and relevance of that QSAR report

for the decision that you're looking to make.

Here I'm just highlighting some of the QSAR validation principles that we think are globally applicable. They're just generic expectations of looking at a defined endpoint. Again, if you're looking for a prediction of carcinogenicity, that's fine. But if you're looking for a prediction of reproductive toxicity, that's a lot more difficult. We've not found a model that is capable of doing that just because it's such a variety of different endpoints to predict.

We're looking for an unambiguous algorithm, so something that's transparent and clear and that you could reproduce and go back and retrace on how you came to that conclusion, that predicted outcome. That is really key. Probably the most key for our pesticide chemistry is ensuring that our pesticide chemical domain is captured in that QSAR model.

So, if that QSAR model has just pharmaceutical chemistry in its training set, that's not necessarily going to be applicable for our pesticide chemistry. So, that's really important that a negative is truly a negative. It's not a negative because that training set

isn’t able to speak to your chemistry.

Testing for goodness of fit and robustness, again this is getting at the accuracy and the how (inaudible) you are in that QSAR prediction, and then capturing it together with what you understand about its biology. So, thinking about (inaudible) and chemical structures that you already know a lot about, perhaps you can blend in that information on how you evaluate your QSAR prediction.

Documentation is listed here as C because we’re looking to assure that we’re consistently applying QSAR reports and predictions across the board in our evaluations.

Integrating QSAR into hazard assessment. Here we’re emphasizing that QSAR is just one component in the weight of evidence assessment, and that you really need to evaluate your empirical data against that QSAR prediction to see if it really makes sense. Does it hold true when you understand that mode of action?

Future conclusions in terms of shifting forward in the 21st century toxicology testing, we’re building on what we understand with the adverse outcome pathway

starting from the molecular initiating vents carrying all the way out to human population level understanding and information of what's going on at the human level.

Then, here stressing that whatever you use in terms of a QSAR prediction, those QSAR predictions are really critical to how we demonstrate consistently the application of such. So, the need for scientific judgment peer review is critical. We emphasize that in our guidance document as well.

In the appendix associated with this guidance document is some key information, some links. Again, this document isn't intended to replace any existing guidance that's available. It's looking to provide the necessary information for a risk assessor who might not be as familiar with QSAR. So, we provide some links and guidance documents so that if you're interested, you can dive deeper and go into these sites.

One of the riches of this guidance document is also the inclusion of case studies, how does the application of this guidance look for real life situations. It provides some key examples on applications to QSAR, for pesticides and other chemicals.

It provides an ecological example as well. But we're here stressing the validation and use of models, including things like read across and integrating QSAR along with other information you have.

That concept is depicted here in this figure. On your right is how we think about chemical risk assessment and how we want to evolve towards a more targeted testing approach, going to prioritizing for testing, targeting in vivo testing, making hazard characterizations and the ultimate risk assessment.

You'll see a similar depiction of how we're approaching this for the endocrine program, but speaking to QSAR, QSAR is able to at least be informative for how we begin to prioritize our future testing, along with what we know about the exposure information. It also can give you added information for the hazard information we've just spoken about. Thinking about utilizing chemical grouping and read across is a really rich combination for how we anticipate moving forward for tox 21 testing.

This document is really the fruition of so many experts across our agency and across other agencies. So,

listed here are the internal reviewers, internal workgroup members that have been crucial to making this particular product come to life, if you will. So, we have experts from OPP, toxics, our ORD. We also reached out to FDA who has a lot of experience with QSAR, as well as our experts in Health Canada.

We had a very large external peer review process that included experts internationally. So, we have the European Joint Research Center, USFDA, OECD, and Environment Canada involved in our external peer review. One of the recommendations from this external peer review is to take the richness of this established document that speaks to guidance for pesticide risk assessment and really broaden it to include other chemicals and making this an OECD project.

So, that’s the proposal that was developed, to take this document and use it as a baseline, if you will, to create a guidance document that is applicable to all chemicals. This proposal was presented to OECD this past June and was accepted formally. The new project leadership will be provided by our own Office of Pesticide Pollution and Toxics, as well as Health Canada

and Environment Canada.

The next step for this NAFTA QSAR guidance document has already received approval by the NAFTA executive board. It will be loaded in November on this particular website, and that will be today. We've also been thinking about other legs of this stool in terms of implementation.

So, while creation of a guidance document is great and it captures all of our intelligence in how we plan to move forward consistently and systematically, we also want to make sure that there is support in doing so. So, as I had emphasized, it's really important to have an expert consultation group to provide that expert guidance, people who have experience in looking at QSAR for our toxics and Health Canada groups, for example, can lend their advice for how to do we move forward. Each situation will be case by case, depending on the volume of information, the richness of the current data, as well as read across.

So, we're looking to the formation of an expert QSAR group that will probably be embedded in our current (inaudible) committee, the residue of concern knowledge

based subcommittee. We'll be reaching out to our (inaudible) counterparts, as well as members from the workgroup.

We've also thought of plans to develop a QSAR training module, both internally and externally. This is again based on our examples and how we've gathered examples through experience. We want to emphasize that as we move forward, this guidance document is a guidance document, the guidance document that will be enriched by experience gained and case studies as we evolve. So, we're going to continue to learn by doing and learn by implementation.

This slide is probably the most important slide of my deck. It's to acknowledge again the project lead, Jill Patterson from Health Canada who is an incredible scientist as well as a proficient writer. Calling out Dr. Ray Kent (phonetic) from HED and Jonathan Chen (phonetic) from AD, critical key lead authors for this document. The (inaudible) displayed really provides that richness of experience.

I want to call out the new OECD chair for the OECD project, Dr. Yintak Woo (phonetic) from our OPPP, as

well as Dr. Seniel Culcarney (phonetic) from Health Canada.

This is a picture of a board model. Neil Barr (phonetic) was a Danish (inaudible). Here is his model, which displays an electryme that is orbiting around the nucleus, the atom. As it jumped from the outer orbit to the inner orbit, it's releasing a photon of energy. So, it's going from a higher energy state to a lower energy state.

That is how I liken our targeted testing approach, that we're moving towards a lower energy state. I believe that this quote that I leave you with is entirely relevant for this talk, and that is prediction is difficult, especially if it's about the future. Thank you.

MR. BRADBURY: Thanks, Mary. There's a couple of quick questions of clarification on Mary's presentation, or what Jennifer was summarizing. Then we'll turn it over to Mary to give an update on the endocrine program. We'll do just a few quick questions.

Caroline.

MS. COX: When I think about QSAR, the thing

that I always -- I'm not technically adept at QSAR, but the thing that always concerns me is it seems like by definition, it's going to miss any chemical that has a mechanism that's different from what we've looked at before. Looking to see if a chemical has a structure and so forth, that's similar to chemicals that had mechanisms, adverse outcome pathways, I guess, that we know about. But if it's something new, we're just going to miss it. I was just wondering if this guidance document addresses that issue.

MS. MANIBUSAN: The guidance document really, again, is not a step-by-step process. It does articulate that uncertainty in QSAR with respect to endpoints that might not have been tested for. I think that's what you're getting at, where we've articulated this and how we think about incorporating this into risk assessment.

We're very clear in the guidance document that you need to ensure that that QSAR prediction is based on a training set that is informed by empirical data. So, for pesticide chemistries, for example, we have a large set of empirical data from submission information.

We want to make sure that that prediction is

also relevant for how we think about weight of evidence. So, we're building on what we know. We're not just using that QSAR prediction in isolation. So, that's a critical recommendation of this guidance document.

But I think as we move along as we see models start incorporating some of our toxicity information, it will enrich the QSAR prediction. But always I think you do have to ensure that it's anchored by what you know and what you have data to demonstrate before you move forward. So, that is a very good point.

MR. BRADBURY: One last question or comment, Gabriele.

MS. LUDWIG: This may actually be more for you. I guess for all of us, I'm just trying to understand how this transition is occurring. I mean, what I'm hearing now is this is all still in the testing or voluntary mode. But what's the process if EPA decides, okay, this is the way you need to test to submit something to us. What are the time frames and what's the process for that transition?

MR. BRADBURY: I think from all these presentations, part of the message is even before that

NRC report of 2007 was written, some of this was already happening. In other words, as Mary is indicating, the use of quantitative structure activity relationships in the Office of Pesticide Programs has probably been going on for at least a decade. But what's happening is there's more focus now on the advancement of those tools instead of sort of once in a while are we starting to be on a path to use them more consistently.

For probably decades, registrants have done good science and said, you know, I've got all this information that I think captures your information needs. So, I'm submitting a data wave or to say I don't think I need to do this particular bio assay because of this body of information that already exists for the chemical.

Some of what we're describing is trying to formalize that and help set targets so that as the research advances, we can start to use more of that information. So, some of what you're hearing is just getting things organized and clearer and more focused so people can see what's always been going on, but now it's becoming more obvious, more transparent.

Jennifer was describing some of the movement

toward the replacement of the in vivo test for the six pack with in vitro. An example of if you look back a couple of years when we started as a pilot, we weren't so sure how to do this, so let's try it out. We've done it a few years. It's starting to work. Now we're reporting out to you we're ready to move from pilot stage to we'll take that data and we've got a way to deal with it on a routine basis.

I think what you're seeing, Gabriele, is evolutionary steps. So, if we stand back from this meeting and look back two or three years, you'll see this progression. When it gets back to Mark's point, I think we need to do a better job of capturing what we've been doing and where we're heading.

Matt.

DR. KEIFER: I'm very excited to see this and I think you did a great job both of presenting this and it looks like this is going to be a great document. The one question I would ask is, is nano particulate delivery systems affecting understood involving or somehow modifying or understanding of the QSAR system?

Given what we've seen in some environmental

exposures with nano particulate toxicity, which differs substantially from the toxicity when delivered in other methodology and other techniques, is that part of the QSAR? Is it considered? How are we integrating that into the process?

MR. BRADBURY: We had a science advisory panel meeting about two years ago which wasn't QSAR, per se, but it was about how do you take a look at hazard information, exposure information, how do you integrate that in a risk assessment for nanomaterial as opposed to non-nanomaterial. It was a nanosilver case study, if you will, in getting feedback from the SAP on when is sort of bulk silver the same thing as nanosilver or when is nanosilver really different and you need perhaps a different kind of information or testing.

So, I think we're more at that level in one sense and starting to work through empirical information, when is silver silver and when is whatever, copper or whatever example you want to use, I want to pick on silver, but when are they the same bulk and nano and when is it different. If it's different, what's the kind of information you need to get going on that?

The Office of Research Development is doing a lot of work on this along with other partners in the federal government. It has a QSAR component to it at some point. I think, as Mary was implying, you've got to build this empirical dataset and understand the adverse outcome pathways and the mechanisms before you can loop back into the nano.

That SAP was clear. Sometimes nano/non-nano it doesn't matter; sometimes it can matter a lot. We're kind of approaching it on a case-by-case basis in the program right now.

UNIDENTIFIED FEMALE: Just really, really quickly. I just wanted to thank you guys for putting out these documents because I was probably one of those sequels, as you said. I don't know what you guys accept. No one knows what the plans are. So, for the genetic toxicology, that's great for the waiver (inaudible) document. There's been a lot of stuff coming out (inaudible) that's really helpful. So, I just wanted to thank you for that.

MR. BRADBURY: Okay. I think Mary has had a chance to rest her voice. Mary Manibusan, who is the

director of the Endocrine Disruptor Screening Program, is going to provide an update on the status of the program.

MS. MANIBUSAN: Okay. So, hello again. I'm going to put my hat on as the endocrine director. Again, just to emphasize that I'm coming to you from the Office of Science Coordination and Policy. As its name indicates, I do coordinate very closely with the Office of Pesticide Programs, the OPPT, as well as Office of Water, which we'll talk a little bit about.

So, I want to talk to you today. It's been about nine months since our last update on the endocrine program. Things have changed. So, this morning what I'd like to do is reset the table for you in terms of laying out just our overview of the endocrine program as a baseline, just walking you through really slowly with that.

Then, I would like to center my talk on (inaudible) activities using the recently published comprehensive management plan as the umbrella to capture some of the key activities that are listed here, such as tier one screening data reviews and weight of evidence, as well as capturing our work on finishing up the tier

two methods development.

Then I'll pick up the pace and talk to you about future activities with regards to use of computational tox tools in the advancement of the program and starting with the chemical prioritization process that will be up for SAP review the end of January.

So, I typically start with reminding everyone that our mission as the endocrine disruptor screening program is to protect public health and wildlife by screening and testing chemicals and then taking appropriate action for those chemicals that are found to have endocrine effects.

We do so under two primary statutes, the 1996 FFDPA section 408P. You can read the text, but I want to underscore that we were directed to develop this screening program and use validated test systems and to focus at that time primarily on the esergenic pathway. We've expanded from there.

We also have statute provided by the Safe Drinking Water Act. Here, different from FFDPA, it speaks to those chemical substances that may be found in sources of drinking water if there is substantial human

populations of exposure. So, there's an exposure component here in the (inaudible) language but not in the FFDPA.

The endocrine program is a two-tiered screening and testing program. Here on this slide are the 11 assays that we include in the tier one screening. These are to capture whether a chemical has the potential to interact with the endocrine system, again not causal, but it's a screen. It's a screen in the sense that they are meant to be redundant and they're meant to be complementary. They speak to not only the esergenic pathway but the androgen pathway as well as the thyroid.

We're currently working on some proposed tier two methods, the first two from the mammalian two generation as well as the extended one generation reproduction studies. These are already validated and are in place.

We're looking to utilize that same thinking in terms of moving from a two generation to a one generation study for the new ecological tier two method, no listed tier, the avian two generation reproduction study, the larval amphibian growth and development study, the fish

and inverta multi-generation reproduction study. These are currently in progress.

This is a quick snapshot of our current timeline, starting from 1998 and 1999 when we had our EDSTAC report finalized in 1988. That really provided us key recommendations that really formed the basis for our program in terms of being a two-tiered testing program, expanding from human health and also include wildlife and ecological, as well as looking beyond estrogen inclusive of androgen and thyroid.

We formed the EDSP program in 1999. In 2008-2010, we had a number of critical milestones such as the validation of the full battery in 2008 with our SAP. We also issued our initial test orders for list one in 2009 comprised of 67 chemicals, including 58 active ingredients and 9 high production volume ingredients, which we're in the process of reviewing data for. We also issued an FR notice publishing the proposed list two along with the ICR statements of purpose and our policies and procedures that are captured for list two that we're currently undergoing evaluation.

In 2011, we issued two critical documents, the

EDSP 21 work plan summary, talking about our vision and incremental progression with use of (inaudible), as well as our weight of evidence document that really pulls together how we are thinking about lending in not only the tier one battery but also consideration of the richness provided to the park 168 tox submission information and other scientifically relevant information.

In 2012, we issued our first comprehensive management plan. I'd like to spend just a few minutes focusing on that as our umbrella document. Just going back really quickly, I provide a picture of the cover of the management plan because in the future, as you look at documents for the endocrine program, it should look just like this. So, if you see a document with a cover page like this, this is the endocrine program.

So, this comprehensive management plan was issued on June 28th, 2012, in response to our OIG recommendation to have a document that really speaks to how the agency plans to and endeavors to hit our milestones and achieve the mission that we set out for, covering over a five year time horizon.

The strategic plan, however, is critical for us internally. So, it has primary importance there for our staff and managers to think about how we operationally focus ourselves and coordinate among the various offices. It's clear that it's not intended to provide any policy or procedures or impose new requirements. It's again an internal document that we share publicly. We want to ensure that we're transparent and that we're involving the public as we move forward.

It's important to know that this is a living document. We indicate in there that we will be revising it on an annual basis because we know that things will change, new science will come to bear, and we'd like to make sure that we are updated.

So, here is a layout of the management plan in terms of the various components. I'm going to want to focus today with you on the four areas here. The first is a management organizational chart. This is speaking to how do we coordinate this program, which is a coordinated program, across OPP, OPPT, and Office of Water, and engaging our Office of Research and Development.

Then I want to talk about the critical activities that we have before us, that is the technical data reviews, both using high throughput as well as looking at tier one in terms of uniformity, consistency, and accuracy, talking a little bit about the validation process for our tier two test methods for the multigenerational (inaudible) studies.

Then, lastly, spending a little bit of time talking about the EDSP 21 work plan and kind of our evolution in utilizing these computational tox roles, as well as exploring different ITS sects to ensure that we can move forward in e-submission and e-data review.

So, here's a picture that was pulled from our comprehensive management plan. It really demonstrates how do we coordinate and make decisions as a management structure so that we can capitalize on the different expertise in the different offices, as well as engaging all of our partnering offices in making critical decisions.

We have a public outreach team that will ensure that we are sending forward a consistent message. We're also providing information in a timely basis. We have a

science committee ensuring that our scientific methodologies have been reviewed, have been coordinated.

One of the workgroups that is a permanent workgroup that reports to the science committee is the EDST 21 workgroup that Dr. Vicki Dellarco and I are currently cochairing with involvement from our Office of Research and Development both from NHURL as well as our national computational tox center.

The policies and procedures committee that makes up our partner, Richard Keigwin from OPP, Maria Doer (phonetic) from Toxics, as well as risk managers from OW. We have guidance provided from our OGC and our RCS group. Both of those particular committees really are part to our steering committee. That includes a deputy office director. Marty Monell is a key member in that committee. That committee really reports to the management council. That's all our office directors, including Dr. Bradbury here. All the decisions are really well flushed out, but they're engaging all the critical offices that we need to partner with to ensure that there's a seamless process as we move forward with the endocrine program.

Here's a table again extracted from the management plan that highlights some key activities. Here I focus on 2013. You see here we're starting with the chemical prioritization and use of computational toxicology in 2013. We have the completion of the data reviews of the initial list of chemicals in 2013, as well as taking all of this information before our science advisory panel. So, everything in terms of the tier one assay by assay, battery performance, and weight of evidence determination will be presented in a very public and open forum to undergo strict scientific scrutiny and rigor.

In 2013, as well, we're hoping to complete the tier two internal laboratory method validation and bringing that before the SAP, and then looking to finalize list two chemicals as well as putting forward test orders. But this is highly dependent on a number of activities such as finalization of the list two, as well as ensuring that we have finalized policies and procedures. Very busy year.

This next document is the EDSP 21 work plan. This was issued in September 2011. The objective of our

EDSP 21 work plan is really to segue from the traditional methods into computational toxicology to ensure that we're as efficient and expedient as possible in meeting our missing and goals. We're wanting to do that in a very incremental and measured fashion.

So, here are the objectives we see to ensure through the work plan. That is, speaking to the 2007 NAS report, we're looking to maximize all existent data, not just the swift tox 21 tools, but any information that we have, chem properties, information on structurally similar compounds. We want to maximize and optimize that use to really formulate a more targeted testing approach for in divo toxicity screening.

We're using a variety of tools in a very tiered fashion, and we provide a framework for how we plan to do that, again stressing the systematic approach in incremental fashion of incorporating these new tools and methods all under the umbrella, if you will, with a key understanding of the AOP and toxicity pathways.

Here's a figure pulled from the ESP 21 work plan. It's meant to only (inaudible) provide that increasing level of confidence as we move forward. The

key here is fit for purpose. What are we trying to do with the computational tox tools and how we plan to use it will drive the need for increased scrutiny and validation and peer review.

So, starting from the first step, that is where we are today. How can we use computational tox tools to help us better prioritize what chemicals go into our screening program first and what is lower tiered because of information that we have?

The second phase is taking that next step in terms of utilizing high throughput information and computational tox tools to better inform our decisions about which particular tests we need to select. So, it's more of a targeted testing approach. We're only asking for particular studies that we need to inform our judgment. Lastly, it's the data replacement phase, which is a longer term endeavor, and that is to use computational tox tools to replace our entire tier one screening battery.

Today we are at the chemical prioritization phase. For the chemical prioritization that we plan to take before our science advisory panel come January is a

consideration of multiple data screens. So, we're looking at the utilization of not only high throughput assays for estrogen and androgen and thyroid, if they're available, but also considering inherent chemical properties. Things like acidity and basic and TKA values will all be considered in how we rank and order particular chemicals for screening.

We're also looking again to utilizing some of the model predictions, such as QSAR, and some of the expert systems that the ER experts just always brought before the SAP in 2009. We intend to capitalize on that information, as well as looking at read across and chemical categories and how do we think about structure analog, all again linked together under the framework of what we understand about the AOP concept and toxicity pathways and mode of action.

One of the key documents that we just issued on November 27th, this week, in fact, is the EDSP Universe of Chemicals and General Validation Principles document. In that document, we really key in on utilization of these OECD QSAR validation principles for review and evaluation of computational tox tools for the purposes of

chemical prioritization. So, nobody can argue that you need to have a defined endpoint. For the endocrine program, that's the estrogen, androgen and thyroid pathway.

We also want to ensure that there's an unambiguous algorithm. Again, this is speaking more to transparency and making sure that we can cross (inaudible) the prediction or the outcome as to how we came to that information. Defining the domain of applicability, our domain of applicability is defined by our statutes.

So, FFDCA and the (inaudible) chemicals universe provides us about 10,000 chemicals. That is the domain of applicability that we'll be exploring, as well as looking at the appropriate measures of goodness of fit. Perhaps the use of balanced accuracy or controlling for false negatives and false positives is appropriate for our EDSP chemical prioritization. Again, ensure that we have a good understanding of the toxicity pathway and how each information fits along with our understanding of that, so key considerations in implementing EDSP 21 beyond chemical prioritization inclusive of data

replacement.

We want to ensure that we have a clarity of programmatic goals. What are we trying to do? What are the questions we're seeking to answer? Define the application and regulatory decision context. Again, depending on how we're planning to use these computational tox tools will define our level of confidence and our level of uncertainty that we're willing to accept, if you will, and also building on the transparent strategy, making sure that we're doing this out in the open, we're taking everything before our science advisory panel and engaging the public, but overall determining scientific validity in these tools and how we seek to approach utilization of those.

In terms of ensuring that we have scientific rigor and public participation, here's a timeline that is illustrated for 2013. So, the first item I list here is the January SAP on use of computational tox for chemical prioritization. We're working very hard on building that document for review.

The subsequent SAPs will be focused on the tier one assay by assay battery performance as well as weight

of evidence analysis. Then, finally, we're hoping to take before our SAP the validation of our tier two methods. That will close out our year of 2013.

So, I leave you again with another quote. I love quotes, as you can tell. And here's a quote from the father of evolutionary biology. I think the statement is really relevant here. It's not the strongest of species that survive nor the most intelligent but the one that's most responsive to change. I think we are in a generation where we are expecting change. Thank you.

MR. BRADBURY: Thanks, Mary. We've got time for a few questions of clarification.

Cindy and then Jennifer or Robin. I can't tell. Robin, okay.

MS. BAKER-SMITH: Mine isn't so much a question or a clarification. I just want to make a request, I guess, which is a lot of this is not something I'm deep in knowledge in. But I know from a high level view that the registrant community has spent a significant amount of money generating data on these first round of tier one battery tests, something in excess of $50 million, I

think, has been spent generating this data. So, I appreciate the updates.

I think the idea of having a dialogue about what are we going to do with this information, what does it mean, what can we actually go forward with needs to continue as we go through this process, because I think it's not clear to even us as registrants. It's certainly probably not clear to all the stakeholders who could be impacted by decisions that come out, and it's precedent setting.

I think that the European Union is looking at what we're doing. I think Brazil is looking at what we're doing. I think that the actions that the agency takes have for real consequences for a number of stakeholders, regardless of what you think about it. So, I would just encourage the agency to allow enough time for people to comment during these SAPs. I mean, four SAPs in a year, to look through that much data is a lot of lift for you guys as well as for those of us who have submitted data.

So, I would just request that there's sufficient materials generated before these SAPs so that

people know what's going to be discussed and have an opportunity to provide comments. That the way that the information is communicated is taken into the context of the international impacts that it will have and those kinds of things. I think it's really important.

MR. BRADBURY: Thanks, Cindy.

Robin and then Mark.

ROBIN: I don't see anywhere on the list of partners the Office of Children's Health. I strongly encourage them to be at least part of the public outreach plan because although they're not directly involved in the process of the scientific testing, they could be very useful in the outcome because they are the direct recipients of the results.

MR. BRADBURY: Thank you.

Mark and then Joe.

MARK: I though that this was really informative and useful and contextually concise. So, good job.

The one thing that I was wondering about -- and you went through it so quickly that maybe it's just me not being able to catch up. But when you were talking

about how you were going to handle goodness of fit and false positives/false negatives, how do you integrate those two processes such that you avoid the one side of that fault in another?

MS. MANIBUSAN: I think a lot of the issues with combining sets of information as well as exploring the use of computational toxicology is looking at that ability to predict knowns. So, a lot of the information that we'll be presenting to SAP will be inclusive of looking at the schools tested for reference chemicals, a broad array of chemicals for different strengths in terms of its responses and its ability to detect those, as well as explain the universe that our endocrine program has purview over.

The key question we'll be asking the SAP is whether these tools have the level of accuracy that's necessary for prioritization purposes. As we move forward, that will become even more of a focus for the agency.

MARK: I can really see that as you build the database. You get more confident. At the beginning it's going to be slippery, though.

MR. BRADBURY: Joe and then Susan.

JOE: First of all, great presentation. You've done this before. I deal with the public and public perceptions of public health pesticides on a daily basis. I'm just wondering what plans do you have to make the portal that you've got there at the EDSP web site to inform the public about what constitutes a (inaudible) endocrine disruptor, because that's a game changer when it gets out into the media?

When something is labeled a suspected endocrine disruptor, that congers up all kinds of stuff for the general public. I'm wondering, do you have any initiative there to really explain if something is undergoing a tier one battery (inaudible), what that actually could mean to the public?

MS. MANIBUSAN: So, as the agency has evolved the endocrine program, we've been very careful to be clear that as chemicals are screened, they are not listed as endocrine disruptors. They are screened for potential to interact with the endocrine system.

Subsequently, for tier two, the chemicals are not automatically advanced to tier two. It's based on a

weight of evidence decision. But if they are advanced to tier two and are tested, they blend right back in to the risk assessment. So, it's really capturing what sensitivity in terms of (inaudible) parture and how we regulate that chemical and less about calling a chemical an endocrine disruptor or not.

But to the extent that we have clarified our universal chemicals on the 27th, we also posted on our web site the universal chemicals. To the extent that we have prioritization statuses for each of those chemicals, that would be provided to the public on an annual updated basis.

MR. BRADBURY: We're going to try to get through everybody that's up. First, I want to check Matt and Kristie. Are your name tags up from before? All right. So, people that are up, we'll get to all of you and then we've got to get along with the agenda.

So, Susan and then Cheryl.

SUSAN: A couple of things. EPA is doing a really good job of making it clear that just because a chemical is on a list for screening does not mean it's an endocrine disruptor. But, in fact, when you look around

at third party certification programs and other messages that come out, if somebody sees the name of a chemical that's on a list for any reason linked to the word endocrine disruptor, it's an endocrine disruptor.

So, as careful as EPA is being about it, don't think that it's not -- people look for these lists and say, okay, we can't use this chemical at all because if it even shows up on a list, it's going to be screened. But that wasn't the main thing I wanted to say.

The main thing I would say is that I'm a little disappointed that you're putting a lot of work into this SAP in 2013 that's going to review the assays whether or not the performance of the assays gives you the answers that you need to move forward. But when you talk about sending out test orders on list two, the only thing that's holding you back is finalizing the list and policies and procedures.

The SAP process is going to take time and a lot of work. How are you going to use what comes out of that to inform what happens for the second round of tier one testing, because they seem to be (inaudible) completely. Are you just going to move forward with the same assay?

MS. MANIBUSAN: So, let me answer that really quick. The agency recognizing the timing of the SAPs to when we anticipate issuing the list two test orders, but we are not insensitive to the fact that we are taking the tier one assay by assay and battery and weight of evidence review to the SAP. The agency plans to take all of that intelligence to bear as we move forward in issuing additional test orders.

But going back to the rationale for why the agency is taking the tier one assay by assay and battery to the SAP, this was a specific recommendation by the joint panels, SAV and SAP, in 1999. While these are again validated test methods, we do not move from that point. We do recognize that when they were validated, they were validated for a small group of chemicals and a small list of laboratories. Now we're expanding that to a larger chemical domain and a wider and broader range of laboratories.

So, that was a suggestion and recommendation that we're consistently following. But we want to emphasize today that the agency will seek to use all of the intelligence from the SAP before proceeding in

issuing additional test orders.

MR. BRADBURY: Cheryl and then Caroline.

DR. CLEVELAND: So, I'm still a little confused about the connection between EDSP 21 from a priority setting in list two and the same question that really Susan was asking, how do these two things fit together? I've actually tried to draw out my diagram of (inaudible) to test orders that goes to tier one tests and then it goes to these (inaudible) and then you come out with tier two tests on one level. You've got this list two that's sitting in the wings ready to go. You talk about the EDSP 21. I'm having still some confusion on how you put them back together.

I would also like to reiterate what Cindy said in terms of planning for these SAPs. I understand everybody is overworked. I understand you shake your heads and you say it's really important. But can you put some parameters around the time frames for these SAPs that might be just a little bit different. Every issue is important. Every SAP is important. We wouldn't have it if it wasn't. But this is maybe super important because of the international attention that it's going to

receive and the amount of information. You've got four in one year.

Can you please extend public comment period? Can you give panel members a little bit longer to digest the material before you get into these important conversations? Do you have some time frames for when you're going to post the questions and how you're going to form up the panels so that we're not into these last minute got to get it done kind of thing?

MS. MANIBUSAN: So, just for clarification, because you had a lot of points, really good points, in your talk. Just recognizing that there is a distinction between the operation that we have currently on our agenda, that is the list one and list two, and that having a time for us that is different from the advancement of these new computational tox tools.

The use of new computational tox tools has never been demonstrated before in a regulatory framework in a decision-making process. That's what we're talking to SAP in January. That is not to say that we're going to use everything that we take to the SAP. We're looking for recommendations on how do we proceed forward. So,

there is a longer time span, if you will, for implementation for ESDP 21 for both prioritization as well as targeted testing and then full data replacement.

In the work plan, we've included a time range going out past five years. As we look back to list one, and you're focusing on list two, list two has been proposed since 2010. The agency again is still working through all of the public comments and looking to finalize the list, as well as the policies and procedures. What I've said to you today is that the agency plans to take all of the intelligence to bear before we proceed forward and requiring additional test orders issuance and additional tier one testing.

MR. BRADBURY: Thanks, Mary. I think in your presentation you've got the citation for the management plan. I think that's sort of helpful to get sort of the sequence of these things together. There's a lot of hard work to get that planned.

Caroline and then Susan, and then we'll move on to the next topic.

MS. COX: So, I think a lot of people in the public interest community share my sense that 1996 was a

long time ago and that we had really hoped when FQPA was passed that this process would be a lot quicker. Endocrine disruption is an important health endpoint and one that really hadn't been included in the previous evaluations of pesticides. So, it seems like there was a sense in 1996 that there was some urgency to this.

That said, I'm really glad to see that you're making progress. I was kind of reminded of what we heard yesterday about the EPA budget and all that. I just wanted to ask if you feel like at this point you have the resources. The agency allocated the resources to this program to really make progress more in the time frame that we expected when the law was passed.

MS. MANIBUSAN: So, I purposely put a time line in my presentation today to really give you a sense of that span of time from 1996 to where we are today. I think it's important to recognize that any pest method development process and validation takes a long time. Ten years is a long time. We have 11 assays. We're moving forward with tier two.

So, I think the pace has picked up, but you should also recognize that the bulk of the work has been

ongoing. Where we are today in 2013 is because of the benefit of all the work that's been happening.

In terms of the evolution, what I also wanted to highlight is that we're moving from a time frame of test method development and test order issuance to now into the data review phase. So, all of the SAP work that's demonstrated in the future time line, that's all being coordinated across OPP, toxic, water, and our Office of Research and Development, very much a shared program, if you will, in many respects. So, a lot of those activities are already allocated in terms of time, sweat equity, and people's manpower and expertise.

MR. BRADBURY: Thanks.

Susan.

SUSAN: This will be a quick one. So, there are differences in the endocrine disrupting ability of different compounds and the doses at which the affects occur. I think people are most afraid of the low dose endocrine disruptors where you get 10 to the minus 9th molar concentration and you've got a problem on your hands. Then it turns around and it maybe doesn't cause a problem at higher doses.

So, I guess I'm wondering -- and this may be in the documentation somewhere -- are you going to calibrate these things equivalent to the cancer QSAR potency evaluation, because it's a real difference? Is it endocrine disrupting at really high doses, in which case the regular tox test may pick it up, or is it a low dose endocrine disruptor? So, are you distinguishing?

MS. MANIBUSAN: Good question. So, I go back to thinking about the impact to the endocrine system. The endocrine system is a very flexible system in terms of its internal compensation mechanism. We get stressed, we eat, our endocrine systems are activated. It happens.

But what you're keying into is whether or not we're not capturing low dose affects in our screening and testing program. So, I want to speak a little bit just to the functional aspect of that.

So, tier one, just a reminder, is a screening battery. We're screening for what goes and is advanced to tier two. So, they're already heightened for a false positive, if you will. They're meant and intended to identify molecular initiating (inaudible) such as receptor binding, a very first step that must occur. The

binding alone doesn't initiate and guarantee that you're going to have an adverse outcome. We need to make sure there's gene activation and we need to see (inaudible) endpoints in in vivo systems. So, that's what tier one cannot do, speak to quantitative dose response. Never said it could, wasn't designed to do so.

However, as we shift into tier two, these are quantitative dose response studies. They're intended to give us that point of departure so that we can ensure safety to human health and environmental organisms in our risk assessment. To that extent, no different than chronic bioassays.

We do a dose range finding study. We make sure that we're going down as low as we can and as high as we can to pick up different effects so that we're not missing that spectrum in which we're expecting to see effects. So, that's tier two. That's undergoing interlaboratory validation that I'll be taking to our SAP for that particular purpose.

I want to also state as an overarching issue, the low dose issue, is it's critical to the agency. It's very important not only for the endocrine program but

across the board chemical risk assessment. To that extent, our Office of Research and Development has focused a group of our experts, four experts in endocrine disrupting capability and effects, to focus on looking at the literature in a comprehensive manner, looking at different pathways, E, A, and T, and we're bringing all that to an external peer review body probably in the spring. I don't have any specific time frame.

But we're looking to make that review a transparent process where we're laying out all the information. We're being very careful about selecting the studies that could inform one of low dose effects that wouldn't be captured by the typical dose response curve.

MR. BRADBURY: Thanks, Mary, good job. So, we're going to switch to a different e-topic. We'll switch to Endangered Species Act. Don Brady was originally going to do this, but Don got really sick over the last 24, 48 hours, and his associate division director had a doctor's appointment. I said it's more important that you go to your doctor's appointment. We can cover.

So, Rick Keigwin is going to cover both the endangered species update and the registration review update. They kind of get intertwined, so I think Rick will try to take a look at the clock and lead in both concepts as we go forward. We'll kind of play with when to pause and take questions and move on.

Rick.

MR. KEIGWIN: That was Steve's way of saying don't ask the hard questions on ESA because only Don can answer them. That's what I heard, anyway.

So, on the ESA front, and like Steve said, there is an interrelationship between this presentation and the next one. So, if I skip through a few slides here, it's because they will be more deeply covered in the registration review update section.

We're going to cover three topics, not necessarily in this order. One is the public involvement proposal that EPA, USDA, and the services issued in August and where we are with that. An update on the NAS review that the services, USDA, and EPA commissioned back about a year ago. Then, an update on where we are on a youth pilot project that we discussed with you all at the

last PPDC meeting.

So, let me start actually with the status of the NAS review. As you'll recall, the four agencies initiated that review with the Academy in the spring of 2011. So, focus on a number of the science and technical issues that had developed in the course of consultations in the salmon cases and some of the consultations that we had begun as part of registration review.

The NAS is currently on track to issue their report sometime in the early part of 2013. They have held three public meetings today, two in DC and one about a year ago in Seattle. Those were quite well attended.

This slide just presents six charge areas that we thought in our speaking advice from the Academy on to help inform how we go about doing our ecological risk assessments in the context of ESA review. So, advice on what constitutes the best available scientific data and information to be used in our consultation, what types of information should we be considering relative to sublethal, indirect, and cumulative effects of pesticides and other stressors in the environment, the effects of mixtures, which types of models are appropriate for use

when monitoring data aren't available, incorporating uncertainties in the evaluations, and then how to utilize various geospacial information and data sets as part of the evaluation. That's about all we have at this point. Like I said, the big take home is that we are still expecting the NAS to issue their report sometime in the early part of 2013, probably early spring.

On the topic relative to the proposal that we issued this past August -- and we had previewed many aspects of this proposal with the PPDC over the past couple of years relative to how we could make some process changes in the registration review program to not only make the registration review program more efficient and more effective, but how those steps and those process changes might improve our ESA consultations.

As I mentioned, we issued a proposal back in August of 2012 focused largely on process efficiencies and looking for opportunities to get better information available to EPA as we're starting our registration review process, as we're framing the problem formulation and scoping out what the initial parts of our ESA assessment will be for chemicals under registration

review.

In response to that proposal, we received about 35 comments, generally in support of process efficiencies of the program, generally in support of greater stakeholder involvement in registration review, and greater transparency throughout not only the registration review process but the consultation process leading to the development of a biological opinion.

EPA, the services, and USDA will be getting together soon to discuss those comments. They are being organized now. Thirty-five comments seems quite small, but in fact a number of the comments are quite lengthy and not only address issues that were raised as part of the proposal, but address other issues that we've been asked to consider.

Again, and this part will be covered in the next presentation as well, but two of the big proposals that EPA made were to add something called a focus meeting -- Gabriele asked a question about focus meetings yesterday. We will get to that in a few minutes -- to the process.

Then, secondly, to potentially change the point

in the process when EPA would initiate consultation and perhaps use more of an informal consultation step at the point at which we seek public comment on our preliminary risk assessments and moving, if necessary, to have a formal consultation to the point at which we're closer to making our final decision, closest to what would constitute the federal action, and, as I indicated, initiate formal consultation with the services, if it's necessary, based upon that refined risk assessment.

The last topic I wanted to update you all on here is the pilot project that EPA, National Marine and Fishery Service, and USDA initiated about a year ago. The purpose of this pilot was to see how we could best incorporate pesticide usage data into endangered species risk assessment. We selected two chemicals for that pilot, arizalin and difubenzaron (phonetic).

We focused not only on information that was available through the California DPR pesticide usage data program, but also through the NAS chemical usage survey. We thank OPNP for their help in summarizing all the statistics and pulling that information together. We also provided to National Marine and Fishery Service

updated label use information. Both of these biological opinions are now in development by the National Marine and Fishery Service. There have been meetings on both of these chemicals with the applicant, the registrant.

I can say that in the course of those applicant meetings, the services have, in fact, been relying upon a lot of that information that USDA pulled together to help ask questions, better understand the use pattern, better understand how the pesticide fits into the crop production practice. But we have not yet seen a draft biological opinion, so we don't know specifically how that data will be used as part of NOA's evaluation process.

So, we've got a few minutes if we want to take some questions.

MR. BRADBURY: Darren.

MR. COX: I'm just looking at this and I'm thinking for geographical information and trying to provide models, the same thing can be done that you're doing with Fisheries to the bee industry. You can have overlapping models as the geographics of where the bees are actually pastured at. You may have a problem with a

specific chemical on a specific crop that may not be found on a different specific crop, just to the complexities and variations of how the plants would be different.

So, I was wondering if you considered any kind of that form of a model to track mortality based with geographical specifics and models?

MR. BRADBURY: I think I'm understanding the question. As part of going back to the NAS, we proposed to the NAS to get feedback across all the federal departments involved on how to integrate geospacial information. So, where's the critical habitats for the species, where do the species reside, also what are history habits, like at what time of the year do they tend to forage here or forage there, what's their dietary components, what's the age of the first reproduction, depending upon the species? So, get all that figured out.

How do you lay that down, realizing that there will be different levels of certainty with the information. Then, where are the crops grown? Where are the pesticides used? Then, sort of linking that all

together would be our fate and transport models and perhaps our population models or other kinds of effects models. So, we are trying to get to the ability to zoom in or zoom out on a risk assessment based on the quality of the data (inaudible) tenor of the question that needs to get resolved.

So, I don't know if I answered your question exactly, Darren, but we asked the NAS to extend their data that you can get varied geospacial and (inaudible) specific. Where are we today given the data sets we've got. Where are we today in terms of the models that we've got? What would be some insights into the future as these start to go forward?

MR. COX: That would include, say, for an example the area that had a higher percentage of, say, sunflowers growing versus the (inaudible) mortality. We're starting to see that becoming a consistent this year and with beekeepers reporting that, say, for example, hives that were around alfalfa or hives that were around sunflowers or hives that were in a nonag zone.

If we can get the mapping of the various

commodity crops grown and then link it to the type of pesticides that's commonly known to be used for treatment and controls, you may see a variation to where in a drier climate there's more of an effect or a wetter climate there's less an effect. Therefore, you could have a product that would be more likely to be used safe in one area of the country but not as likely to be used as safe in another part of the country and still have it be able to have it as a tool for an effective control in the areas that could be accessed and used to provide crop protection and also at the end provide colony protection.

MR. BRADBURY: Yes, exactly. That's the path that we're on. Some of it is reflected in the ESA and some of it reflected in other work we're doing to be able to do exactly what you're describing, how the tools and the technology and the data layers at various stages of development implement that, but that's the path.

Mike and then Mark.

MIKE: On the one side where you talk about the pilot -- if you want me to discuss this more with somebody else in a sidebar, I'd be glad to. But when using California DPR data, you have a lot of data that

links pesticide use to sites. Now, that data mostly does not exist with that degree of specificity of tying those two things together in any other state. You might have usage data, but you don't know maybe exactly where the site was that it was applied.

How does that work? How do you sort of try to pour that information you're getting from the pilot to maybe those other situations?

MR. KEIGWIN: That's actually part of the charge that we all had, was how do you use information that is well established in one part of the country and look at what the use pattern might be in a neighboring state, in another part of the country.

It was a challenge. It was initially an area that we weren't sure that we could do. That's a long-winded way of saying we're not sure what the outcome of that is. Fortunately, there are some NAS data that sometimes can help us inform that. So, to the extent to which you're seeing some consistency between the data reported out of specific, almost census-like, usage in California compared to what you see in NAS, maybe you can make better correlations to other areas of the country.

Where you don't see that, it creates some uncertainty.

MR. BRADBURY: So, it's a charge to the group to try to deal with that uncertainty going from California to maybe another state that's not quite the same. How do you use NAS data and what would be some options for extrapolating? What kind of uncertainty would that carry with it? It's a work in progress but one of the challenges to take on.

Mark and then Ray.

MARK: I want to also relate somewhat to that mapping trial and the workshop that EPA ran, which was really helpful in a lot of way, and conceptualizing how one might get into the spacial development dimension of endangered species.

We, in Michigan, worked up a carna blue (phonetic) process and looked at that very intensely. So, I was just wondering about update and other trials. It's really in line with Mike's question about how to transition. I'm thinking something like the carna blue, which its distribution is really well known, and its proximity to some key production areas is really well known. The maps are there. The USGS has worked on some

of that, as the core service has and has a number of grower groups have contributed to it.

So, I'm wondering about kind of next steps. Are we going to see other trials in states where the spacial information isn't as good but as a step down maybe?

MR. KEIGWIN: Maybe we can hold that for the reg review discussion, because I think when we start talking about preliminary risk assessments at that point, maybe I'll address that better at that point.

MR. BRADBURY: I think you will start to see more of that as we have the data to do that. Marty also yesterday talked about some of the PRIA-3 funds that are helping us get our data sets organized within OPP that we already have on species location and related things, and the USDA land cover. But I was also indicating that there are conversations going on across a number of federal agencies that are all needing this information. The discussions are getting going in terms of how do we get this organized at the federal level so that everybody is accessing the same information in each group that's responsible for the quality of the data associated with

their mission is feeding into a common data set. If we can get that information together, then I think you can start seeing it on a more routine basis.

Probably at the beginning, it will be those carna blue butterfly examples where you've got really tight data you can reach out to. It's moving to all corn and all the species in corn. It's going to take more data layers to pull that on.

Ray and then Gabriele.

MR. MCALLISTER: I have a question about the NAS review process and the proposal for ESA consultations. First, I believe during this whole NAS review process, there were recommendations to stakeholders to take into account the economic impacts. But this is not mentioned in your summary of the NAS review process. I was wondering how economic impact would be taken into account and at what stages?

MR. BRADBURY: I think from USDA to EPA to Fish and Wildlife Service, the National Marine and Fishery Service, the charge to the NAS has been very clear where the charge components that Rick put on his slide. That's the contract with the NAS. So, the charge to the NAS

doesn’t get into the economic and technological feasibility components of the overall process.

So, the first bite of the apple, if you will, is assuring the science underlying our risk assessments and the science that the services (inaudible) first focus. The document that went out for public comment that Rick reflected at the time is a component -- I’m trying to get at what you’re discussing, Ray -- how do we go about trying to make sure we’re getting the best information about the cropping patterns and the different ways to control those pests.

So, if we move into a situation where we have to look at reasonable and prudent alternatives, we’ve got the best available information to see what’s the most practical but still effective in protecting the -- sort of get to some of the points that Darren was getting in pollinator protection.

Ray, I just want to be clear that the charge to the NAS was around science doing a risk assessment. It wasn’t the economic aspects of evaluating RPAs. The executive branch hasn’t changed the current charge to NAS at this point.

So, what the NAS panel may do with public comments that were provided to them in that topic, I can't speak for the panel and what the panel may do with that information.

MR. MCALLISTER: The other question relating to the process that was proposed, what do you anticipate the result will be or the range of possibilities from guidance to policy to regulations?

MR. BRADBURY: From the NAS report itself when it comes out?

MR. MCALLISTER: No, the August proposal.

MR. KEIGWIN: So, certain aspects of that we're actually going to cover in this upcoming presentation. But some of them had already started to be underway and we sort of memorialized them in that proposal, things like the focus meetings. Other aspects of that had been the subject of fairly significant comment in the public comments. So, I think before we give a time line for when we might be able to resolve these things, the agencies really just do need to get together.

We're hoping to get together soon. It's always tough in December to get together, but, hopefully, if not

this coming month, in the early part of the year the four agencies can get together to begin to work through the issues that were raised in the public comment. Based upon that, we'll have a better sense of what the time line would be.

MR. BRADBURY: Gabriele.

MS. LUDWIG: This is partly clarification and partly question. In the slide about the consults during the registration review, you talk about using more of the informal consultation. A, I just need a reminder of the difference between the informal and the formal. Then, B, I suspect it relies on sort of the good graces of the services to do the informal consultation.

So, I'm trying to figure out what is their willingness or how has that discussion been going.

MR. KEIGWIN: Information consultations, there's a wide range of things that can happen as part of informal consultation. What we've been discussing is as we're going about doing our risk assessment but maybe before we make a formal effects determination, we think we need better information on species habitat or the critical range of that species or the life history of

that species. So, in order to make a better, more informed effects determination, that would be an opportunity as part of that informal consultation stage to approach either National Marine and Fisheries or Fish and Wildlife Service to obtain that information.

So, rather than make a formal may effect call, if you will, to make sure that we're relying upon the best available information from the expert agency before we move forward, as opposed to at the formal stage when we would have made a formal may effect type of determination.

In terms of the willingness, I think we have developed some very good working relationships, in large part, through the salmon biops that we've been working on the past several years. So, even a simple phone call to the services could be part of an informal consultation, if you will.

MR. BRADBURY: Okay, thanks. Now, we'll ask Rick to give an update on where we are with registration review, and some of the things we talked about will come back around in this presentation.

MR. KEIGWIN: Thanks, Steve. So, this

presentation will just give you all an update on where we are with moving forward on the registration review program. Then, I'm getting into focus meetings and what we have been doing and what we're planning to do as part of the focus meetings. Then, we'll wrap up by giving you an update on some upcoming preliminary risk assessments.

So, just to refresh everyone's memory, FQPA amendments in 1996 required EPA to establish a registration review program to have a more than one time look at each pesticide's registration. This first round of registration review covers all pesticides that were registered as of October 1st, 2007. We were directed to comprehensively review each pesticide registration at least once every 15 years.

The program very much developed through -- I believe there was actually a workgroup of the PPDC that helped to inform how we would go about developing the registration review program. It was designed to be flexible, transparent, and have an open process with multiple opportunities for public comment throughout. The original design actually had about three public comment stages.

We began implementation of the registration review program in 2007. There are over 1100 active ingredients subject to this first round of registration review. That covers about 750 cases. Certain active ingredients can be grouped together. Maybe there's (inaudible) of each other, for example, to help to make the program somewhat more efficient.

As we previously discussed at PPDC meetings, out intention is to address our national ESA obligation as part of registration review, and then to also incorporate the endocrine disruptor screening program as part of that review. Mary Manibusan gave us a really good update in the past hour. We are statutorily directed to complete the first round of registration review by October 1st of 2022.

To date, we've opened about 370 cases, so just under half of the cases that we need to open to complete the program by 2022. Then, of those 370 cases, about 320 of them have passed the final work plan stage. So, we've gotten to the point that not only have we presented our problem formulation, but we have revised that problem formulation response to public comment. We've gone on to

moving towards issuing the data call-ins if they're necessary to begin the risk assessment phase.

To date, we've issued about 35 final decisions, so 35 chemicals have made it completely through the program. These statistics cover not only the conventional chemicals but the biopesticides as well as the antimicrobials.

What I wanted to do is spend a good bit of time this morning talking about focus meetings. There's been a number of questions about these over the past couple of days. We have discussed the concept of focus meetings with you all on a couple of occasions recently. But, just to refresh everyone's memory, it's a new component that we're adding to the registration review program. They're designed to discuss a specific chemical that's before us.

They will have many purposes, but overall, it's to hone in on what information OPP's registration review team, the team that's actually scoping out the review of chemical, needs as part of the registration review process or thinks that we need as part of the registration review process as we've done a preliminary

review of the label.

These meetings will generally be initiated by OPP. The chemical review manager will be getting in touch initially with the registrants, but there will be opportunities for people other than registrants to participate in focus meetings. They will typically be between OPP and the registrant. We've had a discussion at this meeting in the past about the high value in EPA having meetings with a licensed holder. We are certainly open to having similar meetings with other interested parties.

So, this, as you all know, and we saw in the previous presentation, is the current process where we open the dockets. We issue the data call-in. We move to the preliminary risk assessment, final risk assessment, and proposed decision, and final decision phases.

What we're planning on doing, as I mentioned, is having these focus meetings at the very early stage in the process. So, after the internal team has begun to scope out the review but before they put final pen to paper, finalize the draft problem formulation, the goal is that the outcomes from these focus meetings will be

reflected in the different scientific analyses that are done to inform the preliminary work plan.

As I mentioned, these will have multiple purposes. It's really designed in large part to have early dialogue at the beginning of the process so that we can focus in on those areas of the registration that might need to be changed. We want to make sure that we get the best information at the earliest stage in the process.

Largely, it's designed to minimize the amount of rework. If we haven't understood the label and we've gone through a risk assessment process and we just completely misinterpreted the label, that's a waste of time for us. It's a waste of time for people who are commenting on our documents.

So, it's an opportunity in these meetings to get good, clear instructions on labels, a good understanding of what constitutes sort of that initial framework, that initial baseline for the use pattern that we're assessing as part of registration review.

We also want to try to identify at an early stage in the process those use patterns that are

basically of negligible or minimal risk so that we can focus our registration review really on those aspects of the registration, those aspects of the chemicals used that are of highest concern. We think in the long run this will save us and all stakeholders considerable resources as we move through the process.

We've held about 20 of these meetings to date, so the focus of each of these focus meetings has varied depending upon how recently we've looked at the chemical, how extensive the use patterns are for the chemical, and how recently we've looked at the chemical. So, potential topics could include what we think our data needs are.

There could also be a discussion of what data the registrants might have developed to support continued registration in other countries, opportunities for label clarity. The teams have been instructed to come in with very specific questions related to ambiguities that might exist on the label. Are there ways that the label can be tightened up to make sure that we best understand how the product is intended to be used?

Sometimes you have use patterns on labels that are quite atypical. So, things like a tree injection use

or a bait station, outdoor bait station, or a product designed to kill tree roots. Ditch bank uses is one that's come up recently and how that's actually applied in the ditch. Is that a ditch that's coming off of an agricultural area or is it some other type of a ditch? Does that ditch feed into another food production area? Just trying to get a better sense of what that use pattern is.

to the extent possible, identify opportunities for early mitigation. So, for example, if an issue has come up as part of a recent registration action, say a new use, we might look for opportunities to coordinate the assessment that was done as part of the registration program with the registration review program.

Then, as I mentioned, data that might have been developed for registration in other countries. They may not necessarily meet EPA guidelines, but they can certainly be very helpful in informing whether or not we have to pursue that line of inquiry for that registration review.

So, our desired outcomes in the end are better understanding of what uses the registrant is supporting

for reevaluation, better understanding of the use patterns, to get agreements on the data to be submitted. To the extent to which the registrant believes they're going to seek a waiver for that data requirement, to maybe begin that process a little bit early before they receive their data call-in so that we can again be focusing in on what data will ultimately be needed to support the registration review.

To date we found that there's been great dialogue between us and participants in these meetings. We've gotten a much better understanding of the use pattern. On occasion, the registrant and the growers have said, we've never used that chemical in that way. So, we'll take off these other application methods because that's just not how it's done in our crops any longer. So, we've actually begun to get some revised labels in response. That, again, streamlines the process quite considerably.

So again, many benefits have come as a result of this early dialogue, opportunity for streamlining data needs, beginning to focus in on what will be the real areas in the risk assessment that are going to need some

more work. The extent to which we can begin to get in front of the ESA issue and take some uses off the table and maybe even preliminarily make some no effects calls so that we can again focus the risk assessment on those areas of highest concern.

The timing in number, this is one of the areas that we've been experimenting with as well. Some active ingredients have multiple registrants, and sometimes it's helpful to have different meetings with the registrants before you have a single meeting with all of them. Sometimes a registrant has wanted to bring others in and have a meeting with them and other stakeholders and then separately have a separate meeting. We do think that as a routine part of the process, particularly for conventional chemicals, we will have at least one focus meeting before we commence the problem formulation.

As I mentioned in one of the earlier slides, we're about halfway through opening up chemicals for registration review. So, half of the chemicals have not had focus meetings. As we're getting ready to do risk assessments, there might be opportunities to have a focus-like meeting before we begin the risk assessments.

There may also be opportunities even for chemicals that had focus meetings at one stage in the process, three or four years out markets change, use patterns continue to change.

So, there may be opportunities to continue to have that dialogue before we initiate the formal risk assessment. So, we're experimenting with different timing approaches to see what works best and make the process as efficient as possible.

So, we're continuing to pilot this approach. We're encouraging the teams to be quite flexible. We're erring on the side of having the meeting. Now, it doesn't have to be a physical meeting. We've been looking at webinars. We've done teleconferences. We've done in-person meetings.

The content of the meeting is very much dictated by the concerns that we might have or the issues that we think we might have as we're starting to review labels. We are committed to making all meeting minutes for all of the focus meetings publicly available. For chemicals that have already entered the program and have a docket established, the meeting minutes will be in the

docket for that specific registration review case. Because a lot of these will be for chemicals that have not yet had a docket established, there will be a special docket that's created just for focus meetings. So, all the focus meeting minutes will also be available in that docket.

Again, we think, and as we highlighted in the proposal that we, USDA and the services, issued in August of this year, we think that this is another opportunity to increase involvement in the registration review process, enhance our transparency, and do what we designed the registration review program to do, which is to focus on those areas with the greatest concern.

Let me talk just for a few minutes about preliminary risk assessment. We are about to begin to issue a number of preliminary risk assessments for public comment, although the scope of what we intended to do will change.

As many of you know, our plan had been that when we got to the preliminary risk assessment stage, if we made a may effect call, we would initiate consultation at that preliminary risk assessment stage. We have done

that for a handful of chemicals, and not only issued the risk assessment for public comment, but begun the discussions and the consultation with the services based upon those assessments.

What we found, and as we discussed in the August 2012 proposal, is that it's probably a bit too early. It's not necessarily reflective of what the outcome from the registration review will be. There's still lots of uncertainties in that assessment. There are lots of areas that could be streamlined. We're not sure, but we actually believe that it's an inefficient use of the government's resources starting the consultation at such an early stage.

We do think there is value in getting public input on that preliminary framework risk assessment as we move forward to developing the ESA part of our risk assessment. So, the revised revision, as we laid out in the August proposal, was we would still issue preliminary risk assessments for public comment. Where we thought we needed additional information and additional support from the services to help further inform and refine the risk assessment, we would initiate informal consultation.

We will still seek public comment, and we will, as part of that public comment period, be asking for some very specific questions to help inform how we revise and update that risk assessment before and as we move to the final risk assessment and proposed decision phase.

So, the preliminary risk assessments are going to focus just on typical use, what we have. They'll focus on the use patterns, what we know, but they're not going to make species specific effects determination calls. We believe that that's most appropriate to wait until we have the most up to date information that is available to make those species specific effects determination calls as part of the refined risk assessment and where we also had the most refined information on pesticide use, including subcounty level or other types of proximity data for co-occurrence of use with listed species and their critical habitat.

We have been working very closely with USDA on how to design an approach for proximity analysis. There's been a great collaboration, I think, between us and USDA on how to use different USDA data layers, crop data layers, and other data that they have available

through the National Agricultural Statistic Service, but we're not quite there yet.

So, because this is also one of the areas that we're seeking assistance from NAS on, the National Academy NAS, we think it's probably best to wait until we get the advice from the Academy and continue our work before we start to incorporate that into refined risk assessment.

So, again, this is all about making sure that we have the most appropriate data and having the best utilization of resources. We don't want people at too early of a stage focusing on something that we know is going to be refined later on. But we do want to get that baseline risk assessment right, because as we move on to the endangered species component, we know that that adds its own set of complexities. Let's get the baseline right and then we'll move to the next higher stage of the assessment.

So, what I can say is we will likely have about a handful of assessments go out very, very soon. Part of the message here is -- and this is consistent with the program -- we're going to be at the point very soon where

it's 70 dockets open in a year, 70 final work plans go out a year, 70 preliminary risk assessments go out a year, 70 proposed decisions go out, and 70 final decisions. That's lots of opportunities for you all to get involved, but it's lots of stuff for you all to be aware of. So, we wanted to give you that heads up.

Being in that fifth year of the program, that's when these things were slated to start coming out. We know you all are busy, but we really value the comments that we get, and we're prepping you now. 2013 is going to be the year where you start to see a lot of these things roll out.

So, with that, let me stop and see if there are any questions.

MR. BRADBURY: Dave, Susan Kegley, and Mark to start

MR. TAMAYO: I guess the main concern is the transparency of the focus meetings. I'm glad to see that you're planning to release minutes. It would be helpful if there was some sort of agenda of the things that you're anticipating going in.

One thing I'd ask about the minutes is that

they really make it easy to find things that were sort of taken off the table and the reasons for that. I understand that there often are going to be really good reasons, and I think it's very helpful to take things off the table that really aren't concern. But we'd kind of like to have a look at that where we have the wherewithal to do it.

Then, the other things is I'm hoping that the overall process of how you're going to be doing these registration reviews is robust enough so that it's really clear that you're going to kind of hold the line if there's good reason to think -- in my case, there might be a circus water quality impact that yes, we're still going to take a really rigorous look at that.

Then, I'm also very supportive of there being other opportunities to have similar meetings. I don't know that we necessarily need to be in directly with the meetings that you have with the registrants. Where it seems like that might be good, then we'd be open to that. But if there's the possibility of having webinars and other ways of getting input early, I think that would be helpful to us.

So, hopefully, there won't be a whole lot of those that we'll have to participate in, but we appreciate that you're open to that. Anyway, thank you.

MR. KEIGWIN: We're very open to that. As you all know, every year we publish the Four Year Horizon for which chemicals are coming up in registration review. We publish the quarter in which we anticipate that registration review opening.

So, that can be a good opportunity for you all to see which ones you might be interested in having a discussion with us about. All three division directors who work on reevaluation have instructed our staff we don't refuse a meeting. So, if you want to come in, if you want to do a webinar, we're more than happy to do that.

MR. BRADBURY: Maybe one other point of clarification, Dave. I may not have been hearing what you were saying accurately, but Rick was getting at at sort of taking something off the table, it could be that during the course of a focus meeting, a registrant and with other people listening in and providing some advice, it may be that a registrant decides a certain will take

it off the label. So, that's a whole risk assessment scenario we don't have to focus on or deal with anymore. So, it isn't so much making decisions that take a potential risk off the table; it may be that a particular exposure pathway may come off the table because that use is coming off the label or the way that use is going to be used is changing significantly. So, instead of looking at four different application methods, maybe it's going to be looking at one application method. So, that's what we mean by taking things off of the table.

MR. TAMAYO: And I think that as long as it's clear what was, what did happen, and why, that's very helpful. Thank you.

MR. BRADBURY: Susan Kegley and then Mark Whalon.

SUSAN: Three things. On your slide three where you talk about what the registration review program includes, the National ASA assessments, the endocrine disruptor screening program, it would be nice to see on that list field volatilization for chemicals for which that may be an issue. That's certainly something that's been a topic of discussion.

MR. KEIGWIN: We specifically mentioned ESA and EDSP because historically they have been programs of their own. This was just demonstrating our commitment to incorporate them in. The volatilization exposure pathway is something that we're more routinely starting to incorporate into all of these.

SUSAN: Then, a couple of clarifying questions. So, the focus meetings happen after the scoping documents are done or before?

MR. KEIGWIN: They are done before. They go out for public comment before they're finalized internally. So, our internal team has met to begin to scope it out, begin to identify where there might be some areas for uncertainty. Then, one of the purposes of the focus meeting is to seek clarification from the registrants relative to those. Then we would go on to finalize our draft problem formulation for public comment.

SUSAN: Then, I guess the question is, how are stakeholders notified of the early opportunities to perhaps meet on these particular topics? Do we just see that this chemical is coming up and we give you a call?

MR. KEIGWIN: Mm-hmm.

SUSAN: I just was at the web page with all the list of everything and the status. It might be nice to highlight the ones that are coming up kind of at the top of the page or something.

MR. KEIGWIN: That's something that we can look into.

MR. BRADBURY: Mark and then Kristie.

MARK: First off, I think the direction that you guys are going in really makes a lot of sense to me, and I applaud that because it saves a lot of work for you and work for registrants. And even the user community, I think, would like to see it.

But one thing that strikes me -- not to draw you out so much but to get kind of a sense of reality, when you talk about your service partners in ESA, what's the likelihood of them coming to the table on something like this?

MR. KEIGWIN: This was the commitment that the four agencies made. We've been having many discussions about this. For those groups that have participated in some of the recent applicant meetings on the salmon

biops, I can tell you that NIMS has come to the table very much prepared with a good understanding of the labels. They come in with very specific questions about the use and the use pattern as they read the labels.

Certainly, over the past six months, the applicant meetings that I have sat in on have showed that their understanding of agricultural use patterns of pesticides has increased a lot. They are very much engaged in the process. I very much expect that to continue, and I would expect to see the same thing once we start working more routinely with Fish and Wildlife Service.

MARK: That's really encouraging.

MR. BRADBURY: Kristie and then Cheryl.

MS. SULLIVAN: So, I have a couple of clarifying questions. You said you were going to create a docket just for focus meeting minutes?

MR. KEIGWIN: Yes.

MS. SULLIVAN: So, will that be linked from the --

MR. KEIGWIN: And we're hoping next week that we will put up some formal guidance on focus meetings,

some questions and answers. Then, there will be a link off of that registration review page into that focus meeting docket.

MS. SULLIVAN: Okay. Are these offered to each registrant or just in cases where you think there might be a need for it?

MR. KEIGWIN: On the conventional chemical side, what we've instructed our staff is to default to having one unless it's pretty clear based upon a reading of the label that we don't really have any issues. So, the vast majority of times we will be having focus meetings.

MS. SULLIVAN: Okay. So, I guess the one final things is -- and just to give you a little context -- your sister office during the HPD program, oftentimes what we found is that registrants or companies are very focused on their own but they don't have a sense of the universe.

Often the environmental and animal protection and human health stakeholders have looked at the whole universe of substances that are being looked at more than the companies have. So, we kind of have a sense of what

strategies might be able to be used, in my case obviously, to try to reduce animal (inaudible) but for other reasons, too.

So, one concern that comes to my mind is that if you're having focus meetings and talking about data needs that the registrant might start the study before public comment process has begun -- because oftentimes to schedule some of this, you have to do it far in advance. Anyway, that's what we found happens sometimes. So, I just want to register that in your minds as something to keep a look out for.

MR. BRADBURY: Cheryl and then Luis.

DR. CLEVELAND: So, I think all this focus on the focus emphasis is really great because I do, as I said last time around, six months ago, it's that use pattern, the driver use patterns that are going to be the most critical in eliminating ways to not wasting time on things that aren't realistic.

You've got a lot of eagerness here for people that want to jump in. But I guess my question would be, in your experience so far, where has the most useful stakeholder input been to help you better define those

driver uses? Do you have a sense of that yet? You said you've had about 20 of these.

MR. KEIGWIN: Most of the ones that we have had have been prior to the issuance of the preliminary work plan. So, they have largely been focused on making sure that we understand the label and getting some early clarity. So, that has come -- the only participants thus far have been registrants. I think USDA has been to a few of them and key user groups, as necessary. We don't have as much experience yet as we're about to start the actual risk assessment. But the biggest areas for resolution thus far have been on understanding the label.

DR. CLEVELAND: Understood. I just wondered if there's been an addition to that, key user groups or key parts of that, that you found useful for clarity.

MR. KEIGWIN: I think it's going to always vary by chemical. Even with 20, it sounds like a lot, but the diversity of uses, there hasn't even been a lot of overlap in uses and use patterns yet.

DR. CLEVELAND: Okay. I had one other comment. I really needed to come back to this. It's basically something that Ray and Cindy said about registration

review. We have a registrant concern that parts of this whole registration review process go off on individual chemicals.

There's been a lot of attention to a variety of things that are going to be impacted through the registration review process in terms of what I would call policies or worker assessments for bystander, for spray drift, for volatility, all those things that have had some preliminary opening SAPs. It's my impression that the final policies on those haven't really been finished.

I understand you've got to work through, so, you're going to go kind of case by case. But when you do that and you're working on a broader policy issue but you do it case by case on the chemical, then you limit the universe of the conversation to a few people, maybe the registrant, maybe not, but you're also making what I consider to be kind of policy decisions, or at least process decisions, where you're going to be picking what models, what algorithms, what data bases where you get your input, what percentiles you go. At some point, that becomes a policy in and of itself.

I'd just like to express the concern that

somewhere in this we need -- you can't always be talking about the chemical that you're working on with everybody, but you need to have enough input into those decisions that set that process up for that chemical in a better way. I don't know how to express it better than that.

MR. BRADBURY: Thanks.

Luis and then Dan.

LUIS: On your slide number two, I guess, the one on registration review, you indicate a 15 year review cycle. That, I'm assuming, is imposed by FIFRA?

MR. KEIGWIN: That is stated in the statute, that's correct.

LUIS: Right. Now, what happens in the case where, for whatever reason, a certain chemical needs to be stopped or recalled, whatever, for cases that have been reported? Does that go into immediate review because of some urgency that it might be creating or do you hold it for (inaudible) review?

MR. KEIGWIN: The registration review is sort of the standard review to comprehensively look at the chemical. We have a variety of mechanisms available to use. If information comes in to us via 6A2, for example

-- we talked a little bit about that yesterday -- as well as other mechanisms, we can begin to take regulatory action on that chemical earlier in the process. We also have the flexibility in registration review that we can move a chemical up earlier in the process if we need to to address the concern.

MR. BRADBURY: Dan and then Virginia.

DAN: Thanks, Steve, and thanks, Rick. I think the focus meetings really add a lot to the process. I think it's important. It looks good.

My question is more at the tail end of the process of registration review. During re-registration a lot of times a division would codify the changes on their own initiative, under their own authority. I wonder if that would be the case when some of these products are finished with the registration review process. My focus is more on harmonizing with Codex, new crop groups. So, would that be something that the division would do or does it go back to the registrants or IR-4 in some cases?

MR. KEIGWIN: We haven't gotten to that stage. to be honest, most of the final decisions that we've issued have either been for non-food uses for which we

made a no effect call or the product we negotiated phase outs or outright cancellations for the chemicals. But one of the things that we have committed to do is, to the extent feasible, work on MRL harmonization as part of that final decision making process.

It's been a particular focus as part of some of the pilots that we've been doing with Canada to see whereas where even going to the risk assessment phase, we can look at where there might be trade irritants and try to resolve those MRL ambiguities, at least within North America. So, that is very much still a commitment as part of the program.

MR. BRADBURY: Virginia and then Ray.

MS. RUIZ: So, you mentioned all these different opportunities for public comment and stakeholders. What are the mechanisms for alerting stakeholders to those opportunities? Are you going to publish all of these in the Federal Register?

MR. KEIGWIN: In terms of focus meetings, the website, the registration review website, lists when each chemical is coming up for review. We do Federal Register notices every quarter for every preliminary work plan

that we issue. We will do Federal Register notices for every preliminary risk assessment that we issue.

We will do and have been doing Federal Register notices for every proposed decision that we do. Complementary to the Federal Register notices going out, because we know not everyone reads the Federal Register every day, we have been issuing OPP updates. So, everyone that's registered with our field and external affairs division for those OPP update (inaudible) would also get notified that way.

MR. BRADBURY: Ray and then Caroline.

MR. MCALLISTER: I just wanted to echo one more time Cheryl's comments about what I call policy creep. The problems you observed in pesticide registration decisions typically come up in the context of an individual registration or registration review action. When the procedures are established and the decisions are made in the context of a single product, it doesn't necessarily include all of the variety of factors that are concerned.

A registrant, without knowing it, may be setting policy for everyone else. So, we need to be very

sensitive to the effects those decisions and procedures can have on other actions, because they're often cited well, we did it here, it worked here, now it's your turn to do the same thing.

One other thing, on your slide three where you mentioned ESA assessments and the endocrine screening program, you've given us a lot of very useful detail on the ESA assessments. But this is the only mention of how you're going to incorporate endocrine screening in registration review going forward. Is there any more detail available at this time?

MR. BRADBURY: The SAPs that will happen during the course of this year I think will be really important to help visualize how the future is going to be for EDSP. Back, I don't know how many years ago, we thought there was a good likelihood the EDSP assays would be online at about the time the reg review program started and everything would line up. That didn't happen. But I don't think that means they can't get aligned.

As we start to get the information this coming year, I think we'll get some insights into what's going to be -- is the nature of the battery going to be the

same or is it going to change? The weight of evidence SAP will give us additional advice, new advice on how existing information can be used in the context of perhaps new information. Maybe the SAP will say do it just like we thought it was back in the mid 2000s or they may have a different approach in how to do it.

So, I think as those SAPs come in, we'll have a better insight into how to move forward. My personal feeling is if some of the concepts around Tox 21 play out, we may see that there's a more streamlined way to make sure we're doing what we need to do in a way that can realign the reg review schedule with the information needs. But that's a hypothesis on my part to be tested as we go forward in the SAPs.

So, I think right now our goal is to still try to see if there's a way to get alignment between screening through EDSP and a reg review. We'd like to be able to (inaudible) one reevaluation pipeline and not multiple reevaluation pipelines so we can maximize resources.

But I think this year will be important to see what kind of feedback we get on the battery performance

and the weight of evidence approaches that we'll be proposing and some aspects of the Tox 21 that may give us insights of where to focus.

Caroline.

MS. COX: I think that from a public interest standpoint, the support for including registration review in FQPA came from the sense that there were pesticide chemicals that had been on the market for a long time. There was new information about human health or ecological hazards. There was no systematic way of that agency evaluating that. So, this was meant to provide that.

My 25 word sound byte, or whatever, when I talk about this is, like, well, if Apple was trying to sell phones that were two years old, they probably would be laughed out of the industry. But in the pesticide world, we have products that have been on the market for decades and decades.

So, what I'm wondering is if there's anything built into the registration review process once a mess of the decisions have been cranked through to kind of evaluate and see if that particular registration review

is actually being met and if the process is actually accomplishing at least what the public interest community was hoping it would.

MR. BRADBURY: Thanks, Caroline. The feedback in terms of how do you measure not just outputs, for example, number of preliminary risk assessments or number of proposed decisions, but getting a handle on what's been the outcomes of those decisions in terms of human health protection, environmental protection.

Point well taken in terms of our overall efforts to try to be able to track what's the outcome in terms of insuring there is safe food and fiber and protection of the environment and people. That's a point well taken and something we continue to try to work on, what are those measures that we can trace back to.

I'm checking the clock. We're running a little long, but 12:15 isn't here yet. So, what we have -- oh, Marylou, I'm sorry, I didn't see you.

DR. VERDER-CARLOS: On the focus meetings, is there an opportunity for the (inaudible) SFYREGS to be involved into conversations?

MR. KEIGWIN: I think we're open to figuring

out how to best make that happen. As coregulators, we think that could be a very important piece of participation.

MR. BRADBURY: So, Dave, did you want to talk on registration review? Okay, sorry.

MR. TAMAYO: One small point that I forgot to mention was that if waivers are being granted, it would be really great if there was very clear documentation as to what they are and why they were granted. Then, also, I wanted to agree with Ray and Cheryl about the policy issues that sort of start to emerge when you start making decisions on sort of procedural things.

Then, I guess I'm requesting that management keep an eye on what sorts of things are sort of emerging and starting to set policy. Sort of figure out a way to start getting input on those before things get too set in stone. We have similar concerns about procedural things that start spreading.

I realize you can't get too tied up in knots. Every time something touches on a policy, you can't necessarily stop the process. But really, keep an eye on where things are starting to probably affect the way

business is done for subsequent chemicals. Thanks.

MR. KEIGWIN: So, let me just clarify the issue on data waivers. That is not that we would grant the waiver in the context of the discussion during the focus meeting, but we would initiate that conversation and know where we might be, where the registrant might be. But, as we do with all data waivers, it's a very comprehensive look at the rationale that the registrant may put forward and then a response to that. Then, that ends up as part of the docket for that registration review case.

MR. BRADBURY: I'm hearing the request of how do you balance I think everybody's realization that there's a statutory end day, October 1, 2022, so you've got to keep moving. But how do you take a snapshot in time as certain policies or implementation of SAP blessed risk assessment methods are starting to show up. So, we're definitely going to be looking at that.

I think one thing that you do know is when we went into reg review, we looked at groups of chemicals. They have similar, but not exactly the same, sort of issues to deal with. So, for example, the OPs tend to be in the same three or four year window. The carbamics

tend to be in the same three to four year window. The pyrethroids tend to be clustered together. We've moved all the neonicotenoids together to make sure we got the bee issue sorted out the right way. So, that could perhaps lend to seeing some things coming, having some dialogue around general principles that are starting to play out.

So, hopefully, some of the things that we did when we set up reg review, not anticipating the detail we're starting to talk to now but our intuition telling us there would be certain common themes that may emerge with certain groups of compounds and how they're used, hopefully can facilitate these check-in points without -- I have this image of this train that stopped and all the cars start piling up.

We'll figure out a way to keep things moving but have the check-in points that are necessary so everybody knows what's going on and can give us some feedback. But there may be multiple ways we can do that, not just one way to do it for a given situation.

Jacob.

MR. VUKICH: Just a quick question, Rick. How

soon after the focus meeting do you think that the minutes would be published?

MR. KEIGWIN: Well, the regulation says 10 days. It's intended to be very quick.

MR. VUKICH: Exactly. So, that way, if there are interested parties that want to make comment --

MR. KEIGWIN: There would be an opportunity for them to make comments.

MR. VUKICH: Exactly, and you'd get it early enough in the process.

MR. KEIGWIN: Yes. Thanks for the question.

MR. BRADBURY: Okay. So, thanks. Good input. I'm glad we had this on the agenda to get the feedback. So, even though it looks like an update, I think some of our updates turn into really good opportunities to get feedback on going forward. So, perfect. Thank you.

So, we have three things left to touch on. There's a public commentor, there's to kind of highlight what we accomplished in terms of action items for the next meeting, as well as getting some additional ideas for the next meeting, and then Margie wants to talk a little bit about some of the turnover in membership that

plays out.

So, even though our agenda says to do public comment last, I'm suggesting we have the public commentor speak now, because it might be important to think about for the other two topics we'll touch on. Then, we'll go from there. So, Dudley Hoskins from Rise.

MR. HOSKINS: Thank you. First off, my name is Dudley Hoskins. I'm the manager of Regulatory Policy for RISE. For those of you who don't know, RISE is the trade association we represent, especially the pesticide and fertilizer industry. I had a quick comment. I guess I'm the only thing between you all and adjournment, so I'll try to get out of the way quickly.

But before I do that, I just wanted to reiterate everyone's gratitude for the work that this group has been doing all the time, the toil and efforts you all have invested. I just really appreciate everything you all have done and are continuing to do.

With that, I did want to make one point of clarity, going back to yesterday's discussion on IPM. If I recall correctly, I think there was reference to a DC bill that banned all cosmetic use for pesticides. I had

to go back and look that up, but what I found was that I think the bill in question, which is the Pesticide Education and Control Amendment Act of 2012, actually didn't make any reference to cosmetic uses, but it did address nonessential uses. That bill went into effect about a month ago, October 23rd. Really, from an industry perspective, we just want to encourage this group to continue to address IPM through the statutory definition of IPM codified in FIFRA. That's really about it.

MR. BRADBURY: Okay, thank you.

So, what I'd like to do now is spend a few minutes -- I will highlight my notes which I think captures some of the action items for the next meeting and the workgroups in between. Then I'm not looking for the exact nuance of the words, but if somebody hears something that's wildly different than what you thought, let me know, and then we can kind of tune up by working with the chairs of the workgroups as we get to the next six months.

I just want to make sure we have a general uh-huh in terms of sort of the basis charges to a degree for

the next six months. Then we'll spend some time thinking about other topics. Then, just like other meetings, we'll kind of work over the course of the next few months and hone in on how we'll do it.

So, as far as the PRIA-3 budget conversation, my thinking there would be that Marty pointed out certain specific IT enhancements or other activities we need to do under PRIA-3. She gave us sort of a sense of the time frames when different ones would kick in.

At a minimum, as appropriate, we'd give you an update on some of the PRIA-3 initiatives, if you will, that have to kick in. I don't know if we'll do a big back and forth but at least make sure you're staying current as the different PRIA-3 activities kick in. There will also be some process changes that are starting to happen with PRIA-3. Marty outlined some of those.

So, certainly at the front end of PRIA-3 and some of these new components of the actors starting to come into play, we'll at least make sure you're getting an update on how that goes, not too dissimilar to PRIA-1 and PRIA-2 as they got off the ground. After awhile we'll kind of ease back probably because it will become

more or less routine.

Pollinators and some of the homework, if you will, that I pulled out from that, which I would expect them to get some feedback from the workgroup and getting a chance for the full committee to give advice in terms of recommendations back to the agency. One subgroup in the pollinator protection area was labeling. My notes indicated that we charged the workgroup to take a look at the universe of potential areas for label clarification. That group identified three of the six.

Don’t take me literally, but that’s sort of a zone of phrases or concepts that are in those labels to start focusing on ways to -- if a consensus can be reached, great, but if options is where you’re at to get back to the full committee in six months about (inaudible).

Related to that would be maybe not full documents but at least sort of an annotated outline of best -- looking back at history, what was the rationale behind those phrases in those label statements? There could be a combination of education going along with trying to get the labels clarified.

In terms of BMPs, communication, education, training, they were kind of blurred, but that's okay, across the two workgroups. One charge is for USCPA and USDA to get together and figure out what's going to be that federal government node or entity or person or office that's going to help in this communication process and help figure out which websites are connected to what. Obviously, there's a federal portal presence to the ideas of getting information out to growers.

One of the requests was we need someplace in the federal government to be connected up to help this stuff go. So, we have that homework responsibility to get back. I'll probably work with the workgroups and let you know as that gets resolved.

Having said that, the workgroup would be thinking about the nonfederal entities, purely federal entities. It could be part of this network of nodes of information. Start to give us some advice on how to start to zoom in on different nodes that are part of this interconnection. I think we talked about there's lots of places you can go to get information, which is cool, but we need some structure around there and understand the

structure that people go to to get their information for the workgroup reporting back on that.

Also, the workgroup reporting back on -- I don't know what the right word exactly is, so don't take me literally, but sort of what's the process to take a look at all this information and start to figure out how to hone in on sort of tiering your way through the information or realizing if there's lots of different ways to do this thing, that's okay, too.

How do we help to provide some structure to folks as they see the wealth of information that's out there so that users aren't just buried with information, but they've got some help in terms of drilling through the data that could be out there. So, it's a homework assignment to the workgroup to feed back on how to do that.

I know there was talk about the RT-25, the residual time that's pretty close to 25 percent effective. I think the feeling was, at least I'm going to interpret the agency's feeling, that putting that on the labels isn't the right time or place. But there could be something with regard to information and giving

information to users and growers and applicators that may be useful in terms of making some choices.

So, I'd like the workgroup -- and I don't know if it's BMP or the communication/education training, but you guys can decide to think that through a bit more in terms of what would be some options to at least get information available to people, not in the context of on the label but in terms of information sources people can get at.

Then, the homework assignment back to EPA, OPP, was to working within the EPA family and across the state EPA family to come up with a way that PPDC stakeholders could provide some insights to groups that are starting to work on enforcement guidance and training. I don't have the magic way that that's going to happen yet, but we'll take that on to try to figure out how to get that conduit so the information flows.

Once we figure that out, we talked about at least preliminarily the workgroup dealing with enforcement can at least start to share some ideas, but not necessarily speaking for PPDC, but at least sort of getting the radar screen game turned up. Then we could

loop back around in six months and refine some ideas that we can feed into those efforts.

So, that sort of captured what I thought were some action items combined with homework assignments that would come back in about six months when we meet again. Let me stop there and see if -- again, I'm not trying to get it down to nuance, but if there's something that I completely missed or something that you feel was completely off base, it would be good to hear it.

So, then, the IPM -- sorry, Gabriele and Marylou.

MS. LUDWIG: I guess one other thing I would say on the pollinator stuff is that EPA really articulate every six months what actions they've been doing. I feel that there are things that have been going on that we've been hearing in dribs and drabs, but we've not had a nice summary of here's all the things we've done in response to either the PPDC recommendations or the other things. Just another homework for you guys.

MR. BRADBURY: Okay, good.

DR. VERDER-CARLOS: Also, for the labeling group on the three to six items, that would mean that we

would need the definitions of how it has been used in the registration division.

MR. BRADBURY: Definitely we'll feed into that. That will also feed into at least the annotated outline of what was the rationale behind those three.

Now, let me switch to the IPM discussion. There were two groups. One was metrics of IPM starting to move into the school systems and things plan out. The other workgroup was focusing on what kind of information can be gathered to show what the benefits are of putting IPM into play.

I'm not going to repeat the three recommendations on the first one, but we all agreed that those were going to be three things we were going to take on. They included the engineering, the metrics that are in the six grants, and cooperative agreements that are in play right now and re-engineering those metrics back into the agency's strategic plan, implementation plan, which we will do.

Then, the other charge was that with that metrics information from EPA, working towards a yearly report as to how we're seeing things play out as we go

forward. We're going to do that. Then, the other charge to EPA from the group was to continue to work on enhancing the partnerships with other federal and/or state entities that are focusing on children's health and how to make sure we're linking up children's health activities in the universe of school systems. We'll take that on, too.

So, my sense of that was mostly everybody agree with those recommendations and the agency is now going to look at those three recommendations and start to work on putting them into play. We'll report back to you where we are in those implementation steps as we get to six months from now, but probably the workgroup will give you a more timely feedback of how that's working.

Let me stop there. Did I get that right for folks that are on the IPM group? Okay.

Then, the second area was the benefits. It seems like the consensus there was let's focus on schools first, not that we're taking public health or ag off the table from the charge, but in terms of a temporal sequence of what to try to take on, take on the school issue first. So, that was what I heard.

Then we talked about daycare and childcare scenarios which aren't in the definition of EPA's school IPM program. But my sense there from the conversation, we're not going to -- it's very logical that if some ideas around schools would naturally fit right in with a daycare center, a childcare center, I would suggest do it.

But my feedback to the group would be that if a childcare or a daycare analysis would spread us way beyond where we're thinking with schools, then to pull back. I want to make sure we get the school part, but if it's easy to squeeze in daycare/childcare, do it. But that would be our focus.

Then, the workgroup is going to think through the recommendations Dave talked about and fine tune those and then report back to us six months from now about the specific recommendations to undertaking the tasks to get at the benefits. Did I catch that right? Okay.

Then we have the comparative safety and standards discussion. We talked about reach consensus on one, we're going to go ahead and extend the pilot for another couple of years because the anniversary date is

coming up. We have the green light, if you will, to explore the biopesticide universe of compounds, realizing that there's some things to work through there with our colleagues over in OPPT.

Nothing is going to be decided without getting back to you, but we need to do some work. We need to kind of explore what are the possibilities there so that when we meet in six months, we can have a more in-depth discussion about pros and cons of different approaches. So, one of the homework assignments will be to get that done working with the workgroup and then be able to report back to the full PPDC on what some options may be if we move into the biopesticide area. To me, that was one of the bigger issues.

I know Kristie talked about the animal metric thing. You've heard about the repellency thing. So, there will at least be updates and feedback on how some of those are evolving as we go forward.

Then, OPP databases, I think again that will be more of -- some of it's tied into PRIA-3 updates. Just sort of keeping you posted as things go along. We've got an alternative analysis and how we're trying to move

towards that paperless environment. So, probably more feedback. There may be points in time over the next six months to identify feedback from you in terms of options that we may have before we start pulling the trigger on making some changes. So, that will probably be a combination update feedback, I imagine.

Then, my biggest take-home message on the general update section that got reinforced here today was we'll figure out how to do this but when is something just a unique new thing that happened for that chemical. It really truly is just unique to that compound.

You probably aren't going to stop the presses and have a big policy discussion over a truly unique sort of scenario, but as we're starting to see trends happening as we look into the future into reg review and see sort of commonality in emerging issues, how do we blend into the overall engines that are running some dialogue on that while ensuring that October 1, 2022, we're still getting everything done on time. So, we'll kick around that.

I can see that being a set of options that we might talk about. Maybe use the reg review section we

usually have as a venue to get into that in more detail in terms of what would be some process thing that could work to get the information flow going but maintaining the efficiency of the process moving forward.

At that point, I've run out of gas. Again, at least for that summary and some hints and not so hinting in terms of homework to do in in-depth areas to discuss, I want to open it up now for a little bit with all of you in terms of anything I missed or some things to start putting on the list of possibilities for the agenda.

So, Susan and Susan, Gabriele and Cindy. We'll start with that first four.

SUSAN: I might have missed it, but did you mention the biobase? I think one of the things that we're coming back around with is the discussion about what kind of disclaimer could go along with the biobase in USDA?

MR. BRADBURY: We'll look back at the agenda, this agenda, and make sure there's follow up and feedback on everything in that comparative group. I just tried to hit a couple.

SUSAN: This is for next time, or some ideas.

There's many situations where we run into issues with the label. I'm wondering if there could be -- this may end up being another workgroup, but for deconstructing the existing label and turning it into something that people will actually read the important parts of, because that's not happening. Maybe this group could provide some feedback on how best to make that happen.

Two is, it looks like you guys are starting to implement some of the NRC's recommendations on best practices for risk assessment and risk management in terms of putting together scoping documents, looking at the Tox 21 stuff. It would be nice to see -- this is kind of an involved update, but a presentation on kind of a global overview of what all these things are. We're seeing it piecemeal here and there. But it would be nice to see side by side with what are the recommendations, what is EPA doing, what is EPA planning to do in the future?

MR. BRADBURY: Okay. Maybe we'll even show some of the things we started before the NRC published their report.

Cindy and then Gabriele.

MS. BAKER-SMITH: I put mine into the two categories. One is just an update that you could slip into whatever we do next time, and that was the question to Marty in terms of budget impacts for you guys. I think you'll see something six months from now in terms of FTE for divisions, but also real impacts on programs. What are you guys seeing in terms of impacts on programs?

Then, for a more heavy agenda item, I guess, or discussion items, certainly support for the workshop that was talked about on AOP. One of the areas that I think that people have identified, and we've talked about it in a couple of different forums here, is the bystander exposure and what you guys are actually doing and what the results of that are.

Certainly, with the NAS report expected early in 2013, what are the implications of that for ESA? I think that would be a real logical topic to have.

MR. BRADBURY: Gabriele.

MS. LUDWIG: I think this is a bit of a commentary on this meeting structure and then again a reminder for the future. Really think about, as you're putting the agenda together, what are things that the

public, this group, can comment on? The budget I can't do much about. As I say, I'm a disenfranchised American voter. I have zero responsibility for the congress we currently have, okay.

As I look at yesterday, when we did all those updates of all these different things that are to me core activities of what OPP is doing, how you're doing your risk assessments, all of those policies, that was done at 4:00 in the afternoon when we're all brain dead. I really think that's something that's very key.

Then, you also kept hearing you're in the process of thinking through policies that have pretty big impacts on how we do these risk assessments, all these different aspects. I'm not familiar with all the ins and outs, but certainly the volatilization is a new thing.

Cindy just mentioned bystanders. You have the drinking water. Again, I don't know all the ins and outs, but I really think those are things that need to be brought back to us earlier in the agenda, let's just put it that way, not just as a five-minute update.

Then, you saw on the endocrine and stuff, which was supposed to be an update, there was valuable feedback

there. So, again, how do we utilize that a bit more in my mind? So, just as a general principle thinking through, what are things that are just informational versus what are things that we may have opinions on? Let's just put it that way.

MR. BRADBURY: I agree. In a collegial way, I'm going to also flip it back to the panel members. For example, the update section that we did was frankly based on -- the most input that we got from you, which is just give us a snapshot, turns out, which is very logical, some things that people thought, me too, would be a snapshot weren't. So, you never know exactly, but it would be helpful. There are things you'll be feeding into Margie as you get more time to think about it.

But to the extent you can give us some insight and maybe talk to some of your colleagues on the committee, we truly think this would just be nice to get a 10-minute snapshot just to make sure we're keeping track of which website to go to versus an update. But we think there may be some significant dialogue because will help us prune and lump and split the agenda.

So, I agree with you, Gabriele, that it would

be helpful to get dialogue going so we kind of know how to shape some topics.

Tom.

TOM: I suggest for maybe the next meeting have a presentation on incident reporting. It came up in the pollinator discussion, but it would be helpful in some of the other areas of what information is recorded and what is done with that information. So, I talked to a couple other members, and they it would be of interest, too. So, we may even make some comments on it.

MR. BRADBURY: Good.

Susan.

SUSAN: To Gabriele's point, I think a little bit given that we're supposed to be sort of advising on policy, the two SAPs that you'll have theoretically before we have this next meeting, they're supposed to be informing your policy as well. So, it would be really great if EPA could come to the next meeting with their takeaway from what the SAPs mean and what they're thinking about potential policy changes.

MR. BRADBURY: So, I'll weigh in now on that. Given that the SAPs will have just happened and we won't

have the reports, we won't be reporting upon how we interpreted the verbal report out by the SAP because that's inappropriate.

I also don't want to have two FACAs getting overlapped. The SAP is a Federal Advisory Committee. It has a public process period that waits for the public to hear what the SAP is saying. I want to avoid just duplicating what the SAP does.

Now, having said that, Susan, there will be some time after the SAP report has been published and we've figured out what we're going to do, maybe 12 month cycle out, which would be completely appropriate to share with you.

So, here's what the sign says. I'm not going to come to the PPDC and have you secondguess the SAP or our expert interpretation of the SAP, but we can communicate how this is going to start to phase in to what we're doing. But six months from now it would be completely inappropriate for us to be talking about the SAP review before they've even published their report.

Caroline.

MS. COX: I totally appreciate your comment

about the budget stuff. I understand where you're coming from. I think I was actually the person who asked to have that budget item on the agenda. My thinking was just that it helps us all in our discussions with the agency if we understand that resource piece. Make it an update.

MR. BRADBURY: Susan, did you have another? Okay. Oh, Dave, I didn't see you. Sorry, Dave.

MR. TAMAYO: I'd like to see us start having discussions about use data. I noticed that there were a number of people yesterday who were interested in it for various reasons. I anticipate that that could be a pretty lively discussion and also really informative. I'd like to see other people's ideas about what they think can be done, what can't be done, and how not having adequate data can -- it really seems to get in the way of some of your activities and then also even our discussions because we just don't have the information.

MR. BRADBURY: We'll work with the group to figure out how to hone in on that specific topic. Some of it is (inaudible) and some of it isn't. So, we'll figure out the right dimension to that point and bring it

up.

Virginia.

MS. RUIZ: I was just going to echo support for two of the recommendations on incident reporting and use data.

MR. BRADBURY: Okay, thanks, very good.

Margie, can you come up and just walk through bureaucracy at one of its finest in terms of the process for some of the turnover of the membership of the group?

MS. FEHRENBACH: Every step?

MR. BRADBURY: Not every step.

MS. FEHRENBACH: We're making our lists and checking them twice. That's my other job. The goal is to have a diverse broad representation of stakeholders. So, over the next few weeks, the proposed membership -- many of you have reapplied. Not everybody has reapplied. There's been several members from the public who have applied.

So, OPP with Steve, Marty, Bill, and the senior managers will be going over the list. I've put a proposal together. We'll also have to develop a federal lobbyist search certification. I have to go through that

process. Develop an outreach plan and show how we've reached out to a diverse set of nominees, including women and minorities.

Then we'll go to our system administrator, Jim Jones, for his review and approval. Then it has to also go to our general counsel's office and Federal Advisory Committee management office. They look and check everything. Then the nominations are submitted to the deputy administrator or the administrator. Actually, one of them makes the final selection of committee members.

So, this process will take a few months, three or four months. Once we get that approval, I will be in touch. Letters will formally be sent out to the people invited to the committee. So, we hope to have this done in late February/early March.

I also have some proposed dates for the next meeting.

MR. BRADBURY: Are there any questions on the process?

MS. FEHRENBACH: You can always contact me separately.

So, looking at your schedules and the

availability of this room, May 15/16, June 5/6, or June 20/21. If you could let me know if there are any major meetings that conflict with those days, and we'll try to work that out.

UNIDENTIFIED MALE: Could you repeat those?

MS. FEHRENBACH: Yes, and I'll send them out to you electronically, May 15/16, June 5/6, or June 20/21.

MR. BRADBURY: Okay. First, I want to thank everybody on the PPDC and members of the workgroups. I think it was a very good meeting. We got a lot of information going. Got some good feedback and a game plan for the future. So, thank you all.

I also want to thank Margie for all her hard work in organizing this. (Applause) I also want to thank Glen McCloud (phonetic) who helped with the AV and getting the Power Points up and making sure the mics all worked. (Applause).

So, thanks again. Safe travels back to wherever home is, and we'll see you again in six months, and be in conversation before then. Thanks.

(The meeting ended.)

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