UNITED STATES

ENVIRONMENTAL PROTECTION AGENCY

PESTICIDE PROGRAM DIALOGUE COMMITTEE MEETING

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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. HOUSENGER: Welcome. It's been close to a year, I think, since we met in person, so welcome back. We've had a few webinars to keep people updated, but there's nothing like meeting in person.

I don't know if you knew or not, but we threw a new wrinkle in to getting into the building today. We've had construction going on for what seems like forever. We're betting that the casino down at the waterfront gets completed before this little road out here.

So, we're a little behind, so let me turn it over to Jim Jones who is going to give some opening remarks.

MR. JONES: Thanks, Jack. I won't be long. I'm Jim Jones for those of you who don't know me. I'm the assistant administrator for chemical safety and pollution prevention at EPA. That's the pesticide program that's one of the three offices within chemical safety and pollution prevention. The toxics program is another one, and then we have a small office that does coordination, who you often hear from, the Office of Science Coordination and Policy. They help manage the endocrine disruptor screening program.

It's great to see so many familiar faces. A

couple of you I saw yesterday in a little Hill visit that I had. For those of you who I don't know, I look forward to going around the room and getting to know you a little bit better.

This is a committee -- actually, Ray McAllister from Crop Life mentioned that he thought this might be the 20th anniversary of the PPDC. I cannot confirm that, but that sounds about right. One of Jack's predecessors, and one of my predecessors, in the director's job I think was somewhat was a forward-thinking individual, Dan Barolo.

When he became the office director, he recognized that one of the struggles he had in that job was getting a sense of the breath of stakeholder input on the sort of decisions in front of him on a day-to-day basis, but on some of the bigger issues that the office confronted.

I think he, in his previous life as a state director in the water program in New York State, had experience using what we at the federal level call a federal advisory committee, a FAC, pulling together a group of stakeholders in a very structured way to get feedback, again, not on the decision of the day but on some of the challenging issues confronting an organization.

So, 20 years ago, probably 21 when he started

pulling this together, what we now commonly refer to as the PPDC, the Pesticide Program Dialogue Committee -- I think Jack and I and Bill have been involved at some level the entire 20 years. I can't say we've been to every meeting, but darn near close in some form or another.

I believe firmly that it serves this institution very well, and I think it's a model for how government can get a breadth of feedback across stakeholders within its space on the issues that the office struggles with.

Pesticide regulation, I foolishly thought when I had Jack's job that after we met the FQPA deadline in 2006, that the challenges would sort of fade away, because we were kind of done. How foolish was I. The challenge of pesticide regulation I don't think ever will fade away. I think inherently it is going to continuously be difficult in many respects.

The kinds of issues that we bring before this group represent some of the big challenges of regulating in such a complex area that matters so much to the health and well being of all citizens in the United States. So, as I often do opening these meetings, I really want to most importantly convey the thanks that we have for all of the work that you do, and it doesn't just include the

couple of days a year here, either annually or bi-annually, helping us at these meetings, but the time that you spend in between these meetings, not just giving us your wisdom and the perspective from wherever it is that you're coming from, but the experience that you have in your regular jobs that allows you to then bring that back to us.

I often say participatory government is a great ideal, but it is not that cheap to deliver on. I mean cheap for you. It takes a lot of time and energy to be able to meaningfully input back into the government. We recognize that, and we thank you for all the time and energy that you have all individually given to give us your perspective.

The other part, and this is just worth reminding ourselves, Congress has given the administrator, and then the administrator then delegates it down to people like us, the decision authority in this case as it relates to pesticide decision-making, whether it be under FIFRA or FFDCA. That decision authority lies with the EPA.

We firmly believe, and we believe it because we've got a lot of experience having done it, that those decisions are better informed when we understand the perspectives, the diverse perspectives of the various

stakeholders who are impacted by those decisions. That's what's represented in this room here.

But we also think it's important for everyone to recognize that those decisions still lie with the EPA. I say that because sometimes people can feel like the decision didn't break my way. Some decisions we're going to make would be impossible for them to break all of your way because you all don't have the same perspective on decisions that we make. That is not to mean by any stretch that you have not been heard. What we try very hard to do is make sure that we hear it.

When I say hear it, I mean in the real sense of hear. We hear it and we understand where it is that you're coming from. Again, every choice is not going to land the way everyone in this room is going to want it. That would be impossible to achieve. But we are committed to making sure that we are working hard to make sure that we've captured the range of perspectives. That, in and of itself, is no small feat because this is a big country with a lot of perspectives. We're trying to capture the range of the perspectives and that we've really heard them before we make our decision. So, that's what this is about. That's what this meeting is about. That's what the workgroups are about. That's what the interactions in between the meetings are about.

I really feel strongly, having participated in this group in one way or another from a junior staff person to a manager to an office director and now to the assistant administrator, that we have benefitted dramatically over the course of that 20 years from this institution, the PPDC.

I sort of would jokingly say that when I was coming up the ranks, I didn't resent the PPDC, but it sort of seemed like more work. I couldn't wait to be the office director so I could disband it. And then I became the office director and I'm, like, we are so not disbanding this. It's almost that until you're in that seat that you don't quite recognize just how useful it is, how important it is to have a group like this to get advice from.

So, thanks again for all of your service. Once again, you're going to spend a day and a half, and I think many of you spent the day yesterday, working on some really tough issues, some tough issues that we are grappling with. So, I will have a chance to spend a little bit of time with you guys. I think I'm here until about 10:30 or so. Then I will have to get back to other duties as assigned by Jack and others.

So, I'll turn it back over to the Chair here.

MR. HOUSENGER: Thanks, Jim.

One of the things I wanted to mention before we get into the meeting too far is that the next time we meet, which I think is in October, some of the members that are sitting next to you won't be here. They exceeded the length of time they can serve on the PPDC, and we're going to be choosing new members or they decided to let their membership go. So, I want to thank those people that have served so nobly and helped us out. We'll see who joins us next time.

This is a very big group. As I look down, there's not much room for public to watch what's going on. We try to get every interest that we can and get good representation, so that's what we're going to be doing from now until October. I think the terms expire in July.

I also want to acknowledge the workgroups that have been going on and meeting. I think a lot of good work gets done in those workgroups. They get into the substance of what we're going to touch on a little bit today. But I know that those workgroups are active. I think what we also need to think about is which workgroups we want to continue and which ones we need advice from, and are there new ones to consider.

We have a range of topics today, some of the ones we've talked about, seems like we've talked

continually about, endangered species, pollinators, endocrine disruption. Then we're talking about IPM in schools and topics like that. So, it's a broad range of subjects. We have a bunch of updates to do.

Since the end of the year, Margie Fehrenbach retired. Margie was our designated federal official serving on the FACA group. We've replaced Margie with Dea Zimmerman. I'd like to introduce her now and have her say a few words about PPDC.

Dea.

MS. ZIMMERMAN: Thank you, Jack. So, thank you very much. I really do miss Margie a lot, but I am honored to have the opportunity to work with you, and I look forward to meeting you.

Just a couple of housekeeping things real quick. We have this wonderful new audio system that we're going to try out today. You notice it's about one mic for every two people. We do ask, though, that you keep the microphones off, turned off. There's a toggle switch that you'll see on the mic. We ask that you keep them off unless you want to speak, because if we have too many of the mics on at the same time, you will hear noise. I know you don't want to do that. So, it's probably best if you do want to speak to put your tent card up first, and then we'll acknowledge you, and then you can toggle

the mic on, and then you can speak.

We also opened up our teleconference line, and hopefully, with this new audio system, they can hear us just fine. We have globally muted it, so for those of you who are listening on the phone, please do not unmute your phone. We'll handle the muting and unmuting from our end here.

I just want to acknowledge the public comment session at the end of each day. So, if you do want to make a public comment, please sign up. There's a public comment sign-up sheet on the registration desk. Hopefully, you all registered. If you didn't, please take an opportunity at the break to register with Doris at the registration desk.

There's a folder on your desk. Today's Power Point presentations are on the left. Tomorrow is on the right. The Power Points are also on the website, the PPDC website. You've got to get to the new website, though. I know we've got some issues with the website that we'll try to address.

Most importantly, bathrooms, if you haven't been here before, are down the hall and on the left.

I think that's it. If there's anything I can do to make your meeting better, please let me know.

Thanks, Jack.

MR. HOUSENGER: Thanks, Dea.

We're pretty good on time, even though we started late. Let's go around and do introductions quickly so we can get to the meat of the program. Susan, you want to start out?

MS. STUDLIEN: I'm Susan Studlien, and I work in the Boston office of EPA. That's called Region 1. I'm sure, as you, I'm sure, know, EPA has 10 regions. My regional office is charged this fiscal year and next to be the sort of coordinating arm for headquarters with the other regions. So, I try to keep them up to date on important issues that come out of meetings like this. Then they, in turn, work with the states in each region. So, happy to be here.

MR. BUHLER: Good morning. I'm Wayne Buhler, Professor at North Carolina State University, the North Carolina State University. I also work as the pesticide safety education specialist and provide training certification and recertification for our restricted use pesticide users. I'm representing the American Association of Pesticide Safety Educators.

DR. CARLOS: Good morning. I'm Marylou Verder-Carlos, Assistant Director for the California Department of Pesticide Regulation, and I'm here representing the states and AAPCO.

MR. VUKICH: Good morning. I'm Jake Vukich from DuPont Crop Protection. I'm a manager of the U.S. Registrations and Regulatory Affairs Group.

MS. RUIZ: Good morning. I'm Virginia Ruiz, Director of Occupational and Environmental Health at Farmworker Justice.

MR. COY: Good morning. I'm Steve Coy. I'm a commercial beekeeper and represent the American Honey Producers Association.

MS. PALMER: Good morning. I'm Cynthia Palmer. I'm the Director of Pesticide Science and Regulation at the American Bird Conservancy.

MS. CALLIES: Rachel Callies. I'm the Director of Product Registration for S. C. Johnson & Son.

DR. LAME: I'm Marc Lame with Indiana University School of Public and Environmental Affairs. I represent the National Environmental Health Association.

MS. HARRIOTT: Good morning. I am Nichelle Harriott. I am the Science and Regulatory Director at Beyond Pesticides.

MR. WHITTINGTON: I'm Andy Whittington with the Mississippi Farm Bureau Federation and the American Farm Bureau Federation.

DR. WHALON: Mark Whalon, Michigan State University. I represent the Upper Midwest Horticulture

Association.

MR. SCHERTZ: I'm Scott Schertz, Schertz Aerial Service, Illinois, representing the National Agricultural Aviation Association.

DR. KEIFER: I'm Matt Keifer from the National Farm Medicine Center and the Marshfield Clinic.

DR. CLEVELAND: I'm Cheryl Cleveland. I work for BASF in the Global Consumer Safety Unit. I reside in RTP in North Carolina.

MR. TAMAYO: Dave Tamayo, Sacramento Stormwater Program. Unfortunately, we don't have any stormwater this year. I'm also with the California Stormwater Quality Association.

DR. GILDEN: Good morning. Robyn Gilden with the University of Maryland School of Nursing.

MR. BOTTS: Good morning. Dan Botts with Florida Fruits and Vegetables Association and also the Minor Crop Farmer Alliance. I'm representing Mike Willett who is meeting with the Chinese delegation to be sure that they can continue to ship cherries and apples to China moving forward.

Just one note, Jack and Jim, as a charter member of this organization back in 1994, we had a unique distinction of having the first meeting set and they promptly shut down government for six months. So, we had

to delay our first meeting for six months. So, a little historical perspective there.

MS. SELVAGGIO: Hello. I'm Sharon Selvaggio with Northwest Center for Alternatives to Pesticides. I'm the Healthy Wildlife and Water Program Director.

MR. HANKS: I'm Douglas Hanks with the National Potato Council. I'm on their Environmental Affairs Committee.

MS. GOUGE: Good morning. I'm Dawn Gouge, overly enthusiastic entomologist from the University of Arizona. My focus is on public health.

MR. TAYLOR: Donnie Taylor, Vice President of Agricultural Retailers Association, representing the suppliers of farmers across the U.S.

MR. SANCHEZ: Valentin Sanchez, Oregon Law Center. I represent the farmworker community.

MS. REA: Liz Rea, Sipcam Agro USA. I'm here representing the Biopesticide Industry Alliance.

DR. FERENC: I'm Sue Ferenc with the Council of Producers and Distributors of Agrotechnology, representing manufacturers, formulators, and distributors of agrotechnology products.

MR. DELANEY: Tom Delaney, Director of Government Affairs for the National Association of Landscape Professionals, new name.

DR. JACKAI: I'm Louis Jackai. I'm employed by the other university, the other ag school in North Carolina, A&T State University. We serve the small growers.

MS. BISHOP: Good morning. I'm Pat Bishop with People for the Ethical Treatment of Animals, also known as PETA. I'm representing the animal welfare issues associated with pesticide testing.

MR. MCALLISTER: I'm Ray McAllister with CropLife America, Senor Director, Regulatory Policy. I have been to every single PPDC meeting.

MS. LUDWIG: I'm Gabriele Ludwig, Associate Director of Environmental Affairs with the Almond Board of California. I haven't been at every one, but the very, very first thing I ever did in D.C. was a PPDC meeting.

DR. CALVERT: Hello. I'm Geoff Calvert. I'm a physician with the Centers for Disease Control and Prevention. I coordinate the Center's pesticide program, which is involved with tracking pesticide poisoning across the country.

MS. KUNICKIS: I'm Sheryl Kunickis. I'm the Director in the USDA Office of Pest Management Policy. We work closely with EPA on all pest management issues.

MR. JORDAN: Bill Jordan, Deputy Director for

programs here in the pesticide office.

MR. HOUSENGER: Do we have anybody on the phone who is a member of PPDC calling in?

DR. KASHTOCK: This is Mike Kashtock from FDA. I don't know if you got me.

MR. HOUSENGER: Okay, thanks, Mike.

Our first topic is one that everybody always likes to hear about, our money, our resources. Marty Monell is going to give us that update.

MS. MONELL: Thanks, Jack. You should all be familiar with the format of these slides. This is a presentation I try to give every six months, whether it be via webinar or in person. So, the first slide is our appropriated budget. You will see the totals, and this is for the pesticide program. So, this does not include other areas of the regulation of pesticides that are affected in the regions and in the AA's office. So, this is strictly -- oh, I guess it does have the regional. I take it back.

So, the green bars, the light green bars are the pesticide program, specific appropriations. The dark green are what is sent to the regions. The orange is what is provided to the AA's office for their contribution to the licensing of pesticides and the review of the old chemicals.

You'll see that the '16 president's budget is a little bit higher than we have been appropriated in the past, and that is because the president's budget normally contains sufficient funds to provide for the minimum appropriation requirement under PRIA. The congress has not provided those funds in the past couple of years, but we, nonetheless, because the president supports PRIA, we have provided for adequate funding in our president's budget.

The next slide depicts the minimum appropriations requirement in just the lump sum. You'll see for the 2016 president's budget that there is a bump up. It's about $2 million more than the president's budget for 2015. That is because of the provision for pollinator protection funding.

Ray, I believe you asked this question at the webinar, how that might impact PRIA responsibilities. I would say that a million and a half of that additional funding is provided in the science and technology account, which is specifically designed for our labs to do analyses and research type work on pollinators. So, to help us better understand the science of what's going on with pollinators. So, that is an account that is not used for regular PRIA work, so it will not have any impact on our ability to do the PRIA work.

The other $500,000 is designed to go to the states. It's what they call STAG money, State and Tribal Assistance Grants. This is awarded through the regions to the states to help implement programs. In this case, it's particularly identified to provide assistance to states and tribes to come up with pollinator protection plans. I'm not going to go into that because you're going to hear a whole session on the state and tribal protection plans for pollinators.

The next slide depicts FTE. This is full time equivalents. This is government jargon for our ability to have people do the work. As you all know, as a licensing program, the pesticide program relies heavily on government employees for the decisionmaking, for the review of studies, for the development of risk assessments, and for the ultimate regulatory decisions. So, this will show you essentially a decline in FTE from 12 to 16 in the president's budget. We've lost quite a few, about 60 FTEs.

The regional portion of that has been pretty steadily declining but has proportionately been better maintained. Then, as you'll see in the AA's office, the assistance that's provided to licensing program by Jim's staff has been pretty steady after an initial decline in 2012.

The next page is sort of a description of the two pre-fee programs that we have in OPP. You can see that the PRIA collections, the registration service fees, have been pretty steady, around $15, $16 million for the past few years. It appears that we're on track to collect about that same amount this year.

We historically have projected that we would collect around $11 or $12 million because we don't want to be caught short. So, for planning purposes, we generally have projected lower than the $15 or $16 million but have been able to collect more.

The maintenance fees, these are fees provided under FIFRA. They support the registration review program and can only be used for the registration review program. We're authorized to collect $22 million in '12. And then, under PRIA 3, that ceiling was raised to $27.8 million, $800,000 being dedicated to enhancements to our IT system. That's still a work in progress.

We have developed a tracking system whereby e-mails are sent out to registrant companies as to the status of their applications, but we have yet to fully implement a new modern 21st century technology system in the pesticide program. But we are aggressively pursuing it.

The next slide depicts -- it's just another

view of our collection of PRIA fees, same for the maintenance fees on the next page.

Lastly, I wanted to talk a little bit about the FTE. Although the FTE have seen a decrease in the past few years, we have been able to do some hiring. We recently found a provision in the Office of Personnel Management that enables any federal agency to hire what they call term hires for a year, and then they can be renewed for up to four years.

This particular authority is extremely effective for work under PRIA and work on the registration review program, because absent the statutory authority under PRIA or FIFRA, we would not -- and the mandates for completing the work -- we would not need the additional personnel. So, we currently have on board about 40 term hires.

We have 53 additional term hires in process to bring on board. This will enable us to get the PRIA decisions done in a timely fashion to meet our statutory commitments there, and will also enable us to complete the registration review work, or at least give us a best effort towards completing the registration review work, which, as you know, the first round is due to be completed in 2022 under the provisions of PRIA.

This past year, the agency also, as part of a

government-wide effort to sort of reduce the number of personnel for which payroll is increasingly become an issue, we've offered what they call early outs or buyouts. Early outs are for those that are not quite retirement eligible, but it's an opportunity for them to retire without incurring any setbacks to their pension. The incentive program is essentially a buyout where you're eligible and you can receive -- in our case, it was a $25,000 figure to retire.

We had 20 people take advantage of that in the Office of Pesticide Programs. I believe most of them were retirement-eligible. We tend to have people stay for a long time once they start working in this program. As a result of that, we obviously lost a lot of knowledge and experience in the program, so we have been aggressively pursuing the backfilling of those senior positions and then aggressively pursuing permanent backfills for the 20 that retired, for the aftermath of the 20 that retired.

So, we are not only hiring sort of junior level staff to actually grind through the work, but we're also backfilling vacancies caused by the more experienced staff that have retired. This is all, as you might imagine, a very complicated process, but we have our entire senior executive team working on it and coming up

with proposals to Jack, Bill, and I. We're trying to move as expeditiously as the agency can allow.

PRIA itself, I'm pleased to say, that we have increased our on-time completion rate. Last year, due to the shutdown, the almost three weeks shutdown, and a few days of furloughs, we had a setback in our ability to complete the PRIA actions on time. We were down somewhere around 86, 87 percent. We're now, as of mid-year, halfway through the fiscal year, we're at 97.7. We expect to be back up to 99 percent on-time completion.

Renegotiations, on the other hand, this is when you have a PRIA date that's due, an action that's due on a specific date but, for whatever reason, it cannot be completed on that date, both parties, both the EPA person responsible and the company representative agree to an extension of the date. That's called the renegotiation. We were up into the 20 percentile ranks for that, that amount. We're now down to 15.3 percent.

A lot of that is because in PRIA 3, we provided some technical assistance advice to the PRIA coalition along the lines that if we had the ability to do a more thorough screening of applications before we actually committed to doing the work, we could eliminate the number of renegotiations and identify problems in a more timely fashion and deal with them.

We call it the 45/90 day screen. It's a 45-day period for short term actions; it's a 90-day screen for the longer term, new AIs, new uses, and so forth. So, we screened over 1,000 actions under this particular provision. We've sent out what we call 10-day deficiency letters. That means we've identified deficiencies. It's often where there's a claim that something is substantially similar to another registered action. In fact, it's not.

So, anyway, we send out these 10-day deficiency letters, enabling the company to come back in and correct the problem. So, we sent out 10-day deficiency letters to about 10 percent of that 1,000 that have been screened. So, I think not a whole lot are subject to these deficiency letters. We've only rejected one. I know there was a great concern throughout industry that we would be slap happy and just reject applications willy-nilly. In fact, we've only had to reject one. Sixty-seven of the actions have been withdrawn, however. I guess companies don't like the label of having been rejected. They prefer to withdraw it themselves, which is fine, because in most of those cases, the work has been done, the application fixed, and then it's resubmitted. We can properly address it without wasting anybody's time.

I guess, in sum, this is quick, in sum, the PRIA 4 apparently is being advanced for reauthorization. I suspect the coalition doesn't want to have a reauthorization discussion with congress during an election year, so we have been recently asked to provide technical assistance to the coalition for PRIA 4. I suspect we'll be embarking upon those discussions within the next month or so.

Any questions?

MR. HOUSENGER: Sue.

SUE: We've just been hearing that you've been having trouble kind of with some of the renegotiated due dates. I know that you guys are doing the best you can to try and get all these things done on time. Has there been renegotiated due dates, not because of a problem with the application but because you guys don't quite have the staffing yet to be able to get done on time? What's the trend in your renegotiated due dates now?

MS. MONELL: See, I can tell you that the one category that seems to be experiencing the most difficulties are the inerts. The inerts are, as you know, under PRIA 3, it's the first time we've had specific categories for inerts reviews. We had no experience, really, in judging the amount of time necessary, including the amount of time required for the

FR notice process. So, we've had to -- I've noticed because I sign all of the renegotiations, for the most part -- that that area is probably about a 60 percent renegotiation rate.

So, I can tell you that, the others, I don't have that sense at all. Quite frankly, in the Registration Division, we're down about four percentage points from the rate of last year. In the Biopesticides Division, it's down about seven percent from last year. Antimicrobials is about the same as last year, about 14, 15 percent. So, other than those trends, I'm not seeing it. I'm not aware, Sue. If you have a particular example, I'd be happy to follow up.

MR. HOUSENGER: Ray.

RAY: A couple questions. Do the PRIA completion dates include renegotiated dates as completed on time?

MS. MONELL: Yes.

RAY: And those rates, can we determine those on a category-by-category basis? Is that information available for us?

MS. MONELL: You mean the renegotiations by action code or do you mean --

RAY: Well, if I've got category R-127, can I get a renegotiation rate for that category?

MS. MONELL: Yes, you can. I believe, though, that information was provided at the last coalition meeting, the quarterly coalition meeting.

RAY: Okay. In some federal budget negotiations one or two years ago, some PRIA funds were sequestered. What's the status of those?

MS. MONELL: There's about $800,000, assuming it's not earning interest, that is still sequestered because we don't have the statutory authority to release those funds back to the program. So, they're still being held in a sequestered account until such time as congress acts. If you recall, there was a provision in the 2014-15 president's budget that would have provided for the return of those funds. It was not acted upon in our appropriations.

RAY: You spend PRIA funds on several different projects/categories. Whose hide were those sequestered funds taken out of?

MS. MONELL: It's taken off the top. We never saw the money.

RAY: I mean, you have less to spend, so where did you not spend it?

MS. MONELL: Where did we not spend it?

RAY: Yes. Was it spread across all categories?

MS. MONELL: Oh, I see where you're going. Yes, it would have been a reduction in the amount of money spent on payroll, as well as the amount of money spent on contracts.

RAY: What about the specialty programs?

MS. MONELL: Set asides are set in the statute, so we did not take the money from them.

RAY: Okay.

MR. HOUSENGER: Wayne.

WAYNE: Marty, thank you for this efficient report. It's good to have this format to look at from year to year.

I just have a question regarding slide 5, the authorized pesticide fees and the comments for the PRIA 3 mandated programs. Can you explain how monies for worker protection and partnership grants are distributed? I'm familiar, of course, with PSEP, but what about the others?

MS. MONELL: The partnership grant set-aside was utilized for the past two years to support NPIC, National Pesticide Incident Information -- yes, thank you. We believe that that is an invaluable resource for the public and something which is certainly a partnership. It's a cooperative agreement that we fund. Working with them, we have been able to leverage a lot of

service with a very small investment.

WAYNE: Worker protection?

MS. MONELL: The worker protection, we've done things like -- it supports -- I don't have the exact list, but I can get it for you. As a matter of fact, I'll see that the exact expenditures are posted on the PPDC website, where all these materials will be found. It's all activities to support either the certification and training of applicators for restricted use pesticides, the training program that we used to fund through USDA but they no longer are in that business. So, part of the funding goes there. Part of the funding goes to various outreach activities for the workers.

MR. HOUSENGER: (Inaudible) for training farmworkers under the new rule.

MS. MONELL: Right. I was going to get to that. This year, in FY 15, in anticipation of the new worker protection rule and the modifications to the certification and training rule, we have set aside not -- we are going to be utilizing not only the PRIA set asides, but we're also dedicating some resources, some discretionary resources, from our EPM accounts towards outreach activities and training and so forth, so that we will be ready.

As Jim just mentioned, there's an RFA out for

the pesticide safety education program. Stay tuned, keep your eye open, because there will be lots of announcements of funding availabilities. We're also dedicating about a million dollars to help fund IPM in schools again, this time with EPM money, not with STAG money, so that we can broaden the funding available to various organizations and entities to increase our efforts in the school IPM area.

MR. HOUSENGER: Robin.

ROBIN: Thank you. Just an administrative comment and then a real question. Is there any way that we cannot print out the full slides? EPA wastes trees.

The early outs and buyouts, the 20 people, from where are you recruiting or advertising? Is it within the agency, outside the agency, both? Where are you trying to get those people from?

MS. MONELL: Well, a good number of the backfills for those that retired will be promotional opportunities for those within our organization or within the AAship or within the larger EPA. It sort of depends on what has been identified as a priority need for the backfill.

Then, there will be another probably dozen that will be announced through USA Jobs, broadly announced. Also, when we do announcements like that, we also make

sure that we get the word out to minorities serving institutions, both the HBCUs and the HSIs, anyway, minorities serving institutions, so that we get as broad and diverse a candidate pool as possible.

MR. HOUSENGER: Gabrielle.

MS. LUDWIG: This is a little bit more on the details, but given some of the losses and given some of the loss just in general to FTEs, where and how has budgeting been going on for international efforts?

This president has made a priority for enhancing trade and exports from the United States. To be honest with you, our sense is that we've lost capacity, not just because of certain individuals but just in general.

There has not been a priority given to these international issues from working with OECP on biopesticides. How do we set up those standards so there's more uniformity from the get go rather than getting to where we are on the conventional arena to really working on MRL issues as part of TTIP (phonetic) and all those kinds of stuff?

So, I'm just trying to get a sense of, if you're looking at the budget, and I know there's been cuts, and it may not be a question for Marty, it might be a question for Jack or Jim, how are you prioritizing or

where does that whole effort come from on really making sure that the United States and EPA is represented in these international arenas in terms of how you do pesticide risk assessments, MRL setting, all that kind of stuff?

What is the definition of a biopesticide? When is something exempt from a tolerance? I mean, there's a whole bunch of things along those lines that require effort. If we don't pay attention, they make it really, really hard to use new products.

MR. HOUSENGER: I think we actually do a lot on the international front. We participate in the OECD. We have just hired a new person to be the OECD test guideline coordinator. Recently, we met with the Peruvians to talk about a situation on quinoa, to allow them to import quinoa into our country, and also set tolerances to help our domestic growers grow quinoa effectively.

You know, I think it is a balance about how much of your resources go to international and what you get out of that. I think that's one of the things we're looking at now, is how often do we play in the OECD meetings. But I think next week we have representatives going for those meetings as well.

So, I actually think we give quite a few FTEs

to OECD international activities. I think we're doing a good job. We harmonize with Canada on our MRLs. Australia, we conduct global reviews. So, I guess I see it differently.

Scott.

SCOTT: A question for Marty. You referred to one rejection and 67 withdrawn registrations. What time frame is that current to? What are you actually referring to?

MS. MONELL: From October 1st. In other words, the beginning of this fiscal year to the end of March, which was the end of the second quarter of this fiscal year.

SCOTT: Okay, thank you.

MR. HOUSENGER: Sue, I assume you don't have another question?

Let's go on to our next topic, which is one that we spend quite a bit of time working on, ESA. For those of you who are familiar, you know that the NAS gave us recommendations on how to implement ESA with the services. We've been working successfully. We're gearing up this summer to issue our first biological evaluations on three pilot chemicals.

We're looking closely at when we grant a new active ingredient, about whether that shift is a good one

in terms of the alternatives that are available and what it would go to. We've been conducting ESA assessments for herbicide tolerant crops, such as 2,4-D and upcoming Dicamba (phonetic) decision. And we've been dealing with a lot of litigation.

So, Anita and Craig are going to give us an update on everything else.

MS. PEASE: Good morning, everybody. I'm Anita Pease. I'm the associate director of the Environmental Fate and Effects Division. And Craig Aubrey, who is the chief of the Environmental Review Division and the Fish and Wildlife Services Ecological Services Program. We are going to tag-team this presentation.

So, for today, we're going to give you a little background on ESA. We're going to tell you what we've been doing since the National Academy of Science issued their report in 2013. Craig will be talking about that, giving you a status of our ongoing activities. I'll discuss our most recent stakeholder meeting that we had in mid-April and some of the work that we've done to date before that meeting. Then, we'll finish with some challenges and perspectives.

I'll turn it over to Craig.

MR. AUBREY: Good morning. Thanks for having us. So, like Anita said, I'm going to go ahead and give

a little bit of a background on how we got to where we are today.

Basically, in April of 2013, the National Academy of Sciences released a report on how to basically improve the way we are assessing risks that threaten endangered species from pesticides. This report had been produced at the request of the U.S. Fish and Wildlife Service, National Marine Fishery Service, EPA, and USDA.

What we were trying to do was basically overcome years of difficulty trying to figure out the best way to approach this. We had a lot of questions regarding what was the best science to use, what was the best techniques, that kind of thing. So, the whole idea was to turn to the National Academy of Sciences to try and get over some of these obstacles that we had had.

So, what they recommended in the report was a three-step approach that would integrate ecological risk assessments with the endangered species section 7 process, basically. So, the three-step approach is illustrated up here on this screen. This is actually straight out of the NAS report.

So, what we have is step one, which the first step is basically determining whether or not the registration or re-registration of this pesticide and its use may effect a federally listed species or designated

critical habitat, which is actually a pretty low bar. It's just kind of the first initial screening step of the process.

Once we get through that step, the second step is step two, likely to adversely affect. So, is the use of this pesticide likely to adversely affect an individual listed species or designated critical habitat? If we had determined no affect for a species, you're basically done with that species.

Step 2 is likely to adversely affect. If EPA determines that it's not likely to adversely affect that particular species or designated critical habitat, and the service concurs, either one of the services concur, then we're done for that particular species.

However, if we don't concur or if EPA determines that it's likely to adversely affect that particular species or designated critical habitat, then we would enter into formal consultation on that particular species or critical habitat. That's where the services would do a more in-depth analysis and at the end have to make a determination as to whether or not the use of that pesticide would either jeopardize that particular species or, in the case of critical habitat, adversely modify or destroy its critical habitat.

If the answer is no to jeopardy or adverse

modification, then that's essentially it. We produce that within our biological opinion, which is given to EPA, and then they can move forward with the registration or re-registration. However, if we do find that there's jeopardy or adverse modification, that's when we'd be looking at developing a reasonable or prudent alternative, which is what additional measures might be necessary to avoid jeopardy or adverse modification.

So, throughout this process, we're employing the current ecological risk assessment framework. Another kind of important thing to kind of point out is ultimately, steps one and two, is it may affect or is it not likely adversely affect determination, that's EPA that is making those determinations.

Step three is for the Fish and Wildlife Service, National Marine Fishery Service. That's where we're producing our biological opinion, basically.

One thing I do want to point out here, though -- so, we just kind of focused on who has ultimate ownership or responsibility for a particular step -- is that throughout this process, all four agencies are at the table. Staff, I would say, if they don't talk daily, they're talking throughout the week, as we're trying to work through integrating these separate processes.

So, when I keep turning my head or people are

getting noise then not noise, I just got to notice that I'm kind of sometimes talking into the microphone and sometime not. Is that starting to be a problem for people? I just wanted to make sure.

So, like I said on the previous slide, the goal we have right now is to have a unified approach with agreement in processes across all these phases. So, from staff all the way up through management, there's really a concerted effort to work through, using the recommendations out of that NAS report and the interim approaches that we've developed, to come to a consensus on how to move forward so that there would be no surprises and, hopefully, we're getting the best possible product that we can.

One of the things that we've kind of made a concerted effort and we back up is the idea that each of the agencies be open to changing how it views risk assessment methodologies. So, truly, if you sit and listen to staff, they're really open, trying to work with each other to figure out the best solutions.

And then, kind of recognizing that although the NAS report is really a great product for us to work from, that A, not all of the answers are in that report and B, that we can't necessarily implement all of the recommendations right away. To some extent, we have to

get through these first couple of biological opinions as we're working some of these recommendations out, how do they actually apply in the real world, the idea that we're recognizing that we're learning as we go, conducting an iterative approach, basically, and with the goal, hopefully, as we learn to improve the processes and to have the most streamlined approach that we can.

The idea, when we're working through steps one and two, we're doing so with the idea of informing step three, if it's necessary, for a particular species and that we're really thinking these things through so that as we get through these first couple of chemicals, they're really going to help inform our thinking as we go forward in the future.

So, a kind of basic time line, in 2013 the NAS report was released. Since then, we've had three interagency workshops. The last one was actually the first one that I had attended. It was the better part of a week. It was a really good opportunity for all of the staff and all the agencies to get together and talk through some of these really difficult issues that we've been trying to get through.

We have had four stakeholder workshops, the last of which was last month. The first couple actually focused on the idea of getting feedback on the interim

approaches that we had developed and for us to provide updates. And then, this last one in April really focused more so on us providing updates on where we were going.

One of the things that we have done since the 2013 report is we had a variety of settlement agreements. Each of the agencies had a variety of settlement agreements on a variety of chemicals and species and that kind of thing. There was a concerted effort by all of the agencies to kind of go back and consolidate, I guess would be one word for it, what we are supposed to be doing so that we could unify resources and priorities.

The last thing that I would mention is that in addition to having stakeholder workshops, staff from each of the agencies have been providing presentations at a variety of scientific conferences, other stakeholder group presentations, you kind of name it. So, we are trying to keep people as informed as possible and solicit feedback as much as we can so that we're providing the best products we can.

So, right now we are working through our first three chemicals. These are our first national level pesticide consultations, so we're looking at re-registration for these three chemicals nationwide, so having to look at every listed species and designate a critical habitat throughout the U.S. It's a pretty big

list. I would say it was pretty much an all hands on deck approach with each of the agencies from staff up. It's a truly collaborative effort. I definitely feel and believe that. It's being conducted consistent with the interim approaches that were based on that NAS report.

The first three chemicals are listed here, chlorpyrifos, diazinon, and malathion. We are shooting to have our draft biological evaluations for these first three pilot chemicals this fall. We are scheduled to have our final biological opinions for these first three pilot chemicals in December of 2017, which seems like a long way off, but it doesn't feel like a long way off at all for us.

MS. PEASE: Thanks, Craig.

I'll just also mention that as these documents go out, as we release drafts, there will be multiple public comment periods. So, as the draft BE goes out, you'll have an opportunity to comment. As the draft biological opinion goes out, there will also be a public comment period. So, although, like Craig said, it's a long way to 2017, there is multiple opportunities for stakeholder engagement along the way.

So, I'm going to update you a little bit on our last stakeholder meeting, and this meeting provides a good opportunity for me to tell you what's been going on

in terms of the ongoing work. This was probably our most interactive meeting of the four that we've had so far. There was a lot of dialogue between the technical folks that are working on these draft BEs from all three agencies. There was a lot of good dialogue at that meeting.

So, basically, what we did was we provided an update of the problem formulation. If you recall back to the slide Craig presented with the three steps, along the side of that was our risk assessment methodology framework, which includes four steps, problem formulation, exposure, effects analysis, and then a risk characterization. So, the problem formulation is really the first step in that process, in drafting out that BE. It occurs in all three steps of our consultation process.

We also had a presentation on the geospacial data that will be used throughout the three steps. I'll talk a little bit more about that. We also presented work that's ongoing right now in developing a weight of evidence approach, which is really the key framework we'll be using to make that likely to adversely affect or not likely to adversely affect as part of step two of the process.

Then, there were also presentations, some specific examples relative to some listed species, the

Kirkland's warbler, which is a listed bird, as well as a short-nosed sturgeon. I'm not going to go into those today, but the slides from the stakeholder workshop are available on our website. I encourage you all to look at them because there's a lot of really good information, especially in those last two presentations, in terms of the tools we'll be using and how that information will be presented in the draft BEs.

So, relative to the problem formulation, the teams are pretty far along in this section of the draft BE. They have good drafts. They've already circulated the documents for comments amongst the technical staff, so we're in pretty good shape with this.

This section includes four different subsections. We'll be describing the scope of the federal actions for these three chemicals that Craig mentioned. We'll be providing information on the pesticide, the active ingredient. We'll provide conceptual models, which I'll discuss a little bit. Then, we'll also lay out the analysis plan for steps one and two in the problem formulation.

So, in terms of the federal action, the federal action is really based on the product label for all the pesticide products that are contained in the pesticide that we're assessing. This includes all the formulated

products, everything that's registered along with that active ingredient.

Right now, you can understand that clear labels are extremely important in us determining what the federal action is. If we don't have clear labels, then we have to make assumptions, and they're usually conservative assumptions about maximum rates, number of applications, and such.

So, we have been actively engaging the registrants for these three chemicals to try and get some clarity on labels when they're unclear, especially for use patterns that can be anywhere in the country. So, this would include things like wide area uses or mosquitocide use patterns.

In terms of the pesticide active ingredient information, this will describe the fate properties of the chemical. All three of these chemicals are acetylcholinesterase inhibitors so they all share a common mode of action. They have all common degradates, so that would be described there.

In terms of the conceptual model, I think most of you have seen this, but it's basically a figure that depicts the stressor, the exposure pathways, the receptors, and the attributes that are changing based on the stressors.

In terms of the analysis plan, we will describe how we're making that may affect/no affect determination in step one. Basically, that's a co-occurrence of the area where pesticides can be used. That's the footprint. Plus, in the offsite transport distance, based on spray drift or runoff, which we call the action area, and where species ranges overlap within that action area.

Then, step two is a not likely to adversely affect or likely to adversely affect (inaudible). As I mentioned, this is largely based on our weight of evidence approach.

So, in terms of the geospacial data, I first want to mention that we have had a lot of engagement with a couple of industry task forces in developing these approaches. We've engaged with generic endangered species task force, GESTF, and the federal endangered species task force, FESTF. GESTF has been very instrumental in helping us work out our methodology for defining the footprint of pesticide uses; whereas, FESTF has been instrumental in helping us develop range maps for species. This information, again, is critical for step one. Obviously, step one is the overlap of these two layers, so it's very critical for step one. But it will be used in all three steps of the consultation process.

In terms of the pesticide use site information, for agricultural use patterns, we have agreement to use existing USDA spatial layers. So, this would include the crop land data layer, or CDL, as well as the National Agricultural Statistic Service, or NASS, census data on a county level to ensure that we're not underpredicting the footprint based on the CDL layers.

We have a methodology we've worked out for binning 111 thematic classes of CDL layers into 11 bins for different agricultural use patterns. For nonagricultural uses, this is a little bit more tricky. We're trying to make use of the existing data sets, and we have agreement on what we'll be using for forestry and nursery use patterns.

Again, some of the more challenging use patterns to describe are some of the mosquitocides that can be used anywhere. So, in situations where the label doesn't restrict use in any part of the country or we don't have a spatial layer, we will be assuming that that pesticide can be used anywhere.

Again, use site is really defined by areas where the pesticide could be used, not necessarily where it is being used. That's an important distinction to make. We hope to bring that information into the assessments later on, but right now we're basing it on

what's on the label.

In terms of the range maps, FESTF was instrumental in helping us gather some of this information. We do have all the range maps from Marine Fisheries in house, and this is approximately 100 species. Right now, we're working on gathering that information from the Fish and Wildlife Services field offices for their species, which are really most of the endangered species that are out there. We are doing that in a phased approach right now, so we're getting that information right now.

In terms of the risk hypothesis and weight of evidence approach, the teams are really developing this right now, so it's not fully cooked. But I will tell you that they've made a lot of progress in working out a methodology for step two. They have developed risk hypotheses. These are basically directly linked to our protection goals for step two. So, the slide provides an example of a risk hypothesis.

So, the question we're asking for all these chemicals is, is it likely that the fitness of an individual -- and I want you to pay attention to this fitness of an individual because that's the ESA bar for step two. So, again, as Craig mentioned, a very low bar that we're talking about, one individual being impacted.

So, is that fitness of that individual listed species or what we include as part of an analysis of designated critical habitat, is that being adversely affected by the pesticide according to the product label? That's the question we're asking.

As part of the weight of evidence, we have developed various lines of evidence and will be assigning them weights of high, medium, and low. They are based on confidence in the exposure and the effects data that are based on existing criteria.

So, the data that we're going to be using is the exposure data, which will be based on our existing models, our existing tools, targeted monitoring data, as well as environmental fate data. We'll be looking at the relevance and robustness of that information.

In terms of the effects data, we'll be looking at registrant submitted studies, as well as information in the open literature. The criteria we will be using to evaluate the effects data is biological relevance, species surrogacy, and robustness. Then, we'll be comparing all of that information, so we'll be comparing the exposure concentration to all the effects data that we have and determining where the overlap is.

If you look at the slide from the presentation, what you'll see is we're presenting that data in what we

call a data array. So, we'll provide all of the toxicity information along an exposure concentration gradient so you can see how all the information is being used to inform that weight of evidence. Like I said, the teams are working on this right now. We expect that it's going to evolve over time and that we may include additional lines of evidence, and we'll learn lessons from the draft BEs.

So, in terms of challenges and perspectives, just to give you a sense of the modeling effort for diazinon, malathion, and chlorpyrifos, the number of modeling runs per chemical ranges from 2,000 to 8,000 runs. Assuming that we're going to be looking at different types of bins, so we'll be looking at water modeling beyond our farm pond model, we'll be looking at static flowing water bodies, as well as esterine and marine water bodies.

We're looking at species within different HUC 2 (phonetic) regions, so 18 different regions around the country. So, when you do that math and multiply that out, it's a lot of modeling efforts to come up with exposure concentrations for these species.

In terms of the terrestrial modeling, we have to really account for three different sets of units when we're looking at the data, the toxicological data that we

get for terrestrial species. So, a lot of information is coming in, and the teams are evaluating that now as we speak.

Also, we're looking to integrate our existing tools. So, right now we have separate models. T-REX for birds and mammals, T-HERPs for reptiles, TerrPlant for plants, and then AgDrift to estimate offsite transport distance due to spray drift. We're looking at integrating all those tools into one specific model right now.

The other challenge is just the sheer number of determination calls we need to make for each chemical. So, if you assume that there's 850 listed species out there, including all the proposed and candidate species, we need to make calls for each of those species for each chemical. In addition to making the call for whether or not the critical habitat is adversely modified, you do the math for that, you're looking at about over 2,600 determinations per chemical. Then you further subdivide things into different use patterns. So, you're looking at really an enormous amount of work that the teams are doing right now.

So, these are really complex, very challenging assessments. Obviously, everyone recognizes that we've had some historical differences with the services and how

we carry out our science relative to pesticide risk assessment. I want to dispel the notion that there's a culture, an EPA culture and a services culture.

Really, what we're trying to do is each agency is just trying to carry out its mandate under the statutes that it operates under. So, the pesticide program operates under FIFRA and the services operate under ESA. We also at EPA have obligations under the Endangered Species Act to ensure that the federal actions that we authorize, which are the labels, that they don't jeopardize the continued existence of listed species.

So, we're all operating under our current statutes and mandates. I think the teams have really done a remarkable job at trying to see through the lens of the other agencies, which we were not able to do so well in the past.

So, the NAS report helped us do that, obviously. This report really did provide a road map in how we should evolve the risk assessment tools. I think we recognize that. As Craig mentioned, there's some things that we can do now, other things that will take longer to implement. So, we're trying to use the phased approach based on these interim methods.

There are a lot of gray areas in the NAS report that require interpretation and judgment. So, the teams

are really trying to do the best that they can to come up with methods and methodologies that follow the recommendations of the National Academy of Sciences and also meet each agency's statutory mandates. So, it really is a very tall challenge, but again, the teams have been doing a remarkable job at this.

Finally, I'll just leave you with the notion that this is a ton of work. We have, like Craig said, all hands on deck for all three agencies in developing these methodologies and trying to get these draft BEs out in the fall for public comment. It's not like we're going to be finished after that. It's not one and done.

These methods and approaches are going to evolve over time. We expect that from public comments that we'll be getting on draft BEs, we'll modify our approaches and we'll learn as we go. So, the conclusions may change from what you see in the draft to what we do moving forward.

So, I'll leave you with that, and I'll take any questions.

MR. HOUSENGER: Dave.

DAVE: Thank you very much. One thing that strikes me about the things that you're working on right now, the three chemicals you're working on right now, they are very data rich. That's an advantage for trying

to work out the kinks. But I think that at the end of that and once you start working with things where you have a lot less data on the toxicology of the chemicals, you're going to end up with sort of a lack of the right tools.

I just wanted to point out that currently there is a tool that OPP and Office of Water have been working on, which is the common effects methodology, is stalled. I would encourage the agency to work through getting the resources to get that tool in place so that that's available once you work through your pilot program. I don't see how you can really work through some of those problems with all the different chemicals you're going to have to work through that don't have adequate data so you can have real certainty with --

You mentioned species surrogacy. So, if you have that tool that's already set up and approved, and Office of Water and Office of Pesticide Programs agree to that, then you'll have that available when you need it to work through the rest of the process that you have to go through.

You do have my condolences on all those different endpoints that you have to work through. But I think it's really important that you have this sort of global tool so that you can sort of narrow down all the

different endpoints, because I think if you have something that's in place, you'll have better ability to work through this at the end. I think that will help simplify the number of endpoints that you're trying to work with.

The other point I'd like to make is that you mentioned use sites. Of course, I'm concerned about urban discharges. I want to make sure that you fully take into consideration and put the models in place to be able to understand how the urban application sites are likely to impact receiving waters. Currently, we don't believe, as stormwater agencies, that the office universally analyzes those correctly. They're certainly not being conservative enough to keep us out of trouble with the Office of Water and the state agency that regulates us directly.

So, I would encourage the agency also to put in place at least better scenarios and make sure that you use the correct parameters in the models that are supposed to evaluate urban discharges. I think otherwise you'll end up with species that are at risk because those types of discharges haven't been adequately considered.

Thank you.

MR. HOUSENGER: I'm going to take all the cards that are up, but no one else put their card up.

Robin.

ROBIN: Thank you for your report. Just to follow up with Dave, I would ask your consideration of lawn care and particularly athletic field chemicals in your model, residential lawn care.

And then, what were the three pilot pesticides discussed in the April 2015 stakeholder workshops?

MS. PEASE: That was chlorpyrifos, malathion, and diazinon.

ROBIN: Okay. So, they were the same?

MS. PEASE: Yes.

MR. HOUSENGER: Sharon.

SHARON: Hi. My question is, can you describe to what extent any mitigations that are common to the no affect step one, essentially, and step two process, will you be considering any mitigations at that step that are not currently on the label? If so, will those mitigations to essentially reach a no affect or reach a not likely to adversely affect, will those be incorporated into the labels?

MS. PEASE: I think we're always willing to have that dialogue with registrants. In fact, we've documented that in a stakeholder agreement paper, I think that went out in May of 2011 or so. But basically, we're calling them focus meetings. The registrant can come in

at any point in time. If you would like to negotiate, if you'd like to voluntarily cancel a use that may trigger a risk concern for a listed species because it's not marketable, we're certainly willing to have those discussions at any point in the process.

What we've been doing, just in terms of how we would change the label, which I think was the second part of your question, is we've been asking for a commitment letter from registrants to change labels by X date, and then we would have that agreement with the services, and we would adjust our modeling and our risk assessment accordingly.

MR. HOUSENGER: Cheryl.

CHERYL: Thanks. You mentioned a couple of times how mosquitocides sometimes are kind of problematic in all of this. There's a clash between the risk benefit laws and whatever, conservative law. How is that being worked out? Then I have one other comment, too.

MS. PEASE: I mean, it's a fair point. I understand that mosquitocides are necessary for public health control. Yet, there are use patterns that may be potentially risky to listed species. The teams right now are working out the scientific methods, and we're doing that based on the label. So, we have had multiple discussions with the American Mosquito Control

Association. We're trying to get better usage and use information from them. I know they want flexibility in their labels.

So, we are working with them to try and get better information to inform our risk assessments. But at the end of the day, that public health concern, I think, is more of a policy call; whereas, we're working on the science.

MR. AUBREY: I think it's worth noting that working it out will not happen until you're in risk management and the schedule that we've seen here this morning leaves risk management happening sometime after December 2017 when you've got biological opinion. So, that is when it would be worked out and people can then state whether or not we've landed it correctly or not. I think we're a ways away from working it out.

CHERYL: Tools for benefit analysis are also helpful as well. So, you spend all your time on risk tools, maybe there's a need to look at tools for benefit analysis.

The other thing is you mentioned that you need to be assessing things that could be used, not are used, today, which makes sense until you take out of that any kind of realistic monitoring data that allows you to validate the exposure estimates. But at what point are

you getting too far from is used to could be used and you negate that ability to use existing data?

MS. PEASE: Well, I can answer, and then maybe Craig can add his thoughts.

I understand the concerns. Right now, like I said, we're trying to base our methodology on what is on the pesticide label, which doesn't necessarily describe how things are actually used in the real world. So, we are trying to bring that information in later in the process.

Do you want to add?

MR. AUBREY: No, I think you're doing a pretty good job. I don't really have anything to add to what she's been saying.

MR. HOUSENGER: Mark.

MARK: I really appreciate the review and going through this process. I've wondered for a long time since, what, a couple years ago when it seemed to go underground. So, I appreciate that. I really like the way that you're moving ahead and the kind of balance of risk that you've set forward. It seems reasonable at this point.

One of the challenges that I think that has been brought forward already is this whole benefit analysis/risk management analysis. I didn't see enough

of that to feel very comfortable one way or another. It would be great to see some more depth to that. I know that there's layer after layer after layer.

I worked around the Kirkland warbler issue, for example, and the public process is probably the most dangerous for the agencies. I'm wondering how are you going to handle that in terms of information and reporting, et cetera, as you move through the process?

MS. PEASE: I mean, we recognize that we'll be getting a lot of mail when these go out for public comment. There will be a lot of information to digest. So, I think that the teams will take whatever information we can. I know Don Brady threw out a challenge to CropLife America at the recent spring conference about coming to us with a revised process that they thought might be better. I know we've heard a lot of criticism of our current methods.

Again, it's easy to criticize but not so easy to do. So, I think we're always open to hearing from stakeholders and how to improve things. We recognize it's a lot of work, and it's going to take time to adjust the methodologies accordingly. But I think we're open to having that dialogue.

MR. AUBREY: I think we're still trying to consider some of the amount of public participation from

the Fish and Wildlife Service or National Marine Fisheries Service perspective. Related to section 7, consultation, we rarely have this degree of public participation. So, we're still kind of trying to think through some of these to make sure that we're providing a solid process, basically, a transparent process.

MR. HOUSENGER: Ray.

RAY: I want to make sure I understood the may affect process correctly. You say that it's based on where a product is registered and where the species occur, not where it's used, just where it's registered?

MS. PEASE: That's correct. It's based on labeled use patterns.

RAY: What about toxicity?

MS. PEASE: Toxicity, there are thresholds that come into play to determine the off-site transport distance. So, the footprint is based on the geospacial air. The species range maps are based on geospacial data. Then the additional distance that's added to the footprint is based on toxicity information.

RAY: Toxicity to the surrogate species?

MS. PEASE: It's based on the lowest toxicity threshold, and these were agreements that we made with the services as part of our interim methods. Again, you know, recognizing that these things may change over time,

that was the agreement we made. If you look at the NAS report, I think NAS was pretty clear about what they intended for step one. I mean, it's this co-occurrence. It's clearly articulated in the report.

RAY: Okay. Others have expressed my concerns.

MR. HOUSENGER: Cynthia.

CYNTHIA: I appreciate all the hard work on ESA. I learned a lot at the stakeholder workshop in April. I especially appreciated the Kirkland's warbler analysis.

On page 5, you speak of an iterative approach based on real world experience. I would just like to emphasize the importance of gathering that data of the real world experience to see if mitigation is actually working.

I hope that the ESA effort is going hand in hand with an upgrade of FIFRA's 6A2 reporting thresholds. Just to refresh everyone's memory, for herding mammals, registrants do not have to report unless at least 50 mammals are killed. For birds, it's 200 of a flocking species, 50 song birds, or 5 raptors. For fish, we're talking 1,000 of a schooling species. For bees, well, for bees there's no reporting requirements under 6A2. So, I would hope that these efforts that ESA and the FIFRA 6A2 upgrade will go hand in hand. Thank you.

MR. HOUSENGER: Dawn.

DAWN: Thank you for your report. I have one comment and one question. The comment is, I just wondered if the FDA might be at the table where it comes to malathion and stormwater issues, because there are prescription drugs that are used for head lice and scabies that are pretty much everywhere. I mean, your geospacial map, I could draw that for you.

My question is, are you intending to triage your species that are being tested? If so, what criteria will be used?

MS. PEASE: So, let me just address your first concern about FDA being included and your issues with pharmaceuticals. We understand that. There will be a description of baseline status in these determinations, which includes all kind of the other stressors that listed species face that I assume would be part of that description. So, that's good to hear.

Your second question was how to triage species data? I just want to make sure I understand.

DAWN: Are you triaging your species according to any level of importance that you're running these tests, or is everything just being tackled all at once?

MS. PEASE: Well, I mean, we rely on the registrants' submitted data, which uses surrogate species

for different taxonomic groups. Then, we really expanded our dive into the open literature. So, we have really more data needs assessments that we've included in any of our other assessments.

We're really moving beyond selecting the lowest endpoint for a particular taxonomic group to looking at all of the data-building species sensitivity distributions when necessary. So, really casting a much wider net in terms of toxicity information. So, I think we're trying to cover more than we have in the past.

MR. HOUSENGER: Let's take a 10-minute break. Try to get back in 10 minutes so we can make up some of the time here.

(Whereupon, a brief recess was taken.)

MR. HOUSENGER: Our next presentation is going to be on Bulletins Live number two. Melissa Grable and Jen Connolly from our Environmental Effects and FATE, the eco part of our program, is going to give this.

MS. GRABLE: Thanks, Jack. I'm Melissa Grable, and this is Jen Connolly. As Jack said, we're from the Environmental Fate and Effects Division. So, welcome to the training and demonstration of Bulletins Live Two, or BLT, for PPDC.

First, I'll provide some background on the

endangered species protection program, or ESPP. I'll briefly touch on our old system, Bulletins Live, and we'll provide a demonstration of our follow-on system, Bulletins Live Two. I'll finish by providing a flowchart for the process that we use when making bulletins.

So, EPA's Endangered Species Protection Program, or ESPP, helps promote the recovery of listed species. When I say listed species, I'm referring to species that are listed as threatened or endangered. So, it's designed to determine whether pesticide use in a certain geographic area may affect any listed species. If it's determined that pesticide use limitations are necessary to ensure that legal use of a pesticide will not harm listed species or their critical habitat, EPA can either change the terms of the pesticide registration or establish geographically specific pesticide use limitations.

So, when these geographically specific use limitations are necessary, they will be reflected in endangered species protection bulletins, or bulletins. The goal of the Endangered Species Protection Program is to carry out our responsibilities under FIFRA in compliance with the Endangered Species Act without placing unnecessary burden on agriculture and other pesticide users.

So, the final implementation of the Endangered Species Protection Program, or ESPP, was designed so that a generic statement on the label would reference Bulletins Live which would show the use limitations. So, the generic label language reads as follows on the slide, that it's a federal offense to use any pesticide in a manner that results in the death of an endangered species. Using this product may pose a hazard to endangered or threatened species.

When using this product, you must follow the measures contained in the Endangered Species Protection Bulletin for the area -- and this used to say county, but we're changing it because the bulletins are no longer county based -- for the area in which you're applying the product.

To obtain the bulletin no more than six months in advance before using the product, you need to consult this web site or call the phone number provided. You must use the bulletin valid for the month in which you intend to apply the product. By including this generic statement that refers to bulletins on the product label, that makes the pesticide use limitation areas, or PULAs, and the associated principle bulletin part of the label and therefore enforceable.

Pesticide users who fail to follow the label

provisions applicable to their pesticide application, whether that failure results in harm to listed species or not, will be subject to enforcement under the misuse provision of FIFRA.

So, the previous slide mentioned a web site. So, what happens when you go to that web site? This is what you see. So, the users will be directed to the Bulletins Live Two web site, via pesticide labeling, which will direct them to the web site that you see here. There's a few quick start steps in the comments in this box over here. It also provides a more in-depth tutorial that you can click on down at the bottom. This takes a user through the steps that are necessary for them to obtain their bulletin.

So, we've talked a lot about bulletins. What do the bulletins actually provide? They provide the date, and that's the month and the year, for which the bulletin is valid. It has a map showing the geographic area associated with the protection measure. It has the active ingredient and/or product, depending on what you select. It has the use, the application method, the formulation, and it also has the code and corresponding description of the protection measures.

So, I mentioned that we had Bulletins Live previously. Upgrades were made to Bulletins Live Two,

and Bulletins Live Two was launched in mid-December of 2014. So, if you are familiar with our old system, Bulletins Live, there are a few differences between the old system and the new system.

The old system had static county-level maps with limited resolution, which meant that you couldn't zoom in and out, and it was sometimes difficult to determine whether your intended pesticide application area was within a pesticide use limitation area. We've included township section range data and tried whenever possible to provide a zoomed-in inset map.

Our new system, Bulletins Live Two, has an interactive map, much like Google maps, into which the user can zoom. Bulletins Live Two is geo-coded so that the user has the ability to enter in an address to search their intended pesticide application area to determine if there's any pesticide use limitation areas within the intended pesticide application area.

However, because of this change, as I mentioned before, from the old county-level bulletins to our new interactive system, as I mentioned, we're working to revise the standard label language to remove the references to county bulletins.

Our new system also allows the user to select base maps. We'll see that when we get to the

demonstration. That will help the user determine whether the specific pesticide use limitations apply in areas where the pesticide is intended for use.

Our old system allowed the user to search only based on the pesticide active ingredient; whereas, the new system allows the user to search based on the active ingredient, the product, and that's either by product name or registration number. And the new system also allows a search by location, so state, county, and specific address. We'll see that.

The old system included the species of concern. However, our new system omits this information. This is in an effort to protect the species location information, which has been a concern that we've heard from the services. So, the new system also provides a mechanism to receive public comments on the draft pesticide use limitation areas, which was not available in the old system. So, in the future, also we're looking at ways to provide services for use with other GIS base systems.

So, what's the schedule for developing bulletins? The schedule for posting pesticide use limitation areas, or PULAs, will depend on the timing of the decisions that are made relative to registration review, consultations, and other litigation. Our focus will be on registration review, but it may include other

registration actions as well.

So, as the pesticide use limitation areas, or PULAs, are developed, we will communicate and disseminate the draft pesticide use limitation areas to impacted stakeholders, and we'll solicit public comment before finalizing them. Once final, we intend, whenever possible, to allow a time period of approximately six months before they become enforceable, and that's to allow for the planning of pesticide applications.

What happens if you go to Bulletins Live and there's no pesticide use limitation area within your intended application area? If there's no pesticide use limitation area for the user selected intended pesticide application area, the user will see the following statement that instructs them to follow the pesticide product label and check back if they're planning to apply the pesticide in a month other than the one for which the bulletin is valid.

So, the statement on the label reads as follows, currently no pesticide use limitations exist within the printed map view for the month and year you've selected beyond the label instructions. Follow the use instructions on the label. Ensure that your pesticide application area is within the printed map view. If it is not, follow the directions on the instructions tab to

ensure that your pesticide application area is captured within that map view. Check back if you plan to apply your pesticide in an area outside the map view or in a month and year other than the one for which the bulletin is valid.

What is in Bulletins Two Live right now? We currently have pesticide use limitation areas in 10 states. We have pesticide use limitation areas in two states, Wisconsin and Michigan, for the use of methoxyfenozide. We have pesticide use limitation areas in seven states, and that's relative to the use of Rozol and Kaput-D Prairie Dog Bait, and that's for the control of black-tailed prairie dogs. Some of those bulletins restrict use all together. Some limit the timing of application in some of those pesticide use limitation areas that occur on Indian land. We also have pesticide use limitation areas in one state, and that's relative to the use of thiobencarb on rice.

So, we're about to switch to the demo unless there are any questions prior to going into the demo.

UNIDENTIFIED MALE: You mentioned that the system does not reveal what species are in the area of concern. How do we comment on those pesticide use limitation areas if we don't know what the species are? I might have information about a particular species,

whether or not it occurs there, but if I don't know which one -- if it's not identified, do I comment?

MS. GRABLE: We're looking at the enforcement side, but we'll have to look at that also.

Okay, we're going to jump into the demonstration. So, Bulletins Live Two works best in Google Chrome, Mozilla Firefox, Internet Explorer, any version later than version 9, and it also works in Safari. So, you need to make sure that you're using one of those web browsers, and that information is provided in the tutorial.

What we're seeing on the screen now is what the public will see when they go to Bulletins Live Two. What I'm first going to do is orient you to what you're seeing here. The first thing that you see is the zoom tool, the plus and minus. Jen is going to point to it up there. So, you can use the plus button to zoom in and the minus button to zoom out.

There's also the arrows at the top. There's the previous view tool. The left arrow brings you to a previous view, and the right arrow brings you to a later view. Then, if you get too far zoomed in or out or something goes wrong, you can always press the little world button, and that will take you to the map extent.

There's also a base map tool. There's the

orange box sort of in the middle there labeled base maps. That allows you to change the base maps. Here you have roads. There's also imagery. There's also a little magnifying glass that Jen is pointing to right now. That's the location search tool.

You can enter the search criteria here that will get you to your intended pesticide application area. Options include, but are not limited to, an address, city, county, landmark, or zip code. It's best to be as specific as you can. It's best to include the state. So, if you put Paris, Texas, you want to make sure you put Texas in so you don't end up in Paris, France.

There's also the opacity slider. This allows you if you've got that imagery below and you want to see whether or not you're within the pesticide use limitation area, you can make it darker or lighter so you can see the base maps underneath. We also have visible map layers that you can turn on and off. Right now, that's just the pesticide use limitation area.

Right now you'll see that the orange tab, the instructions tab, is highlighted on the right hand side of the screen. That allows you to search for the pesticide use limitation areas or the pink polygons that you see on the left side of the screen.

So, you can select the month in which you

intend to apply the pesticide. It defaults to the current month. You can also see and print out bulletins six months in advance. That's for planning purposes. This is a rolling six months, so as we add a new month onto the end of the list, one drops off the top.

You can also refine your search based on the pesticide active ingredient, pesticide product, or pesticide registration number. Jen is going to show us the active ingredient, the product name, and we'll do a test right now of the product registration number. This is the product registration number for Rozol.

This allows you to refine the number of pesticide use limitation areas. Right now, we're seeing all of them, but as Jen does this, it might take a little while. You have to select the product that you want, which does not seem to be working right now. There it is. Then, when you hit search, you will only get the pesticide use limitation areas relative to Rozol. You see the one for thiobencarb that's in California is no longer showing up.

You can also zoom to the geography where you intend to apply the pesticide. You can double click to zoom in or you can press the shift key to anchor and draw a box, as Jen is demonstrating right now. As we looked at the search bar earlier with the magnifying glass, you

can see that. As Jen shows, if you hover over it, you'll get some further instructions.

As we saw previously, you can also change the base map. There's topography and a variety of other imagery options, roads and streets. We talked about the opacity slider. You're also able to click on the pesticide use limitation area, which Jen is going to show us. When you do that, you'll see it outlines in yellow. That indicates that it's been selected.

So, once you've selected the pesticide use limitation area, the results tab will be selected in orange, as you can see it happening up on the screen. You're able to see the effective date and the pesticide use limitation summary table. So, the summary table includes the AIM products. Actually, because we searched on the product, this is just showing it for the product. It also shows the use, the application method, the formulation, and the code.

Then, the code and limitation table below shows the code and the associated limitation. So, here you can see it's for the product Rozol. It's for use on black-tailed prairie dogs. It's a bait. And it shows that the code is R-6. This tells you what that specific limitation is.

You're also able to click on a principle

bulletin. It will give you a bulletin in a PDF format which you can save and print, which we recommend you do. If there's ever an enforcement question, you can show that you have that information. Do you want to show them what a principle bulletin looks like? Great.

Here at the top it has in orange the valid for and the date, the month and the year. It shows the printed map view that we were just looking at. It shows that it's been selected, so it's outlined in yellow. If you scroll down, it has further instructions. It shows you the product use, the application method, formulation, and the code.

Now we'll go ahead and take a look at what happens if there are no pesticide use limitations within an area. We're going to use the address of the building. You can see Jen has put in the whole address for the building here. What you will see when it comes, there will be a popup that says there's no limitations within the map view. Then it will also give you a little --

I'm not sure why it's not working right now, but what you would see is there's a popup, as I said, and it says there are no limitations within the map view. Then you're also able to print a bulletin from there as well. The language that we had on the previous slide is the language -- oh, here's the no limitations popup box.

It says no limitations within the map view, and then you're able to get a printable bulletin from here as well. That has the language that we saw already.

So, now we're going to go into the back end of the system, so not what the user normally sees. I had mentioned that we had a way in the new system to get comments on draft pesticide use limitation areas, so we're going to demonstrate that as well.

What you didn't see Jen do, because we have it sort of set like a cooking show, but she logs in as a guest. So, what we would do is when we have draft pesticide use limitation areas, we'll have a guest login that's just guests. Then we have a password, and that's specific to the pesticide use limitation areas that are drafts that we want comments on.

So, in this case, we have some draft bulletins that are ready in the system to be reviewed. So, what you would do is you would enter that information, the login information. It would take you to this. Again, you would only see those pesticide use limitation areas. You're not seeing any of the other things that we saw on the front side.

It shows you the active ingredients in the pesticides. Actually, it just shows the products here. It shows the product registration number, the crop use,

application method and formulation, and the code, and then down below it shows you what the code limitation is. Then it has a place for you to provide comments, your name, your organization, your comment.

You can submit those comments to us. Then we can see the comments once they come in. We're actually able to export them into an Excel format so we can keep track of the comments that have come in. So, this is a new functionality. The previous version of Bulletins Live Two we sent out PDF of the draft county level bulletins to stakeholders and asked for comments to be sent back for tracking. So, this is a huge improvement that captures the comments.

Note also that we will have the same enforcement capabilities that we had in the back end as we did for Bulletins Live. There's a date filter that will allow you to go back and see what pesticide use limitation areas were effective on a given date to see if that matches what the user has.

So, Bulletins Live Two is a huge step forward in terms of being able to search by product, both by name and with registration number, as well as active ingredient. Also, the spacial resolution has significantly improved from Bulletins Live.

As I mentioned, we're going to go back to

the slides and talk through the process that we use when making bulletins. So, this side outlines the process for developing bulletins and where we'll require some input from the risk management divisions, both within EPA and also from the registrants and external stakeholders.

First we'll overlay the species range shape file with the pesticide use location shape file. It's the overlap of these two shape files that results in the pesticide use limitation areas, or the PULAs, that we were talking about.

We will then determine what use limitation is necessary to protect the species within that pesticide use limitation area. Once we've developed that pesticide use limitation area, we'll share a PDF of the map and the pesticide use limitation area, as well as the use limitation, with the registrant, and ask them to submit a revised label with a reference to bulletins.

We then enter the metadata, including the active ingredient in the product and the EPA registration number into Bulletins Live Two. This step will coordinate internally with the risk management divisions, as well as with the registrant, to ensure that the product names, the product registration numbers, formulations, and application methods are correct. We'll then send the draft bulletin to the registrants and

stakeholders for a 30-day review. That will be using Bulletins Live Two, that process that we just demonstrated.

We'll then ensure that the registrant has submitted and the Registration Division has approved and stamped the label with the reference to bulletins. We'll then finalize the bulletin allowing that six-month time period before the bulletin becomes enforceable. That's for planning purposes.

So, that's it. I'll take any questions.

MR. HOUSENGER: Valentin.

VALENTIN: Just one comment here. When you go to the home page, it seems a bit crowded at this moment. I'm just thinking about the applicators that have low schooling. I think it would be easier if you have a popup screen that kind of shows the bulletin month, shows the EPA pesticide registration number, so people can just enter that information immediately and then get the results. The way it is set up at this moment, I think it's a bit overcrowded. Just one suggestion.

MR. HOUSENGER: Dawn, or Sharon, sorry.

SHARON: Hello. Currently, there are nine active ingredients for which there are mandatory no spray buffers in Oregon, Washington, and California along salmon-bearing waters. I'm just wondering if you can

explain why EPA is maintaining two separate systems to inform people about these, and why those were not integrated into the Bulletins Live. By the way, I like the ability to zoom in and get cite specific information. That's great.

MS. GRABLE: That's great to hear. There are two different systems. You're talking about the salmon mapper, which is a different system. Those are court ordered restrictions; whereas, these are enforceable as part of the label. They're a little bit different, and that's why they're in two different systems.

MR. HOUSENGER: Dave.

DAVE: First, I'd like to say it looks like a really useful tool. I understand there's probably going to be some glitches here and there, but I think it's pretty impressive and looks pretty useful.

Just a minor thing, I think, when you showed how the opacity slider worked, when you put it all the way over to completely transparent, it just disappeared. It seems like it would be very helpful to the user to not let it completely disappear, because -- and I don't know exactly how it works, but if they have that slider all the way over and they look at it, they'll say, oh, yes, I don't see anything.

Also, I was wondering, and maybe I missed it,

can you save those views as PDFs or you just have to print them out?

MS. GRABLE: You can save them.

DAVE: Oh, okay. So, that's really good. That's another reason not to allow that slider to go over, because if you're going to present it to some regulator and say, hey, look, there's nothing here. That could be misleading. Thank you.

MR. HOUSENGER: Mark.

MARK: I, too, think it's a real progress in the right direction. I particularly appreciate the mapping process. There's a couple things that came to me in the process that I'd just like to touch on. That is, when you think about proximity, drift, and other transport mechanisms, and you're going to subscribe or develop a map system, how do you come to that, the edge of that map? How do you decide where and when in that kind of process?

MS. GRABLE: So, you're saying, how would we decide that for the maps that we're showing now?

MARK: That's right. What I'm trying to get at is, is there a buffer zone, is there a range indicator, is there going to be a system of determining that?

MS. GRABLE: So, I'd say for right now, none of

these have that. That's something we could look at in the future for sure.

MARK: Okay. Another follow up is on the comments. Who is going to read those comments? What are you going to do with them? You're going to read them? You don't have enough time.

MS. GRABLE: We'll take a look at them. As I said, these are draft bulletins that will be in there. We'll look at the comments and see if there's something we can do to address those comments.

MARK: Coming back to the maps, then, will you be thinking about or publishing or arriving at scientifically some sort of mechanism of establishing what kind of range around a known area to control?

MS. GRABLE: As I mentioned before, the pesticide use limitation area is where the species is overlaid with pesticide use. So, that is really what generates that area. But we can look, if we wanted, to include a buffer in that. I think that would be part of our discussion with Fish and Wildlife Service.

MARK: As I remember, this is a couple years ago when we had a big meeting, that was a big issue that Fish and Wildlife Service wanted. I'm wondering, maybe you guys ought to come together and have an agreement or something, depending on what the species is and its

mobility, something along those lines.

MS. GRABLE: We can look at that.

MR. HOUSENGER: Virginia.

VIRGINIA: I'm wondering if, in the event that there is a bulletin that would cover Puerto Rico, are bulletins going to be in Spanish? Are there plans to make it bilingual?

MS. GRABLE: That's something we can look at.

MR. HOUSENGER: Nichelle.

NICHELLE: I really like this whole mock view of this whole process. Currently, there are tons of information already on labels. So, how permanent will this statement that you guys have, how permanent will that be on the label? Is there or could there be some type of symbolic pictorial attention-grabbing symbol that can be placed on the label so that applicators can know that this is something they need to pay attention to?

MS. GRABLE: Right now it's on the label in endangered species language section of the label. It's on there right now for the ones I mentioned, Rozol and Kaput. I think we could look at that, but what we've tried to do is to keep the labels as streamlined as possible, even knowing that there is a lot of information on the label. That's why we've got that link that takes

you here to see the spacial information.

MR. HOUSENGER: Ray.

RAY: These technologies are very impressive, and I think it's a big step in the right direction. Could there be a way for a label to have a link or multiple links to this web site, which fills in some of the information that's already known for the pesticide and the particular use, perhaps with a QR code?

MS. GRABLE: We've actually talked about that. I think that's something that would probably be in the future. But that is something that we talked about.

MR. HOUSENGER: And Wayne.

WAYNE: Just a quick, more or less, interpretive or esoteric question. What is considered labeling from the standpoint of training our pesticide applicators? The website is by reference from the label, but would a printable document be considered labeling as such?

MS. GRABLE: It is, yes, because the reference to bulletins on the label, that also makes the document a printable bulletin, also part of the label.

WAYNE: Thank you.

MR. HOUSENGER: Cheryl.

CHERYL: Just a little bit of follow up to Ray's question. It just struck me. CBMS is a very

popular place to grab labels. Are you talking with them about how to coordinate back to links to this site?

MS. GRABLE: We haven't yet, but that's something we could do.

MR. HOUSENGER: Okay, thanks very much. You'd think with that technology, our technology in the program would be a little better, but that's not how it works.

The next presentation is the public health workgroup meeting that was held yesterday. Susan Lewis, the director of the Registration Division, and Susan Jennings, our public health coordinator, will give this briefing.

MS. LEWIS: Good morning. I'm Susan Lewis. Susan Jennings, who is our senior public health liaison for the pesticide program, is going to walk us through sort of the discussions we had yesterday at the sub-workgroup of the PPDC. I wanted to thank everyone who participated, because the input that we hear is extremely valuable. There were multiple different sort of viewpoints on things. So, I found it extremely helpful.

So, with that, Susan.

MS. JENNINGS: Thank you. We'll try to keep everybody on time here. I don't think we're going to use the full time, if people are worried about that. Just kind of sit tight.

I want to go through a little bit about the history of this group and what this group is, because it's a little bit different than some of the other groups. I know that there are some new members on the PPDC since we last did this with the group. So, we're just going to very briefly tough upon some of that.

Basically, it's been around for about five years. It was created to address issues of pesticides that control pests. The reason for this and the reason for the special workgroup is that a lot of the people that sit on the PPDC when we've brought things in the past are not really familiar with some of the details of mosquito control or bed bug control, or depending on what organization is being represented.

It was hard because we had to do a lot of educating and then a lot of getting back input. This allows us to kind of pull it into a group of people that really do know and work with this or other people who are at least interested in it, and then bring it back to the full PPDC to work out.

So, unlike a lot of the other workgroups, this is kind of a standing workgroup that goes on. It's not a real formal rigid this is our goal and now we're done type of workshop, or workgroup. As I said, this is ongoing.

The issues that we address were all over the map. We do regulatory issues, policy, programmatic, environmental, technical, economic, science policy issues. We discuss, we take input, we bring it back to the place within the organization that will address this or has the ability to address it, and then we move forward from there.

There are three really critical roles for the workgroup. One is it's an opportunity for us, as I said before, to get the FACA input on an area that's of limited interest to a lot of organizations. It is a portal for stakeholders to bring issues to us of concern, because just like when we talk to the whole pesticide user community, we're talking to a broad spectrum of people who are interested in different pest and use sites.

Sometimes when people come in to EPA, they don't know quite where to go with their information. They have a problem. They have an issue. They may not know exactly where to come in. So, this allows us to actually have a public forum where we do take in input and suggestions.

Then, lastly, it's just a forum to discuss items of common interest about public health and their control. So, we get the user community, the public

health community, the registrants all in the same place. Then we can have a real rounded discussion about the issues and kind of get down to the root of the problem and move on from there.

So, those are the three things that we do. In each workgroup, we kind of try to segregate the workgroup so that we have opportunities for each. We also have a lot of different stakeholders, different areas, broad input in collaboration with the public.

That was the background part. Now I want to talk a little bit about what we covered at yesterday's meeting. There were probably five sections. Some were bigger than others. We talked about the update to innovations impact project, which is being hosted by the Gates Foundation, the Bill and Melinda Gates Foundation. Ray McAllister came and did a real good presentation to the group. That was mostly just a report out on this is what's going on and people might be interested.

EPA is developing a communications piece, and I'll talk in a little bit more detail later, to help pesticide applicators explain risk to the residential sites and other areas where people might not know exactly what's being applied and what the risks might be.

We talked about updates to the website. Then we had two sections. One was an EPA update, which was

kind of just a quick thing we went through, a few issues. The other was member updates where people could bring things and just bring in what they're working on.

The innovation impact is basically very broad. There's a group -- I did use acronyms without defining them. I thought that might be easier for everybody. We have WHO, the Global Fund, the Presence of Malaria Initiative, NIH, EPA, CropLife, Industry, and the Innovative Vector Control Consortium.

Really, the bottom line purpose of this is to try to make a place where public health pesticides can be registered for over -- a lot of it is concentrated on oversees use, but it's a multi-pronged approach to focus on industry and registrants to try to figure out what needs to be done on a global level to reduce the impact, the disincentives for people to bring these things to market.

It also is trying to work with the people who purchase the products so that it might not necessarily be just cost-based procurement, but they might also look at things such as resistence or such as using a varying toolbox of what's available, and the broader decision-making apparatus for the purchasing and the procurement when they are trying to control disease in endemic areas.

The other aspect of this is they're looking to

EPA to try to support and to try to give examples of it and to try to work with them as the regulatory authority. There are a lot of places that will apply a product if it is registered in the United States, for example. So this gives a forum for them to try that.

We're trying to work with WHO and get the entire market working together to hopefully reduce the disease impact all over the world. We all know that when disease occurs oversees, it can come here as well. We're not this little island anymore. With global travel expanding, it makes it more serious. That was the one thing that was kind of an update piece.

Then we had a piece where we looked for input from people on -- we're working on this communications piece that is primarily for professional applicators who are going out and treating places. They can be resorts, hotels, people's homes, schools, anywhere where they're applying a pesticide. Someone comes up to them and says, what are you applying and what are the risks to me. Or, they go out online and they look online and they find all kinds of scary information about the active ingredient that is being applied, when, in reality, by the time it comes out in a ULV or in a diluted form, the risks might be extremely low.

But when they look at that label and they look

at the label prior to dilution, or in the pure form of the product, it might say do not inhale, wear a respirator, all these things. It's a difficult risk communication process for the person interacting with the public. It isn't always as effective as it could be.

So, what we've agreed to do is to create a fact sheet or a companion piece for people so that when people are looking for information on a particular pesticide, this will be a document that will say you need to be careful what you look at, because that might not be an accurate portrayal of, let's just call it, post-application risk.

So, your post application risk could be significantly exponentially lower than some of the things that are written on that label, and here's why, and talk a little bit about that to try to provide a bridge for the labeling and for the risk that people are actually experiencing, because sometimes it really is varied and very different.

We had developed a draft piece that we wanted to present to people. It really was a great discussion. It was a very good discussion yesterday about this. We took away a lot of good information. We don't interact that way with these people. The best people to give this are the people who are doing the interaction and the

people who work more with the public.

The other thing to point out is this is not going to be product specific. This is one communication piece for all the products. There have been suggestions here that the workgroup made yesterday which was to highlight the difference in messages between ULV and diluted products, because it is slightly different. Additionally, someone brought in that we should talk more about the MSDS sheets and how -- I guess they're SDS sheets now -- how that might play into the perception of risk.

An additional consideration and -- hard on the hazard statements because those are the things that really can get people going when it says do not inhale and yet you're just spraying it everywhere.

Another thing that was pointed out is that everyone appreciated that this would be an EPA authored document so that the applicator is not sitting there saying, oh, yes, actually, it's not going to harm you at all. The person is looking at something that says it will. They can actually take a look at this document and it will be an EPA authorization.

We talked a bit about the web updates. I think some of you are aware we've done a lot of work on the bed bug page. We've done some work on some of the different

sites. We talked more about where we might want to go with the public health page in particular. How do people use it? Where do people use it? Try to get some information.

We're looking at our tick page as well because of the increase in tick activity, where we want to go with that. CDC has a very extensive tick page, so we have no intention of trying to reinvent the wheel, but we might want to vamp up the pesticide portion of it a little bit more than we have at the current time.

So, we talked. That was just a general conversation. We showed what we were thinking of. They gave us some information back. Then we had a section of the group that was called, just quick updates. EPA, we provided updates on where we're going with the efficacy guidelines, which is kind of a standing issue. We talked a little bit about the repellent graphic mark, how that's going. We talked about bed bug updates, the fact that we have issued -- the federal bed bug workgroup, not EPA, the federal bed bug workgroup issued the federal strategy on bed bugs fairly recently, finally. So, that was out.

We have a bed bug clearinghouse section, communications clearinghouse section on our web. We want to continue. That is supposed to be a living, and is a living, area of our site where when people develop really

good communications pieces we can put it on there, and they can share it nationwide or wherever anyone else might want to see it. They can look at it. They can borrow from it. It will just help the communities and the people trying to combat bed bugs to use it a little bit more efficiently and effectively, their own communications resources.

So, we have that section as well. That is something that we like to bring up because sometimes people develop something and say, oh, isn't this beautiful, we did a great job, but they won't necessarily think about that arm of it. So, we find it good to remind people of that on a fairly regular basis.

In the workgroup, there was a companion piece of the meeting where we had a workgroup update. MPMA, Jim Fredericks from MPMA said that they were revamping their best management practices for bed bugs, and that the survey results would be available shortly. So, that's the kind of thing that people are sharing in those sections.

One of the things we also had yesterday was -- this was part of the update section -- was a CDC update on tick-borne diseases. There's a lot of movement on tick and tick-borne diseases. They're increasing. Things that 15 years ago weren't even a concern are now.

So, Dr. Ben Beard (phonetic) from CDC presented this section, and he did a really nice job of just talking to the different areas. He talked a little bit about the federal coordination on the tick and the tick issues.

So, for the next step, this is a list of the ongoing items that we (inaudible) on a fairly regular basis. We try not to make any workgroup meeting focus on a particular aspect of it so that we keep everybody involved. Not everybody is interested in mosquito control. Nobody likes mosquitoes, but we're not all interested in control. Some people aren't interested in indoor control. So, we try to keep it mixed and balanced.

IPM in housing and urban communities, really public health and IPM go hand in hand. You don't really do public health control without using an IPM practice. Efficacy performance standards, bed bugs, IPM, tick-borne diseases, rodents, cockroach, allergies, asthma, these are all issues that the workgroup has identified as potential areas of interest.

Again, it's a really good workgroup for us. It provides us with a lot of good input, and it gives us a way to communicate with people who are interested. We really would welcome if there is anyone else on this group, on the PPDC members at the moment, that would like

-- you do not need to be a member of the PPDC to participate. Robyn Gilden is on it. We do need to have one member, so she does a nice job of being our member. Thank you. But we really would welcome anybody else that might be interested If you want to just shoot me an e-mail or give me a call, I can give you more information on it. Thank you very much.

If anybody has anything they'd like to say, we're three minutes past lunch, which isn't bad.

MR. HOUSENGER: Thanks, Susan.

Matt.

MATT: The work that you're doing is very important. I find an incongruousness about the term public health workgroup and what you presented today. What you presented today I would term more something like vector control agents and its impact on human health. That's more or less what I see you doing. To call it a public health workgroup seems to me to not include things like human health surveillance of pesticide impact or work related exposures to pesticides, which are all under the purview of public health.

I'm leaving the PPDC so won't be here to comment anymore. It's nice to hear that I could potentially participate despite not being a member of the PPDC in the future. I'd encourage you to open your

agenda more broadly so that you do live up to the term public health, because, of course, that includes so many other dimensions that are discussed routinely in many other workgroups in this organization, in the PPDC.

So, right now I see your agenda as being somewhat restricted. If you're to maintain the title public health, I think your obligations extend far beyond the human health impacts of vector control chemicals.

MS. JENNINGS: I don't disagree with you. However, I would say that everything we do at the Office of Pesticide Programs has an impact on public health. That is not everything, but that is one of our very, very main core tenants of what we do. That pesticide impact and how pesticides are effective and everything, that is all part of the risk management, and the risk assessment process, and registration, and registration review processes.

This area is an area that actually started out of FQPA, because what was happening, it goes hand in hand with the minor use. When registrants were coming in and when chemicals were coming in for re-registration, people were saying, oh, don't need that, don't need that, and they were cutting all the public health uses and -- there is a definition for public health pesticide in FIFRA. That's kind of what this public health program keys off

of.

A public health pesticide is something that is used to control pests that vector or transmit diseases. But the caveat in FIFRA -- we try not to use that term because the caveat in FIFRA is to be a public health pesticide, it needs to be used by people who are using tax dollars, federal tax dollars or local tax dollars to do it. So, it has to be kind of a public program.

So, we have broadened that to be really any user group, because mosquito control can be done on a local basis, can be done privately and can be done publically. So, I agree with you that that is a common interpretation of it, but that is how we use it in EPA.

MATT: That presents even a greater challenge to me. You've redefined public health, the purpose of this workgroup, in terms of the way we discuss public health outside of EPA. It becomes even more difficult for me to understand from outside, and anyone else from outside, to look at the term public health workgroup and know that that's principally about public health pesticides, as defined by FIFRA.

I don't know what to do about that terminology. I'm just mentioning to you that it feels funny to me to call this group a public health workgroup with its very limited scope.

MS. JENNINGS: Okay. Well, we'll consider that take into consideration. Thank you very much.

MR. HOUSENGER: Mark.

MARK: Thank you. I think that there's good progress being made. Again, I do have to agree that it's very narrow in scope, but this is about pesticides. So, if I was to criticize things being pesticide centric, that would be a problem. So, I do understand that. At the same time, integrated pest management is not particularly pesticide centric. So, I have one question and a comment.

The question is, after seven years of the CDC doing IPM workshops for vector pest management, where is EPA on collaborating with them on doing that for public health departments, environmental health specialists throughout the country? That's the question.

Then, the comment that I have is, as far as things to look at with regard to global warming and because of that the increased use of pesticides for public health, we need to look at resistence. That's something that I think we should be proactive in looking at. It's going to happen.

Then, finally, and perhaps that group can look at it now that it's been in effect for about three years, the rules both at the state level and with the feds on

NPDES with regard to the use of pesticides on and around the waters of the United States. So, that's my question and comment.

MS. JENNINGS: Okay, thanks. I'll go to the first one first, which was your question about CDC and the IPM work that they're doing. We've always supported that workgroup, and we've always provided technical expertise whenever they've requested it and whenever it was needed. However, there have been times when finances have just not allowed us to actually contribute towards the production of those programs. But we do think they're very valuable and very worthwhile.

My understanding right now is that CDC is moving that program into a recorded webinar-type format. We have offered and will be giving them support for that type of effort on that.

Your third question was NPDES, but the second question was about the resistence management. Resistence, that is something that we do keep very, very -- we participate in that as much as we possibly can. But registrants do bring in the pesticide tools to us to register. We don't create them ourselves.

So, when we talk about resistence management -- and that is actually one of the main purposes of this Gates Foundation eye-to-eye initiative, is to try to

bring in alternatives. So, we're never going to conquer resistence. It is always a problem. IPM is always the best way to try to work with that. But that's kind of where we are.

I'm going to let Susan Lewis answer your question about NPDES.

MS. LEWIS: Regarding the water permitting process, we worked extremely closely with Office of Water in developing the first five-year round of permit. We had many of the public health mosquito control and states involved. They helped develop some of the best management practices. We were worried about resistence management. We have extensive stakeholder input. We continue to work with Office of Water. So, that is something that we have coordinated closely on.

MR. HOUSENGER: Dave.

DAVE: Until recently, I was on the board of Sacramento's mosquito and vector control district. One of the problems that arose that our staff discovered through some research was structural pest control products being pretty much present in the water all the time. I'm speaking specifically about pyrethroids. We developed evidence that that was causing resistence in the mosquito populations. It made it so that the pyrethrins that we were relying on were no longer useful

or significantly less useful for mosquito control.

I would suggest that your workgroup look into that particular issue of the interaction between widely used insecticides with other related chemicals where you might have cross resistence. I think it's a significant issue that could occur over and over again in significantly reducing the efficacy of really important uses. I think that that should be part of the registration process in considering the potential for those products to induce resistence to public health insecticides.

The other thing that I wanted to point out is that similarly with the widespread use of the pyrethroids, it also made it so that because of the persistence of both the pyrethroids and the adjuvants in the water bodies, that that made it so that the applications that were made by the mosquito and vector control district were problematic in waters where just by themselves they may not have been or probably would not have been problematic. So, I think that's another issue to look at. I'd hate to see further limitations on public health insecticides due to what I consider less necessary uses.

I can offer to at least suggest to the Sac Yolo that they participate in these discussions in

your workgroup. Thank you.

MR. HOUSENGER: Robyn.

ROBYN: Thank you. To Matt, I was under the same misconception as well when I first joined the group, that it was going to be focused on public health. But you're more than welcome to join us and broaden our scope.

I'd also like to just say that during our discussion of the companion piece of further explaining the labels, the comment had also come up about adding a contact person, somebody that they could actually reach out and touch and have a conversation with. Anybody who has ever done risk communication knows that if you're leaving it up to written words, there's going to be some misinterpretation.

MR. HOUSENGER: Tom.

TOM: Generic just to the public health products or to any product?

MS. JENNINGS: I imagine if we do it right, it would be any product. I mean, it's mostly designed for what is used in and around places, but there's no reason it couldn't be applied to all.

DR. JACKAI: You have your hands full. That's a really wide scope that that workgroup is tackling. But at the end of the day, you're really

dealing with the issues that we're all concerned about, human health. Pesticide is a major concern in that regard.

You started off your comments by making reference to pesticides in the international arena. I think it kind of lost track of how that kind of interfaces with what you spoke most of the time about doing. Specifically, the fact sheets that you're talking about, are those going to be focused on just the U.S. or are they also going to have to do with international pesticide use?

You almost have to be really careful about that because once you start to tell the users that the pesticides are not exactly as dangerous as the label say, that's going to be taking on a different (inaudible) by some folks, particularly in the international scene. So, we need to be very careful. There's a very easy tendency for folks to misuse pesticides. If you give them a little window, they'll expand it.

MS. JENNINGS: We're very, very much aware of that. That's one of the reasons -- it's just for the U.S. It's not for international. It will be posted on the web, so people will have access. It's in the very, very beginning stages now. We want to just start right from the beginning making sure we've got -- we're not

going to put anything out there if we don't think it's going to work right. You can join our workgroup, too.

MR. HOUSENGER: Dawn.

DAWN: Thank you. It's an awesomely important team you have. I should probably volunteer to join the ranks as well.

Susan and Susan, thank you for your report. I would like to ask that the group put some effort into encouraging strategies for resistence management, specifically for bed bug products. We're seeing some -- I'm sure across the country, but certainly in the west -- some really significant issues emerging.

Secondarily, I was a little concerned, and maybe I got this wrong, but your documents to allay risks or allay fears associated with the use of ULV and diluted products. I seem to spend a lot of my time -- and I do answer those questions, too, where people are just panicking because there's been a vector-related mosquito treatment and fogging in their neighborhood.

But I deal with many, many, many more instances where people are literally abusing/overusing, poisoning themselves and their children. I'm just really concerned that a document that is designed to allay fears associated with these products will just exacerbate this problem.

MS. JENNINGS: I understand from what I've said how that would be the interpretation. But it's really designed to accurately communicate the risk, because reading the label is not an accurate portrayal of the risk to the bystander. So, that's really what it is, is to try to make sure that things are portrayed -- right now they have nothing. So, what we're trying to do is provide something.

We are completely on board with everything that you two have both said about that. That is not the intention. We want to make sure that that's not the effect when we're done. Thank you, though. And we would love to have you.

MR. HOUSENGER: Doug.

DOUG: As you have talked about resistence and what she just said, there has to be benefit risk ratios in there. That's what you need to display also. Thank you.

MATT: Just a quick comment. It just struck me, and it's probably struck others before this, but based on Dave's comment of the resistence patterns that are seen as a result of agricultural use or structural use of pesticides, the pesticides we use in public health is an analogous situation to the antibiotics used to control animal growth or enhance

animal growth and the loss and resistence we see in the infectious arenas. I just wanted to mention it because it struck me so hard when I heard what Dave was saying.

MS. JENNINGS: It's almost exactly the same. It's really kind of uncanny.

MR. HOUSENGER: Resistence has been a big issue for us lately, mostly on the weed side. But I think it's something that we need to consider for insecticides and fungicides as well. We are doing something to put numbers on the labels so you know you can rotate with certain chemistries and stave off resistence.

So, Susan lied. She went over. So, lunch has been cut. Let's come back at 1:10 because it's hard to get to lunch with this configuration out here.

(Whereupon, a luncheon recess was taken.)

AFTERNOON SESSION

MR. HOUSENGER: Our next session is about bees. There's a lot about bees in the news. This one is about state/tribal pollinator protection plans. Marietta is going to lead us through this discussion.

MS. ECHEVERRIA: Thank you. My name is Marietta Echeverria. I'm a branch chief in the Registration Division. Together with Mike Goodis of the Pesticide Re-evaluation Division, we've been leading OPP's efforts to engage with states and tribes on the development of pollinator protection plans. So, I'll go through a set of slides just to bring people up to speed on some of the activities that we've been doing. But then we want to have some open discussion.

Just by way of background, we know over the last 10 years, there's been several federal reports and scientific reports documenting pollinator declines and discussing the possible causes of pollinator declines. We're down to about 2.7 million managed beehives in the U.S. right now, and that's compared to about 6 million beehives that we had in the 1940s.

Back in 2013, the EPA and USDA released a comprehensive scientific synthesis of what we know about causes of pollinator declines. The consensus is that there is not one single factor that is leading to

pollinator declines; there's actually a complex interaction of several stressors, including pests, pathogens, disease, pesticide exposure, as well as poor nutrition because of the loss of bee forage habitats, as well as bee management practices and a lack of genetic diversity.

So, back in June of last year, a lot of you guys will recall, President Obama issued an executive memorandum to the Executive Branch of the government calling for a coordinated strategy for addressing pollinator decline and honeybee health. So, specifically, that memorandum called for commitments from each federal agency with respect to specific activities for pollinators and honeybee health.

It also called for a pollinator research action plan, a public education plan. And throughout the memorandum discussions on opportunities for public/private partnerships because there's a recognition that the federal government is not going to be able to solve this issue on its own.

Specifically for EPA, some of the things that EPA was tasked with, specifically assessing the effects of pesticides on pollinator health. So, that's an activity that we are currently rolling into our registration and our re-evaluation programs by adopting

the new risk assessment framework for pollinators, and then, specifically, to engage states and tribes in the development of pollinator protection plans, which is what I'm going to talk about today.

So, managed pollinator protection plans, this idea was really a state-led idea. Several states over the last couple of years have been working through this issue at the local level. So, prior to the issuance of the presidential memorandum, certain states had been convening local stakeholders, including growers, applicators, and beekeepers in coming to some agreement on how better to communicate and collaborate prior to pesticide applications.

What emerged for us at OPP was what we saw as an effective model. When we say a model, we're not saying that one of these plans is a one size fits all example that should be replicated, but it was really the model of the local stakeholder engagement in that collaboration that emerged that we found to be particularly a potential approach to help mitigate acute risk to pesticides.

So, we believe that these plans serve as an effective communication and collaboration between the stakeholders at the local level. By establishing these plans, we can best balance the needs of growers and

producers and the needs of beekeepers.

Over the last nine months or so, we've been strongly engaging our co-regulators, our state and travel partners. Back in August, the Office of Pesticide Programs sent a letter to the AAPCO president, the SFIREG chair, and the TPPC chair expressing our interest to partner on this issue. Specifically, in that letter, we asked for partnership in identifying the key elements that make a successful pollinator protection plan, and then also to partner with encouraging the adoption and implementation of these plans.

Also, over the last nine months or so, there's been several meetings through SFIREG on this issue. In response to this collaboration, SFIREG has actually drafted guidance that states or tribes could use if they're interested in developing a pollinator protection plan.

We've had similar discussions with the TPPC, the Tribal Pesticide Program Council, and there a lot of the discussion has focused on engaging tribes, identifying specific issues that tribes may face, and, where appropriate, seeing if tribes can collaborate with their state partners to become part of that stakeholder process, if it's appropriate. Of course, we have to respect tribal sovereignty throughout that conversation.

Then, the big topic of conversation right now has to do around measuring the effectiveness of these plans. We recognize if EPA is going to rely on these plans as part of our strategy to reduce exposure to bees, we're going to have to have some measures in place so that we can show that they're actually meeting their goals. So, there's been a couple of meetings focused on this conversation, and it really is still an emerging topic that requires additional conversations.

In terms of the SFIREG draft guidance -- and I want to point out that EPA inputted to that guidance, so we were able to provide comments on that -- the states have identified seven critical elements that we believe are the foundation of what needs to go into a pollinator protection plan.

The first critical element is that a stakeholder participation process has to occur. So, it really is about getting the appropriate stakeholders at the local level together to convene stakeholder meetings, to have the discussions, so that agreements on the additional elements can occur. That is probably the number one important element that really needs to be there in order for this to work.

So, once the stakeholders convene, the second critical element is a method for identifying where

managed bees are located within an area. So, the whole purpose is to increase collaboration and communication between the growers, applicators, and beekeepers. So, there's got to be a method to know, an approach to know where the bees are actually located.

Once you know where beehives are located within an area, there has to be an established framework for communication, whether that's a registry system or you exchange business cards. The method is not important, but just the fact that there is a communication mechanism identified within the plans that all parties agree to.

They also need to include actual measures, whether they're best management practices or they could also be regulatory measures, to minimize acute risk to bees. So, utilizing information that we have on BMPs to make sure that applications are occurring when bees are less likely to be foraging, or other options in BMPs.

Once a plan is established, there needs to be a clear defined plan for public outreach. It serves no purpose if a plan is developed and it sits on a shelf somewhere and folks are not actually adopting it. So, it's critical that there is a role-out plan and there is adoption by the stakeholders in the area.

Then, it's also important to view these as living documents. There needs to be a process to

identify issues, modify plans periodically over time. Then, finally, it goes back to the state of the conversation now. There needs to be a mechanism to measure that the plan is actually effective over time. That's really crucial, like I said, to us because we're considering relying on these as part of our overall strategy for reducing acute risk to bees.

So, moving into our proposal, we've been working on an acute risk mitigation proposal over the last several months. In that proposal, we are considering various scenarios based on the likelihood that bees are actually going to be exposed.

So, in one scenario, we're calling it the contracted services scenario. So, you are purposefully bringing in managed bees on your site for the purpose of pollination services. So, in that scenario, there's large numbers of hives that are actually being brought onto the property. The certainty of exposure is very high. Because of that, what we're considering in our proposal is label restrictions to address that scenario. So, you actually eliminate co-occurrence of the pollinators and the pesticide application.

There's another scenario, though. You may not actually have bees on site for the purpose of pollination services, but perhaps they're within the foraging

vicinity. So, you have another crop that's flowering. You don't have bees on site, but perhaps they're on an adjacent property, or somewhere within the area. That is really the scenario that these pollinator protection plans get at. That's where you have an opportunity to actually identify where bees are located and to have that communication prior to pesticide application. As I mentioned, the SFIREG guidance helps to further elucidate what the elements are in those plans.

So, we're really pleased with the response that we've gotten from our state partners. There's been a lot of activities on their part. In response to the letter that we wrote back in August, AAPCO convened a pollinator committee to look at the state of plans that were currently out there and then to also identify any barriers or challenges, and to survey states. They finalized a report that's available on their web site.

What they identified was five states had already developed and implemented plans. Of course, those were the models that occurred prior to the SFIREG guidance. So, they didn't include things like measures like we're talking about now. But that was the state then.

Also, since we've started this effort, an additional 30 states, approximately 30 states, have plans

in some stage of development. So, they have either established workgroups or committees to look at this issue. They're starting to identify stakeholders and starting to convene these stakeholder meetings. So, we think this is a big success in terms of the amount of adoption and energy that's around this issue.

Again, as I mentioned earlier, the current conversation is really around measuring the effectiveness of plans. There are some themes that are starting to emerge in terms of measures. One has to do with communication. So, if the cornerstone of these plans is to enhance communication between the parties, can we measure that in some way. Are there surveys that we can use or other mechanisms to measure enhanced communication?

Additionally, another theme would be behavior. Are there changes in actual pesticide applications that are being made in response to these plans? Are decisions to use less toxic products being made in response to these plans? Are applications being made at different times of day when bees are less likely to be foraging? Are there ways for us to measure those changes in behavior?

Another theme has to do with actual exposure and risk. Again, we're looking at this from OPP's

perspective as a way to mitigate acute risk. So, are there actual measures of exposure, so residue data as an example? Then, this also centers around bee kill information. Obviously, there's a lot of concern with bee kill information due to underreporting and some of the other challenges around there. So, it is a theme that is being considered.

Finally, overall pollinator health indicators or measures, so honey production, numbers of colonies, reductions in overwintering losses, overall pollinator health as a measure.

So, those are the themes that are being discussed. SFIREG is actually working on a companion piece to their guidance document that would discuss in more detail options on measures. We look forward to having a discussion at the June SFIREG meeting on that topic.

So, in terms of our next steps, we are going to take comments on this proposal. It will go out for a comment period. We expect a robust comment period, as we always get. We're strongly encouraging our state and tribal partners, like I said, to start this process this year. Many of them are doing so. EPA will monitor the success of these plans. We're going to monitor the implementation.

We're going to continue on this discussion with measures to see if this is a successful overall strategy. If we see that it's working, we'll continue down this path. If we have evidence that it's not working, we may need to consider additional measures.

I also want to be specific that this strategy has to do with acute risk in particular. We're getting data now on other routes of exposure. We're going to continue to evaluate those in the registration and the re-evaluation program. If additional mitigation measures are warranted, we will implement them as part of our regular process.

So, with that, I think we can open it up for some questions and discussion.

MR. HOUSENGER: Dawn.

DAWN: Hi. Thank you for your report. I have one comment and a question. My comment is with regard to measuring connectivity and collaboration. There are formalized tools available on the web that you can do that. Being involved in a lot of the grant programs and on the NESA side of things as opposed to EPA, they are going to start requiring some of those maps to be included in some of our grant proposals. Having got my head around this now, they are pictorial representations of how people connect. I would encourage you to

investigate those because it might be ideal for what you're after here.

My question is, will the pollinator protection plans include anything other than managed honeybees? I mean, bats, native pollinators, birds, anything else? Thank you.

MS. ECHEVERRIA: So, thank you for that comment. I'd like to follow up with you to get more information on exactly where that's located.

In terms of the scope of the pollinator protection plan, the initial scope was to focus on managed bees, particularly because it's a communication component that we're really looking at here. However, states have flexibility, in including other pollinators, including other issues of pollinator health, like foraging habitat, et cetera. So, there is flexibility in what a state can choose to do. But the focus has primarily been managed honeybees.

MR. HOUSENGER: Nichelle.

NICHELLE: Thanks for your presentation. First I want to follow up on Dawn's point about needing more focus on wild bees and the impact of bees, pesticides on wild bees. That may be a little difficult because they are wild. We don't really have much data on them. But we really do need to make more of an effort to include

them in pollinator plans.

My actual comment is so this focuses a lot on acute risk mitigation. There's no mention of long-term chronic risks to bees, especially since a lot of the pesticides that are highly toxic to bees are systemic. As you guys know, because of the systemic nature, they are very persistent in plant tissues and in soil and water. So, I really do urge the agency to start incorporating the systemic nature of these pesticides into their mitigation plans for these state protection plans.

Then, finally, do you have some sort of sense or have you identified best management practices of the critical elements to these plans? Can you give us an idea of what that would look like? Like, what are some examples of some of the best management practices that EPA would like to see in some of these state plans?

MS. ECHEVERRIA: So, thank you for that. With respect to the systemic issues and the longer term chronic effects, we are implementing our risk assessment guidance, which considers all routes of exposure. It considers other effects other than acute effects. So, we are evaluating that. Those data are coming in now as part of the re-evaluation program. So, that is part of our routine process. We will be considering that prior

to making decisions and re-evaluation in the registration programs.

Additionally, in terms of best management practices, I will say this is not my area of expertise. There are resources out there. Extension has resources. The universities have resources. Timing of applications, the method of applications, there is a lot of information and resources out there for states to rely on.

MR. HOUSENGER: Mark.

MARK: Thank you. I would like to echo the concern with regard to non-managed pollinators. I have absolute sympathy with the beekeepers and their livelihood. As well, we do need to look at the non-managed ones. The newest evidence seems to indicate that those, particularly the apian pollinators, the wild ones, are much more susceptible to pesticides than the managed ones are. So, I, of course, want to put my name on that concern.

A couple of things. With regard to best management practices, integrated pest management is a best management practice. I'm not going to sit here and advocate IPM as the best management practice for this. I'm not.

What I am suggesting, as a person who spent his career trying to get communities to adopt the best management practice innovation of IPM, is that the EPA in

this perhaps provide more leadership with regard the standards in the implementation of those best management practices as innovations. I recognize one size does not fit all. Yet, if it's too nebulous, if you don't have it defined as an innovation, it doesn't get adopted very well. That is just my suggestion as a person who has been doing this for awhile.

Then, finally, I might recommend with regard to measurement and the fact that it is state by state in a lot of ways, that sometimes agencies in these states have different degrees of concern or empathy, the measuring of enforcement actions in terms of the numbers of enforcement actions and the strength of those enforcement actions where regulation is allowed regarding exposure. That might be one of the metrics or several of the metrics that you look at. Thank you.

MR. HOUSENGER: Cynthia.

CYNTHIA: Hi. One comment and one question. First to echo what Dawn and Nichelle and Mark just mentioned, it would be good to focus more beyond foliar and acute and managed bee populations. It might make sense to start a new workgroup or a sub workgroup that looks specifically at seed treatments, looking at subacute exposures impacts on birds, bats, butterflies, other invertebrates, waterway contamination, some of the

efficacy and benefits questions, the treated seed exemption, the use data or lack thereof, the consistency or inconsistency with IPM. So, that would be a really good path to follow.

My question, I'm just curious, having worked on rat poisons and other pesticide families, why there is this emphasis on state-based approaches for the neonics and the pollinator protection? Thank you.

MS. ECHEVERRIA: So, with respect to the reliance on a local approach, the information that we get back from the local stakeholders is that the situations are so varied across the states in the crop producing areas that a one size fits all regulation may not be the most effective approach. There could be some value in customizing that approach based on local regulations, conditions, and expertise in the different practices.

So, that's the feedback that we've gotten. So, our first instinct is to see whether or not a local approach can work prior to implementing a national regulation which may not be feasible in all places.

MR. HOUSENGER: Steven.

STEVEN: Thank you. First of all, let me say that while the beekeepers are grateful that so much attention in this area has been focused on us, we are not trying to exclude the native pollinators. We feel that

in protecting managed bees, we will inadvertently protect some of the other pollinators out there.

I'm going to jump way back to slide number three. You have about six different pictures on here depicting possible problems. You mentioned a lack of genetic diversity. I'd like to know where the proof is of a lack of genetic diversity in the bee colony, because if we can eliminate one of those potential stressors, then we can focus on what the real problems are.

GABRIELE: Certainly, from the almond board's perspective where we funded research, what we're seeing is the queen breeders pride themselves in their stock. They pride themselves in whatever it is. What we're looking at -- certainly, the almond board has currently been finding research where we're bringing in semen from honeybees from elsewhere in the world to diversify the genetic stock available. Our dream, I'm not saying it's a reality, but our dream is to find genetics that will help with either some disease resistence or help with varroa mites. I mean, we have like the cleaning -- I'm not using the right term now --

STEVEN: Varroa sensitive hygiene.

MS. ECHEVERRIA: Yes, the hygienic behavior, but USDA has other genetics that help with Varroa. So,

can we do that? Again, from the plant world, we're used to looking for genetic routes to help us deal with pest management, so basically looking at that same thing. So, that's what that's referring to, is can we find within the gene pool that exists for honeybees around the world additional genetics that will help with some of the issues that honeybees face. That's what that's referring to, just to answer that question.

STEVEN: I don't have a problem with that. That's a good thing. But USDA's own scientists have research to show that the amount of genetic diversity in the American honeybee population is greater than Italian bees in Italy, where they originated from. So, there's a distinction between lack of genetic diversity and finding improvable traits to bring into. We can discuss that later.

I have a couple other things. The SFIREG draft guidance, critical elements of MP3's slide, it says method to know if managed bees are near the treatment area. Who is to know? Who needs to know? In the development of the state plans, who does the state say needs to know where the bees are? The producers know where the bees are because they are the ones that give permission to locate the bees on the property. And the beekeepers know where the bees are.

MS. ECHEVERRIA: So, in terms of who needs to know where the bees are located, it is the growers, the applicators and the beekeepers. The landowner may know if there are colonies on his site, but also within a forage area. So, within a one or two mile forage range, you may not know exactly all the bees that are located on someone's adjacent property. The idea is to get folks within that vicinity who are placing hives in places and who are making pesticide applications to have the information so the communication coordination can occur prior to a pesticide application that is acutely toxic and could have an impact on the neighboring bees.

STEVE: Okay. So, this is going towards the state registration program so everyone in the state knows, which is --

MS. ECHEVERRIA: That's an option. There are lower tech options if that's not an amenable approach for the local stakeholders. The idea is that there is a method to communicate between -- to know where the bees are prior to a pesticide application. That could be a state registration process.

But if there is another method of agreement on contacting growers within the area by phone, that's also acceptable. It doesn't have to be a one size fits all technological approach. So, there's variability in the

way that a local/state authority who is convening the meetings could approach that.

STEVEN: Okay. The next slide mentions EPA considering label restrictions to protect bees under contracted services. So, in your description, I was thinking mainly of almonds because that is the single largest pollination contract. But those bees need to be protected outside when they leave the almonds so that they'll be healthy enough to come back to the almonds. I don't understand why there's a distinction between a contracted crop label and a noncontracted crop label.

MS. ECHEVERRIA: The distinction between the two scenarios is knowing that the bees are there and that they are going to be exposed, because you know that they're there. There's a large number of them. There's a large number of hives that are intentionally brought in. If an acute pesticide is sprayed, you know there's going to be an impact on those bees.

In the other scenario, there may or may not be managed bees within the area. You need a method to know whether they are there and then to make appropriate accommodations if they are within the area and there is a likelihood that they're going to be sprayed.

So, we looked at a differential in the likelihood that exposure is going to occur in the two

scenarios, and that was part of our rationale for taking the two different approaches.

STEVEN: So, in the State of North Dakota where there's 600,000 colonies in the state, they're just as likely to occur anywhere in the state where there's a blooming crop as they are in an almond orchard. So, why differentiate?

So, it sounds to me like there's going to be a completely separate set of rules for pollinated crops and non-pollinated crops because you're not sure that the bees are there. So, if the bees are there, then you would have the same set of rules.

MS. ECHEVERRIA: I think that the other consideration is the benefit that the grower gets from having the bees on site for the purposes of pollination services. In the second scenario where the bees may be viewed as guests or they're not for the purposes of pollination services, the grower is not receiving a perceived benefit. So, that was another one of our considerations in balancing the risks and the benefits as we're required to under the statute.

STEVEN: I would like to see some more research measuring the actual benefit to that. What research is there is outdated. So, I think that they are receiving, in many cases, a much more benefit than they do perceive.

Thank you.

MR. HOUSENGER: Keep in mind, too, that this is a proposal that we're going to be drawing comments on. So, we may be modifying it based on those comments.

Scott.

SCOTT: Thank you. A couple comments. First off, it is a real need to know. I mean, as running a custom application business (inaudible) crop rate with beekeepers and do all these things. But we really do need to know. So, I do appreciate those comments in the last few minutes.

Another part of this, though, is it is very valid. At times, there are very large benefits for protecting crops, even during pollination time. So, we do need these tools to be available.

I guess the other thing, though, that I really question is you've talked a fair amount about the state management plans and sort of the SFIREG interest, et cetera. But we've seen little on the linkage with the label. Will there be a direct reference to this on the label or not? That's probably the pointed question.

MS. ECHEVERRIA: So, as Jack said, it is a proposal. We do expect robust comments. In the proposal, we are not going to be linking the state plans to the label, as our proposal.

SCOTT: Am I mistaken or is this quite a flip in the last, roughly, year?

MS. ECHEVERRIA: Our thinking continues to evolve on this issue.

MR. HOUSENGER: The answer to that question is yes. Our opinions on these positions change probably weekly, which is why we're going out and soliciting comments. It's a fluid plan right now.

SCOTT: Well, it will weaken the state plans if there isn't a linkage to the label. This morning we saw the Bulletin Live scenario where there is a linkage to off label position things. My recommendation and direct request would be that you keep that linkage.

MR. HOUSENGER: Okay.

Dan.

DAN: Thank you, Maria, for your presentation. I guess the discussion and dialogue suggests the complexity and the diversity of opinions around this whole process and how the mechanisms need to work. I'd support Scott's comment.

At some point, there's going to need to be some kind of reference associated with state management plans and their intention from a mitigation standpoint for protecting the pollinators as well as protecting the flexibility to allow pesticides to be used. The only

place that can come from is direct reference on a label. So, I'm fully supportive of that.

Having intimately been involved with the development of the initial Florida State management plan that was specific to citrus, it has now been expanded to look at blueberries and cucurbits where it is a direct contracted pollination service, a lot of the same issues apply across both cropping scenarios.

It's hard for me to understand why there would be a distinction between the two different systems if the whole intent of the programs being developed is to mitigate in the most effective and efficient way the risk to bees. I would argue that the acute exposure is probably the least important piece of the puzzle. It's going to be the chronic/subchronic exposure and some of the other issues.

In Jim's testimony yesterday at the hearing, he alluded to the fact that you all had developed guidance for determining some of the measurements associated with how to determine what needed to be done for that. I'm familiar with the guidance that came out earlier this year based on the European model, but has there been anything officially developed that allows or suggests what the appropriate measurements would be in a managed bee situation to determine what the impacts are so that

we could actually get some real metrics around the impact of the state management plans as they go forward?

MS. ECHEVERRIA: I'm not sure I understand the question, Dan.

DAN: One of the things we struggled with in Florida -- I mean, it's pretty straightforward when you have an overspray incident or you actually cause an acute bee kill where there's numbers that you can measure. The bigger impact that we're trying to mitigate in Florida where we have to have use of pesticides that have been alluded to as being extremely detrimental to bees, we don't see that impact.

We don't disagree that we don't have a measurement process to determine what the subproduct impacts are because we've looked for guidance everywhere to try to come up with how do you measure overall hive survivability. It's beyond just a single measurement of overwintering losses or summer losses. It's the overall health of that hive is what you're trying to measure.

We've looked to try to put together a protocol to look at landscape level impacts of pesticide use and agro ecosystems in Florida in managed bee populations, because that's a community you can measure. I don't know how you would measure wild bee populations in Florida to try to come up with the same thing where you're using the

managed bees population.

I'm struggling to come up with a mechanism to be able to provide the type of measurement at the end of the day that's going to determine success. If you talk to a certain subgroup of beekeepers in Florida right now, at the latest meeting on cucurbits, they said they've had less problems than they've ever had after the totally voluntary program was put into place in Florida a year ago.

It's all based on dialogue and having a conversation and an ability for people who need to know. It's the applicator, it's the landowner, it's the beekeeper who needs to know who is around him as well. It's a two-way street. It's not just a one-way street in this process. It's been fairly successful. It's totally voluntary and working better in certain regions in Florida than it is in others because it is voluntary.

You're going to need at some point to come up with a mechanism that can show that these programs work to achieve the end goal. I'm concerned that we don't have a measurement yet that allows us to establish that other than a warm fuzzy feeling among the two communities that are directly impacted at this point, which is the growers and the beekeepers.

I can tell you right now there's not a lot of

warm fuzzy feelings on both sides of that equation about how this process is supposed to work. It's going to take a lot of dialogue, a lot of effort to get it to the point where there's support for the program going forward. It needs an indication from the agency that you think is going to be successful in stronger terms than what we've seen today.

The other question I've got is directly to the comment that was made on the PRIA funds allocations. Evidently, there's a half a million dollars from the PRIA funds that's going to be earmarked towards supporting development of the state management plans. How is that money going to be spent, and where is it going to be directed? Since Florida has already gone through a whole tremendous process, is any of it going to be available for us to go back and look at some of the other crops?

MS. MONELL: The money I was talking to is in the FY 16 president's budget, so it would be appropriated funds. It would not be out of the PRIA account fees. It would not (inaudible) fees. It is a STAG allocation, state/tribal allocation. Assuming that that budget item is passed and authorized by congress, then there would have to be an allocation process set up for that $500,000.

DAN: But there's been no planning on how it

would be utilized if it was approved yet, other than the fact you want to use it to support plans?

MS. MONELL: Not at this point, no.

MR. HOUSENGER: Wayne.

WAYNE: Thank you for your presentation. It was very good. In North Carolina, we're in the process of developing an MP3. I'm just curious, it appears that the crux of this is all about communication and BMPs. Is there enforceable or mandated language in any of the MP3s?

MS. ECHEVERRIA: So, in the SFIREG guidance, we talk about states having flexibility to adopt a regulatory approach or a voluntary approach. So, a lot of the plans that we've been discussing here have taken on a voluntary approach. Those BMPs are voluntary.

However, there are examples of states who have adopted regulation to deal with the issue, who have issued restrictions of making applications at bloom, for example. So, I know Iowa has a state law, and there's some regulation in California. So, there is the option for states to take either approach.

WAYNE: And would all of those be put online, by any chance, or is there a one-stop shop for these MP3s?

MS. ECHEVERRIA: I think that's a great idea.

We don't have that yet developed. I think that's something that we should take back and consider because I think that would be a great resource for other folks going forward.

MR. HOUSENGER: Gabrielle.

GABRIELLE: Just briefly a couple things. I think I'm also trying to understand the difference between pollinating using and pollinating nonusing crops. Like in the case of almonds, after bloom, those growers behave like every other grower that's not a pollinated crop. So, I get what you're saying. Basically, you're saying that from that communications perspective, the growers know it's there. The question is really more how does a grower who is not an almond grower know that there's hives nearby in the almond orchards and figures out what to do about it.

So, I think we need to figure out how to talk about that in a better way. It's not as black and white as it sounds. As I say, an almond grower after bloom, I'm not sure how much they're thinking about bees somewhere else. I'm just being up front with you.

I understand the concerns about additional pollinators, but I would also say let's try and figure this out for the managed honeybees and see what we can do and learn from this process, as we also figure out what

are the risks or not risks to the rest of the pollinating world. So, I think this is something I view as a learning experience, a way of figuring out what our options are.

I understand the question about why state by state, but I can just give the example that what we can do as BMPs on almonds is not the same thing as what you can do in other crops, even in California. So, you're just looking at that. There's a reason why -- or, like, what a cotton grower can do in California, a cotton grower in Louisiana might not be able to do because of different environmental conditions.

So, that's the reason why it's being on a state-by-state basis, which I realize can drive people crazy at the same time. I mean, that's just the reality of it, but given where we are right now, I think this is actually a pretty good approach to -- really what we're talking about here is gaining awareness. Focus on communications for the almond industry, even the almond industry has had to sit down and look really hard at what's going on in their own industry.

Communication was one of the biggest problems, lack of communication, because you can have a grower, the pest control advisor, the actual applicator, a beekeeper, a bee broker -- the grower is not even dealing with the

beekeeper; they're dealing with the bee broker. So, how do you get communication going on within that chain? That emphasis on communications, even where it's very intentional, bees are going to be there and pesticides are going to be there. That's been something we've had to work on, or are actually working on right now.

So, I just want to reemphasize that that Element- it seems fuzzy. It doesn't seem regulatory, but it's making a difference. I mean, that's something that we hear often from beekeepers in other states where there's been that focus on communication.

I also don't understand how this is supposed to work if there's not some linkage with label, or mitigation, or whatever you want to call it. So, that needs to be clear to us because I think that makes a big difference about how meaningful this effort will be. Just a couple thoughts.

MR. HOUSENGER: Thanks.

Doug.

DOUG: Talking about communications, the things that need to be done as you look at the seven mechanisms to measure effectiveness of the plan, there's a lot of studies going on right now that data metrics need to be included not only in pesticides but also mites, habitat, health of bees. Those all need to be measured and

communicated with the pesticide that we're focused on right now, too. So, thank you.

MR. HOUSENGER: Steve.

STEVE: I agree with Gabrielle that lack of communication has been the biggest hurdle so far, but some of the state plans that currently exist are based on communication. They have absolutely no pollinator protection in them. It's all about communication.

Some other state plans are based on the mitigation measure is to move the bees. That enforces it all on the beekeeper to protect his bees. The applicator makes his application as he sees fit. If the bees are moved, that's great. If they're not, he doesn't care. If you move the managed bees, you can't move the native bees. So, if a state plan core in the protection of the managed pollinators is to move them, then you have absolutely no protection for natives.

MR. HOUSENGER: Donny.

DONNY: Thank you. I'll be very brief. This kind of goes back to the question I asked earlier about best management practices. If you go to honeybeehealthcoalition.org, you'll find some valuable information there as far as bee health is concerned and even what you can do in your own backyard to promote healthy bees. So, I recommend you take a look at that.

That will help answer some of the questions you have around best management practices.

MR. HOUSENGER: Andy.

ANDY: Thank you. I appreciate Marietta going through this, but it sounds like it's created quite a bit of confusion that EPA is looking at this as bee regulatory mechanism. I've always viewed this as in addition to EPA, nothing in these state plans will alleviate EPA's duties under FIFRA to regulate pesticides.

These are voluntary mitigation measures that we can engage in now. We developed these before. We actually brought them to EPA and said this is what we're doing. So, these are in addition to anything that I would expect EPA to do from a regulatory standpoint.

I don't think that there's anything in them -- whether it's communication, or agreeing to a set of cooperative standards, voluntarily supporting the increase of habitat on state and federal lands, or any of those things that we can do, I view them as complementary to, in addition to anything that EPA is planning on doing under their duties under FIFRA.

So, I don't see them as being an alternative to regulation. I view them as being in addition to and complementary of anything that EPA would be doing. Thank

you.

MR. HOUSENGER: Yes, I would agree with that.

Mark.

MARK: Having listened to a number of folks here, I get back to a few things. I think what folks ought to look at is just what Andy said, there's all kinds of things that can delay this. Timing is a bit of concern here. So, we've got to think about how much time we have to study things or put things back on a label or whatever else. While I personally agree with the idea of linking it to labeling, I don't think that that should, in any way, stop the process and the implementation of what currently is going on. So, I will provide comments at the time. That was one comment.

The other thing is just getting back to the idea that I know with school integrated pest management, once the agency took the leadership to help develop some standards in common to where yes, one size does not fit all and things are different across the country, there are standards in common, then that took out some of the wiggle room to go just for communications and things like that.

With the agency leadership, that made a big difference for school integrated pest management. I think it would make a big difference in the

implementation of best management practices for pollinator protection.

MR. HOUSENGER: Louis.

LOUIS: I think for the most part, Don, Mark, Steve can sense ahead. Let's just think about the communication piece for awhile. I sit here thinking okay, a lot of what we say got great application for commercial agriculture. Now, if you were a small land owner and you have a piece of land where you intend to grow your crop, and you're told that your next door neighbor has bees, what do you do? Are you going to abandon your piece of land and make no money that season? I know bees are important. They need to be protected. I'm for that.

But one of the pieces that I think is missing here is sure, you tell somebody that one mile down the road there is somebody with bees. But we need to also tell them what's the buffer zone that prevents us from using pesticides if it's any shorter than prescribed. Again, it would have to do with the flight range of the bees and the drift potential of the chemicals.

It's not as easy as it sounds. I understand that. So, I'll be looking for that proposal because I think you'll get a lot of response from the public. There are issues that are quite complex to deal with, even

though we all recognize the importance of protection to pollinators.

MR. HOUSENGER: Nichelle.

NICHELLE: So, we discussed these state pollinator protection plans which are voluntary and they have voluntary elements, such as best management practices, notification, communication. But what does that mean for compliance and enforcement? Could EPA shed some light on that?

MS. ECHEVERRIA: So, all use instructions on the label are enforceable. Our advice is always follow the label. That is an enforceable piece here. If a state adopts a regulatory approach to a plan, they adopt a state level regulation, that would also be enforceable. A plan that is based on voluntary measures is not an enforceable plan.

NICHELLE: So, in other words, these best management practices don't really have much teeth at the end of the day?

MS. ECHEVERRIA: So, our perspective is that voluntary approaches can be effective, as can regulatory approaches. That's why our discussion on the measures is so important. Voluntary approaches that are widely adopted and change behavior and actually make an impact can be very effective at achieving our goal.

On the flip side, a regulation that is not followed, that is not enforced, that there's no compliance with is not very effective at achieving our goal. We're really looking at incorporating measures into these plans to make sure that they're achieving the goal of reducing risk to bees. So, that's why this conversation around the measures is so important, because we do want to see evidence that we are achieving our goals.

MR. HOUSENGER: I assume that Louis, you're done? Nichelle, you're done? We're done with this session then. Thanks, everybody, for the comments. Those are useful.

The next session speaks to incident reporting and what the agency is doing to improve the ability to report, collect better data, and use these incidents in our regulatory decisions. Rich Dumas and Melissa Panger are going to lead up this session.

MS. PANGER: All right, we'll go ahead and get started. Rich and I appreciate the opportunity to speak with the PPDC today about the OPP's incident workgroup. So, what we're going to be talking to you guys about today is we're going to be talking a little bit, an overview, of the importance of incident data. We'll talk a little bit about the current sources of incident data.

Give an overview of OPP's incident workgroup. Talk a little bit about our current and future projects.

Then, most importantly, while we're here, we'd like to start talking about stakeholder input into some of our proposed projects. We're hoping there's enough interest in this that we can perhaps set up a PPDC workgroup. Rich will talk a little bit more about that, on incidents.

So, just a little bit on the importance of incidents. Obviously, they're very important to us. We want to make sure that everybody is aware of the importance of not just the enforcement type of incidents, but also the incidents that have to do with perhaps a registered use of a pesticide. It gives us really, really important information about what can happen out in the real world when a pesticide is used. So, they're very valuable. It can be valuable for that reason, for characterizing risks. They can help identify problem areas.

So, if we're getting a lot of incidents related to a particular use site or area, then that can maybe give us an opportunity to go back and look a little bit closer at what's going on there. It can inform risk management decisions and obviously support some rulemaking. When we're talking about incidents, we're talking about all

incidents. So, we're talking about human, eco, plant, honeybee, and pets. So, we're talking about all incidents here.

Just talk a little high level about some of the current sources of incident data. Although there's a lot of different sources out there, we kind of think of them in two main chunks. The two main chunks are really the required data incident reporting, which is required of registrants under FIFRA 6(a)(2), where there are some requirements for reporting.

But then, there's also voluntary reporting. Both types of information are very important to OPP. The types of voluntary reports are the sources that we get from our poison control centers for the human ones, NPIC, other countries such as Canada.

We share regularly incident data with PMRA. Obviously, state and local governments provide very important details information on some incidents. Other federal agencies, other EPA offices such as OECA and the regions, can also inform us on incident data. Then obviously the public, including beekeepers.

So, just to provide a little overview of the workgroup. Rich Dumas and I are the co-chairs of the group. We started back in January 2014. It was really designed to be an umbrella group for all kind of

incident-related activities. Prior to that, there were kind of incident things going on in different divisions and different groups. We wanted to kind of make it more efficient and hopefully more productive in terms of making an umbrella group for incidents.

It truly is an OPP-wide workgroup. It has representation and membership from all of the OPP divisions. Our first kind of marching orders for the workgroup was to develop some priority projects, what were the priority projects that we thought would be the most benefit to OPP?

To help frame that, we came up first with a vision. So, the OPP workgroup's vision, as stated here, is really to create a sustainable framework for incidents that improves reporting, both on the registrant and the voluntary side. It enhances the efficient use of incident data, supports quality, science-based decision making, and encourages data sharing among EPA, other agencies, and other stakeholders. So, that's kind of our vision. That's what we're moving towards.

That helped frame kind of where we were thinking there might be some areas of improvement. That's what's on this slide. The slide is really showing the different gears because we're trying to illustrate that a lot of these things are interdependent. They're

not independent. Kind of these different projects are related to each other.

We do see that there is some room for improvement on the voluntary side of reporting, under 6(a)(2) reporting. We think there's some improvement that we can make in terms of the use of data and risk assessment and risk management. A lot of that has to do with creating consistency across assessments and decisions across the divisions.

We think there could be a lot of efficiencies gained by moving towards electronic reporting. Obviously, some of these are very long-term kind of visions. Part of that, going to electronic reporting and improving data quality, is really kind of gaining a solid understanding of what type of information we think is important for incidents.

So, we've been developing these incident data standards and data elements, which Rich will talk about in just a minute. We think this will help improve data management. Then, we'd ultimately like to improve sharing the information with partners, and the public, and stakeholders.

With that in mind, our specific goals are basically to improve reporting. One way we think we can do that is to make it easier for registrants and the

public to report incident data to EPA. We'd like to eliminate or at least ease kind of the time-consuming data entry efforts that are currently necessary to process incident data, which are mainly done by hand now.

We'd like to reduce the time spent on incident FOIA requests and better able to share the data with the public. Obviously, getting the data via FOIA is not the most efficient way to share data. So, we'd like to get better at that.

We'd like to improve the quality of the data that we actually get in. One way to do this is these data standards that Rich will be talking about, to get more detailed information on each specific incident and the type of information that we think is valuable for making it higher quality.

We'd like to improve the consistency in the use of the data across risk assessments and risk management decisions. And then, in terms of just efficiency, a lot of these are interrelated so they seem a little bit redundant, but improve internal OPP incident data management. Ensure consistent use again of incident data and risk assessments and risk management decisions. Then, be better at sharing information with partners and stakeholders.

With that, I'll pass the mic.

MR. DUMAS: My job is to be the pitchman for the PPDC workgroup. So, when we're all done, we'll all be excited about signing up for this workgroup.

One thing sort of going to fuel (inaudible) from Melissa in this schematic of what we're planning or would like to do really illustrates it is this whole incident effort is not a sprint; it's a marathon. Getting a real nice usable system is not going to happen in six months. It's going to take some time to get it right. That's why we really want people involved today from basically all types of stakeholders so we do get it right and don't build something that people will say, I don't want to play or you forgot an important piece of information.

So, what you'll see here is sort of the rough order of how we see getting stakeholder involvement. Actually, you could replace stakeholder involvement with charges for the PPDC workgroup, essentially. As Melissa mentioned, clearly, making sure what we get in a data incident report, what data we collect, and house is the right information.

We've worked a lot to try to figure that out, but we're ready to sort of role it out. There might be one element that we neglected that would be critical to the states, and we might want to build that in. Or,

there will be ones like, really, what do you get out of this.

So, that's really our first step. We really want to start rolling out and having a discussion of the data elements that we've developed internally so far to see if they're the right ones. I would think they're mostly right, but I'm sure there's lots of opportunities to make them better and more efficient.

I think at some point when we get those nailed down, we might think of some sort of pilot, which was for collecting incidents for people who have them. It could be registrants, it could be states. We're not sure what that might mean, but the idea is maybe some sort of pilot to test whatever we come up with.

Another big, big part that we're really going to need a lot of help on is how to build the right system. We want something that's very good for sharing, people can input information for us or get information to us in an efficient way. But also, we want it so it will be useable to other people who care about incidents information.

I think many of you in this room care about incident information and would love to know what's going on in another part of the country or similar sort of issues. So, that's really the goal that we have this

workgroup, the PPDC workgroup, to help us along the way.

Then, the other side I'm not going to spend a lot of time on. These are sort of, we'll call them, stand-alone projects. As Melissa said, everything is interrelated. But things that we're sort of going to be looking at and plugging away with, sort of the sidelines. One, I think we're going to take a little time and take a good look at what we've learned, re: the current 6(a)(2).

Certainly, something that's in 6(a)(2) today that I'm sure drives registrants crazy is if there's a requirement for paper reporting. Technically, you can't submit electronically or you can but you have to do it in paper, too. So, that would be something that seems like a no-brainer that we would want to work towards fixing the rule in that respect.

Then, there's a few IT sort of projects. Right now we have the ecological information system as a free-standing document, database, and we have the incident data system which has human health and ecological. We're in the process of importing it all into the IDS system. In fact, that's a fairly short-term effort. I think we've just sort of figured out a path for doing that. So, that should be something that might happen within the year, hopefully more like less than six months.

Then there's the outreach part. That's here, but I think this is was sort of a kickoff. We'll be talking to SFIREG next month about our workgroup and sort of getting people interested in trying to help us do it right, ultimately.

In internal guidance, the consistency that Melissa already talked about, we're actually got a workgroup working on developing the OPP guide. EFED has had their own guidance for a number of years, I believe. HED sort of has one. The idea is trying to come up with something that would be uniform that all risk assessors could look at when they're considering incidents in their risk characterization documents.

So, there's a lot of efforts going on. Some of them, you are uniquely qualified to help us.

The next slide is really very much I've kind of said all of this. The areas that we're going to be seeking your advice on would be, first and foremost, the data elements. We'd like to know where there's other sources. We know that states, NGOs, others have some good incident data that might inform our decision making or even where we focus some of our resources. So, help in directing us to those. We've got a few specific things that we need to think about as we're getting data incidents from many sources.

Certainly, the needs of the stakeholders. We want this to be an exchange. We're not just saying, oh, we want your data. We want to have a system in which we're creating something for the public consumption that would be useful to many parties and many types of stakeholders. We certainly need your help to figure out what the right questions and directions are.

Then, as we're building the systems, I'm sure we'd need guidance on what has worked. Some of you have probably built big data systems or data collection systems. You know some of the things that have and haven't worked. So, we're really looking forward to that kind of input as we move down the road. That's probably a later charge for the PPDC, but it's certainly something to keep in the back of minds with our goals.

So, just quickly sort of talking about each of those a little bit, we've already put together a set of data elements. It's by category. That is, we have a pollinator one, we have one for pets, we have one for human health, we have one for ecological, and then sort of the general information that we would need for every incident, like who is reporting it, where did it happen, those types of questions.

So, that's what we're talking about when we say data elements. What piece of information would be really

useful to collect in some sort of uniform and strategic way so that it would be useful to us and others? So, our first step is to seek your advice on what those elements are.

The next thing is what I would see as sort of being maybe concurrent and ongoing, helping us identify where there might be some valuable incident data out there already. I think there's a few questions we need. There's identifying the sources, but I think one of the biggest fears when you start getting data from multiple sources is that there's duplication. So, how do we safeguard that we aren't counting the same incidents five times? That's not terribly useful and it's a waste of resources and actually gives us potentially bad information.

And then, what might be the right data, what can we share with the states, the public, in general, how to do it, and what do people really want to see. They might not want to see every data element we collect. There might be certain salient ones that we find just about everyone cares about.

Then, we want to create something that's easy to use for collecting the data. We want the ability to collect and share the information and know what sort of the key characteristics of the data should be. Again,

we're going to be looking for your advice as to what might be the right things we should be looking for in any data we collect, above and beyond the data elements.

Then, the system question will be coming to you, I'm sure, many times. Right now, we have the portal effort that is really pretty much a registrant-focused effort, how to get studies in efficiently and so on. We're certainly going to keep our eyes open and see if there's a way to start building incidents data into this.

It may or may not pan out, but we certainly would like to seek advice before we start putting lots of resources into an approach that, from your experience, we know isn't going to work, or something that will really work and is nice and efficient. Certainly, we want to get some information and thoughts on what data to collect, how to collect it, and so on.

Why a PPDC workgroup? Well, obviously, this is a group of great cross section of interested parties in our work. So, you're sort of uniquely positioned for us to be able to approach multiple types of stakeholders in one venue. Having been involved in a couple PPDC workgroups, I find that the cross pollination across different NGOs, and all sorts of stakeholders, has really been invaluable in getting us to a better place and one that's more acceptable to the people who might ultimately

want the outcome.

Well, this is really the last thing. The way we see this as being structured is pretty much like any other PPDC workgroup. We might have a meeting right before, a live meeting, conference calls, and e-mails. So, open the floor from here.

MS. MONELL: If we could initially address the specific question about whether or not the PPDC would recommend that we create a workgroup, that would be most helpful feedback at this point. Thanks.

MR. HOUSENGER: Cheryl.

CHERYL: I didn't put my card up for that. How do you want to do that? How do you want to do Marty's request?

MS. MONELL: Go ahead, since your card was up before I --

CHERYL: Okay. I'm not sure what to do with what you just said. So, we're clarifying that you've had an internal workgroup within EPA, which was referred to in the beginning. Now you're asking for form a workgroup within PPDC.

MS. MONELL: We want stakeholder involvement in this entire process. We've gone just so far within the program, but we need help.

CHERYL: It sounds good to me, but I don't

know, Jack, how you want to finish that question. Then I have comments.

MS. MONELL: I'll answer for Jack.

MR. HOUSENGER: I was writing down names.

MS. MONELL: Why don't you continue with your comment now that you've cast your vote?

CHERYL: Okay. So, my question is, we launched into a discussion of incident reporting without really having defined what you meant by incident. 6(a)(2) is adverse effects incidents. You can take incidents a lot of places. You can even take it into product performance claims. So, I think it's going to be really important to make sure you don't overreach and that you have clear, clear definition of incident. You're nodding your head so I'm not telling you anything you don't know.

So, the other piece, as you can imagine, when you start talking about how you're going to use the data, you're going to make sure that you've got data for the purpose of whatever you're going to do with it. If you're going to look at screening trends, that's one thing.

If you're going to integrate it into risk management decisions, then the quality and the validation, especially the exposure, not just hearsay but true follow up, you've validated it, you know there was

exposure associated, that becomes really important if you're going to try to use that in a regulatory decision.

Along those lines, on one of these slides you said you wanted to obtain more detailed information on ecological incidents to improve risk assessments. The same thing would apply for humans.

MS. PANGER: It would apply to all of those, that's correct, not just eco.

MS. MONELL: And all of those comments that you just made would be perfect subjects of conversation among a workgroup.

MR. HOUSENGER: Tom.

TOM: Cheryl added some of what I was going to say, especially the definition. If there's a workgroup, I'll be the first one to join. I'm not promoting that there be one, but if there is, I've spent many years investigating incidences and having to evaluate them as a pesticide regulator. I want to make sure the Office of Compliance, OECA, is involved with this because that's a whole other part of it.

I think the quality is one of the important things of this, because I was part of the old PIMS system, Pesticide Incident Monitoring Systems, which was a bunch of garbage in there, which I always complained about how it was used, because a lot was unverifiable.

So, again, that quality.

That list of sources you listed, there's a lot of difference between those. Like, the National Pesticide Information Center has very good information and detailed information, and some of the rest of them don't compare to that.

MS. PANGER: That's part of what we're after, is to kind of standardizing data elements. Hopefully, we can standardize some of the quality across the sources of information.

MR. DUMAS: Actually, our workgroup has been talking to OECA throughout. We're not necessarily moving -- at one point they were developing their system. We were hoping we could tap into that. But its purposes and what they're developing is somewhat different. But we try to keep a dialogue with them because it is important.

MR. HOUSENGER: Matt.

MATT: There's a couple things I just noticed. When we're talking about incidents, my focus is generally -- because I'm a physician in occupational medicine on human health effects, one of the things I note is that there was very little conversation about the enhancement of the ability of the front line people to identify the conditions that you consider incidents. It seemed like I didn't see anything about that. Maybe I'm wrong, but I

missed it if it's there.

The other thing I would say is that at the present time, in our country, 30 states require pesticide reporting as a requirement. If it happens, it must be reported. The remainder do not. That seems to be should be part of the conversation. Obviously, you can't force a state to make it a requirement, but you can talk to a state about making it a requirement. It would enhance your ability to identify incidents in human beings, at least, quite substantially.

I'm going to pick up on what Cheryl said about the validation of exposures. It seems to me the importance of the validation of exposures can't be overemphasized. I'd go back to the biomonitoring committee, subcommittee, who are struggling with what are the tools we use to diagnose pesticide poisoning in a human being, ergo, validating the exposure.

We don't have very good tools. We have cholinesterase for organophosphates and carbamates. We've got anticoagulants, PT for anticoagulants, and a couple of other things that we have at our disposal. But generally speaking, on the practical use of diagnostic tools, there are very few for the practicing clinician to do it. That talks to validation.

Finally, the other thing I mentioned is in the

process of surveillance on human beings, a monkey wrench has been thrown into the works, and that's HIPAA. HIPAA has really created a significant fear in clinicians about the process of sharing clinical data with anyone. The monumental cost of divulging information on a personal medical experience and being then somehow identified as having divulged that without appropriate authority is an extremely scary thing for clinicians.

In these cases of voluntary reporting systems, I would wager that it's virtually impossible for a clinician to muster the courage to even talk to a voluntary reporting system, because if it's not required, they're not released from the responsibility of keeping that information confidential.

So, you've got a number of things that I think you really need to be talking about that I didn't hear talked about in this conversation. I ask you to include those in your conversation. I, unfortunately, can't join your group because I'm no longer on the PPDC as of July.

MS. MONELL: Oh, yes, you can.

MATT: Well, I virtually can join your group.

MR. HOUSENGER: It's not quite that easy.

Jerry.

JERRY: First of all, I think it's a great idea, so another yes vote to answer your question

directly, Marty.

I think a higher level of what Cheryl said is she's talking about exposure. I think you really need to look at quality control, quality assurance of every incident, especially as you open it up to people that aren't in this room that may or may not have a different motive. You may have some unnecessary things come in there. The last thing you want to do is make a regulatory decision based on information that's false or misleading. So, quality assurance/quality control is probably a big thing you have to consider.

MR. HOUSENGER: Ray.

RAY: I'll just speak up to support the concept of the workgroup and volunteer myself or find somebody. I'll volunteer somebody else.

MR. HOUSENGER: Marylou.

MARYLOU: This is a very interesting workgroup, and I'd be interested in joining. Although I am not going to be in PPDC, I will join that workgroup.

You probably already know this, but California has a very extensive database on human pesticide illness reporting and so does Geoff Calvert's group. The validation, all the points that were already said is really important to take note.

In California, it is a reportable incident.

Pesticide illness is a reportable incident, so we do receive them from physicians and the poison control centers. We do receive over 2,000 cases, but only 1,500 are really pesticide illness, definite, probable, or possible. So, the validation really is very important. The investigation and all that is so critical to this type of database. But it's really a great project.

MR. HOUSENGER: Virginia.

VIRGINIA: I also support the idea of a workgroup. I think it's a good idea.

One comment on the data elements, I think specifically within the human health, you should have a category just for workers and their family members. I'm a little concerned about the emphasis on the quality and validation, on their number of barriers to workers and their family members reporting incidents. There's a lot of fear of retaliation if it's a work-related incident. So, they're concerned about keeping their job. Many farmworkers do not have health insurance and access to medical services. It's limited.

Workers who may initially report an incident, if the information that they're providing is not anonymous or confidential, they will not follow through. That doesn't mean that that wasn't a valid incident. So, you can't discount a lot of these incidents, because you

can't verify them. Among farmworkers, many of these pesticide incidents are underreported.

Finally, I just want to say that again, for farmworkers, a passive surveillance system is not going to be very effective. I think you also have to include interviews, or surveys, or qualitative data to capture a lot of this information and look at some of the barriers and the depth of the problem. Otherwise, incidents will continue to be underreported.

MR. HOUSENGER: Nichelle.

NICHELLE: One of your slides called what are our goals, you have improved reporting, improved quality, efficiency. I would like to see improved training for those that are first responders to taking or reporting a pesticide incident. Our organization, we tend to get some calls from the public wanting to report an incident. We will typically refer them to the relevant state agency. Oftentimes, you will hear back saying that they got conflicting information on who they should be reporting to.

Now, this may just be on a state-by-state basis, but I feel like there is a need for some improved training for those on the ground on how to determine whether this is an incident or just for the state agencies to know which ones should be collecting these

incidents.

MR. HOUSENGER: Cynthia.

CYNTHIA: The American Bird Conservancy is excited to see this proposal to elevate incident reporting in the PPDC, for several reasons. The requirement of paper submissions was clearly written in the dinosaur age, and it's a good move to eliminate that.

As we discussed earlier, the thresholds are absurdly high for required incident reporting under 6(a)(2), so hardly anything is getting reported, whether you're requiring 50 mammals of a herding species or 50 song birds or 1,000 schooling fish.

There's also a need to coordinate databases. EPA has the EIIS and the IDS, and Fish and Wildlife Services coming out with the IMRS database which will be mainly for birds but also for bats. So, apparently, not by species.

But how can these databases be coordinated? It's my understanding that the soon-to-be-released signing of the MOU between Fish and Wildlife Service and EPA envisions such coordination under the Migratory Bird Treaty Act.

And then, another question, how to make more of this information public? Perhaps not all deaths of frogs or owls or prong horns need to be state secrets.

Certainly, FOIA is a time-intensive, resource-intensive process for all of us.

As we discussed earlier, this complements well EPA's efforts under the Endangered Species Act to see how these pesticides are affecting/threatening endangered species in the real world and whether our mitigation is actually working.

Finally, incident reporting is a really useful reality check or backstop as EPA moves away from animal testing and the cumbersome 158 data requirements and moves towards greater reliance on more theoretical modeling and computational toxicology.

Finally, I agree with Matt's comments on the importance of diagnostic tools for humans and also for wildlife, for neonic poisoning and other pesticide poisoning. Thanks.

MR. HOUSENGER: Robin.

ROBIN: I vote yes for a workgroup, and I'll be happy to be on it.

MR. HOUSENGER: See, that's how it's done.

Matt.

MATT: I would just add one other thing. Marylou has prompted my memory of it. Electronic medical records, which are now by law almost ubiquitous. That's a real resource that we really ought

to be looking at for surveillance.

One of the meaningful use criteria for inclusion of elements into electronic medical records is syndromic surveillance, which I think will really serve our purpose well in terms of utilizing that. It can be anonymous. It doesn't have to be identifying individuals. But it can be used anonymously so it can avoid the HIPAA requirements, if you can engage with some of the electronic medical record companies or find other mechanisms to get that kind of data.

MR. HOUSENGER: Valentin.

VALENTIN: I just want to echo what Virginia said in terms of fears of reporting pesticide incidents. It's not just about fear of losing their job, but also it's fear of losing or being evicted from the housing that's being provided by the farmers. A lot of them, at least in Oregon, we get migrant workers who come up to Oregon for two months and then they go back.

The other thing is there is a lack of adequate training. One of my jobs is to do presentations about pesticides to parents, to farmworkers, their family members. One of the things I keep hearing is that sometimes it's the first time that they received training about pesticides. The other thing we've noticed is that people are unable to identify the health effects that

pesticide exposure could cause.

Lastly, I think the farmworker population is very diverse. A big percentage of them speak Spanish. So, I would consider those demographics when we try to improve incident reporting.

MR. HOUSENGER: Donny.

DONNY: First of all, I support the working group. I think it's a great idea. I look forward to working and determining how we can take a report and turn it into data so that it can be used, it can have a value. I'm willing to be a member of the workgroup.

MR. HOUSENGER: Dawn.

DAWN: Thank you. I enthusiastically support the proposal to form the working group. I just wanted to give you something to think about. This is just within my little sphere of where I work. The most egregious pesticide use is usually over-the-counter products used by residents for self treatment for bed bugs. Rarely, if ever, does that approach ever actually result in the remediation of the bed bug infestation.

I am beyond convinced that this is having significant human health impacts. Once maybe you are past all of the catastrophic incidents reporting, I would encourage you to focus some attention on the nonlethal but chronic health effects that some of those specific

instances trigger heinous pesticide use patterns in society. Thank you.

MR. HOUSENGER: Okay. Let's take a 15-minute break, and then we can get into the EPA web site and then our quick updates. So, 3:15 by that clock.

(Whereupon, a brief recess was taken.)

MR. HOUSENGER: Our next session is about our web site. There is an agency initiative to redo the whole EPA web site, and probably some of the material that you've seen up there is going away, and it's in a different place. We just kind of wanted to walk everybody through it to tell everybody what we're doing.

Claire Gesalman in our Field and External Affairs Division is going to give this briefing.

MS. GESALMAN: If you visit EPA's web site, you might have noticed that there have been some changes over the past year or so. As Jack said, some things that are on the web site now might be in a different place, or look a little different, or whatever. We're hoping that, for the most part, what's happening for people will be a positive experience. If people have concerns about things, we can work with you to help make it better. So, I'd like to talk about the changes and how they are affecting the pesticide web site and some possible ways

that folks in this group can help us do the best job possible.

One thing that is important to note is that EPA's web site is very popular with the public, and so is the pesticide web site. In both areas, there are a lot of visits with people looking at our web pages, downloading documents, and that sort of thing. So, we're concerned about making sure that people have the best experience possible.

That's what's really driving the EPA web transformation. The idea is to improve web content, and update the format, and better serve the audiences that are coming to the web site. What we're trying to do throughout the process is focus on who the audiences are and what they're trying to accomplish when they come to visit us; in other words, what the task is that they're trying to accomplish.

In many cases, it's fairly clear. If you're in the pesticide manufacturing business and you're coming to our web site, a lot of times you're looking for information about registering a pesticide. So, that's one of the things that we focused on.

We're also, at the same time, potentially eliminating or archiving pages and documents that really don't serve audiences or tasks. If you look at

statistics on web usage, there's a lot of web pages across EPA that maybe have a couple visitors a year. It's like, well, what's the point of that.

We'd like to provide a better web experience for mobile users. How many people in this room use mobile devices, either a phone or a tablet or something, to get web information? A lot of people. So, the latest research study showed that as many as 40 percent of people are using a Smartphone or tablet to access government information. That is something that is growing and growing, and growing extremely rapidly. So, that's something that we're focusing on in terms of the way the web site is being designed and managed going forward.

We started this project under direction of the administrator. We have a schedule that's been set by the administrator's office as well. Our deadline is getting our materials transformed by the end of this September. The current web servers will at that point be used for something else.

We basically started looking at our current web site and developed a list of projects to do transformation based on what we had already. As you probably know, we have a lot of (inaudible). The focus is on making sure that we have high priority content

transformed as quickly as possible. As part of that, we're evaluating that information, making sure it's up to date, and potentially rewriting some things that maybe could be a little plainer, could be a little more clear in terms of how things (inaudible).

We're also identifying some of the older contents for archiving, and I'm going to talk a little bit more. If you go to the web site, some of the newer pages, you'll notice that the format is different from what you've seen before.

UNIDENTIFIED MALE: Could you increase the volume?

MS. GESALMAN: Pardon me?

UNIDENTIFIED MALE: Could you increase the volume? We can't hear you back here.

MS. GESALMAN: Is that better? Sorry about that. Everybody good now?

So, we're looking at some of the older documents to be archived. We've written things more clearly. We have some new features as part of the web transformation. If you went to the announcement of the PPDC meeting, there was an option on the event page that was linked from the announcement to add it to your calendar, which is something that we had not had before this new format.

We expect that search will work better. Our experience is that it really is working better for a lot of things already. The new web pages have a lot more structure in terms of the description and the key words that are used and other what's called metadata to help the search engines work the best that they can on our content. This is true from both outside the agency as well as our internal search engine.

The URLs will be changing for web pages and the web kind of general areas that we have. So, if you have bookmarks to information, I suggest that you take a look at those and make sure that they are linking to the new format pages as opposed to the old pages. We have a lot of redirects in place from the old pages to newer information, but those redirects will actually end when the web servers are turned off in September, except for -- and this is a very big exception -- except for a few specific things that are currently on pesticide labels.

We have a process worked out with the folks that manage all this so that those pages will continue to redirect to the correct page. That may not be forever, but that's something that we'll be able to deal with on a longer term basis. So, for now, all those URLs that are required to be, like (inaudible) credits -- I forget what some of them are, but they are going to continue for the

time being.

Up to this point, we have a list of about 30 projects that we're doing, and we've completed 19 of them. Pesticide registration was one of the early ones that we completed, since that's a very high priority for the program. Pesticide reevaluation. Bed bugs has been on the top 10 list of the agency at some times. It isn't right this minute, but it often is. So, that was another early one that we did. Pollinator protection, of course, is a very popular issue in one way or another right now. So, that's another one that we have a new site for. Of course, the site that includes the information about this advisory committee.

So, the EPA.gov pesticide site lists all the sites that we have transformed. I will show that to you in just a minute. We're working on transforming the rest of the sites that we have to by sometime this summer so that over the last month or so, we'll just be like cleaning up little bits and pieces as opposed to undertaking major projects.

Some of the sites that we're working on right now include pesticide labeling information, the tolerance information, how we set tolerances and things like that, endangered species, which you heard a little bit about earlier today, and worker safety is another big area that

we're working on. Obviously, there's a lot going on in all of those areas. So, they are very important projects.

So, one of the things I wanted to show you is sort of the old versus new. Here's an example of one of the old pages, registering pesticides that contained information linked to various places. Over a period of time, it kind of became like a Christmas tree in different areas of the site where things go to different places. Maybe it's not so easy to find all the details.

So, here is the highlight section of our current web site where you can see the list of projects that we've completed. This is the list of the 19 projects. From here, you can link to any of the sites. I'm going to go to registration which I just showed you on the screen shot of the old site. Here's the new site. You can see that it looks quite a bit different from what it looked like before.

One of the things that we have on this site is kind of a focus on the critical things. Like here is the pesticide registration manual. Here's your fee information for PRIA, which actually has its own site, but we linked to it from here as a big part. If you come down farther, you can see that we have information that is separated out by the different types of registration.

So, you can easily get to your antimicrobials, or inerts, or whatever you're looking for for registration information.

One of the interesting things on this new site, and we don't have it on all of them, but some of them we do, when they're a big site like this, is you can search just within this site. So, one of the things that I search for fairly often, because we're doing updates on it, is child resistant packaging. So, if I just put in CRP for child resistant packaging, I go right to a couple different links that get me to those pages. So, it's very targeted to this particular site area.

So, for bed bugs, we had a site that was basically in the past a single long page with a lot of pretty good writing. It had bullets and some graphics and that sort of thing, but it was fairly limited. So, when we updated bed bugs, we added a lot of new information. If you have concerns about bed bugs, we'll give you some advice on how to get rid of them, like a step-by-step guide to controlling bed bugs, as well as information about chemical and nonchemical options and things like that.

One of the things that I think concerns people fairly often when they hear about the web transformation is the concept of the archives. EPA decided that this

would be a good way to declutter the web site. If you think of your office, and I think of my office, there's paper. There's a lot of stuff and it's like what do I do with all this. Well, if I can figure out how to put it someplace that is out of the way in a file cabinet or something, things are a lot easier to find for the things that I really need.

So, that's what the archive is all about. That is going to be for things that are still of some use, maybe for historical reasons or for research or for whatever, but it's not something that people are using on a daily basis. Maybe the information is a little bit older. The older years of PPDC is a good example of that, as well as the old workgroups on the advisory committees called TRAC and CARAT, if you've been around for awhile. Those are in the archive.

Those documents will be available to you by search, by going to the archive site, which will be live starting in about September, and doing a search. Now they are on the current site and actually cause some confusion because the web page for the PPDC that is the archive actually shows up first in the search results, unfortunately. We modified it a little bit to try to get people to the correct page a little more easily.

We're in the process of designating things for

the archive as we go through the review process for sites. We won't be linking to specific documents in the archive. If we were linking to it, it would be something we should have on the current site.

Finally, I would like to give you the opportunity over the longer term -- I mean, you can make comments right now. I know we're a little behind schedules, so probably we don't want to spent too much time on that -- in terms of things that have been giving you trouble or things that you'd like to see on the web site that maybe you aren't there yet. That may be a longer term project.

Or, if you see some of the things we're still working on, like the labeling or the tolerance information, or whatever, if you have ideas about how we might want to organize or things that we might want to emphasize, you can e-mail this address, pesticidewebcomments@epa.gov and let us know things that are of concern to you.

The last thing is that in the web design and implementation process, one of the really useful things to do is testing. We did some testing on the registration site with some actual registrants and an industry association who came in and spent some time with me looking at things, doing some tasks on the site, and

gave us some really good feedback on some very specific things that helped for some implementation there. We'd like to do more of that on some of the sites that have already been launched in that list of 19, as well as some of the ones we haven't done yet.

Now, whether we have time to really do a lot of that before we get to the end of September, I don't know, but we'd like to have people's interest in that. If you are interested, just let me know. As we sort of move through some of these things, we can set up a session. If you're here for a meeting and you'd like to do a little testing, I can sit in the conference room with you and in an hour go through some stuff and maybe make some suggestions or whatever. So, that's another option, just very informally set those things up.

That's basically it. If there's time for questions or comments now or people can contact me later.

MS. JAIN: Hi I'm Komal Jain with the ACC Biocides Panel. Claire, we definitely support what EPA has done with the web site. This is very clean, and it looks to be an efficient system. I know you've heard from us. We've sent a couple of letters in about the content. I just have a couple questions about the archiving because that's something we've been very concerned about.

You have a statement in a slide that says that there won't be links to specific documents. Can you explain to me what that means? If I put in a search and I'm looking for pesticide registration, will I get a list of documents with links?

MS. GESALMAN: I'm sorry, that was not clear, I guess. Basically, from the new sites, like the registration site, if I go to anyplace on this site, we will not be linking from this site to something that's in the archives. But if you go and search the archive, you'll get a list of results that will link to individual items, or pages, or whatever that are in the archives. But we just won't be linking to those documents from sites like this.

KOMAL: Okay. And then we've noticed in the past, probably the past year, that certain documents have already started to be archived or have been deleted from the web site. Have you been maintaining a list of those documents or should we provide you a list of documents that we find important that we're no longer locating?

MS. GESALMAN: If you or anyone else have things that you are not able to find, please let me know specifically what those are, because there have been a few cases where something somehow got moved or changed in

a way that was not transparent, is the best I can say about that. In most cases, there were some changes that were made to try to structure things for the future archives. That may have messed up some of people's bookmarks. But generally speaking, most things are still on the web site.

If it was something that was actually transformed, that page may have been deleted because it's now here. That old information is no longer necessary on the old web site. So, we've deleted some things that were in the new sites. But, for the most part, if something was not moved into the new site, it's still on the old web site.

MR. HOUSENGER: Wayne.

WAYNE: You may have stated this and I may have just missed it, but are all the WW2 stems modified?

MS. GESALMAN: Yes. WW2 is the URL currently for the sites that are in our new system. When September comes, they're all going to go back to WWW. But even if you put in W2, it will still go to the correct place. So, it's all going to be combined in September or October.

MR. HOUSENGER: Pat.

PAT: So, one of the areas that obviously the animal welfare groups are most interested in is starting

to promote some of the nonanimal methods that are now available for some of the test requirements. I know there's information on the site, and it's in a number of places. There's some policy documents. There's some references to the actual validated methods.

I think it would be great if maybe there is cross referencing among various pages. But if there was a page perhaps just devoted to alternative methods, how a registrant might go about using them -- I know you do some preconsulting before a product is registered as to what tests need to be done and so forth.

Maybe in the interest of trying to promote some more of these uses, some more of these methods, they're out there now. I know I've talked to Jennifer and some others. There's not a lot of results coming in with people using them yet. So, if you could try to maybe work on that, that would be great.

MS. GESALMAN: Okay, that's helpful. One of the things that we're working on right now is the site that will deal with science and risk assessment. All those things like that would be part of that site.

You mentioned the test guidelines. Would that be like the harmonized test guidelines? Is that what you're talking about? Okay, because that's a separate site, but we can make sure that there are cross links as

appropriate.

MR. HOUSENGER: Okay, thanks, Claire.

Our next session is eight topics. It's an hour long. So, it's 7.7 minutes per topic without any questions, which we're not going to take, any questions or comments. Keep these topics in mind for later on when we talk about things that we want to talk about at the next PPDC. Or, if you have immediate questions, you can always feel free to contact the staff here.

Our first one, and Marty has assured me that she will not go beyond 7-1/2 minutes, is comparative safety statements.

MS. MONELL: Thanks, Jack. If you recall, about four years ago, PPDC voted to create a workgroup to look at the issue of comparative safety statements on pesticide product labels. This was in an effort to acknowledge and do something so that the consumer would have some more information about the relative greenness of a pesticide product.

We essentially entered into a pilot program some four years ago that has been extended a couple of times. Basically, we agreed upon working with our sister organization, the toxics program, and their design for the environment, third-party certification program as to the hazard components of chemical properties.

So, we have launched that. We have been successful thus far in improving six active ingredients. A seventh is in the works. There are about 10 products for which federal labels have been approved, have the logo on it. Regrettably, no states are allowing it now.

We have been working with SFIREG and AAPCO to try to address their concerns about the use of allowing these logos. There seems to be mixed rationale for why they are collectively not allowing it. Some states feel that they have statutes that prohibit it. Some states are uncomfortable with it still.

So, we're working it because as you may have heard, the DFE program in OPPT has recently announced its transformation into the safer choice program. Under our current regulations, we cannot allow the use of those words in a logo of any sort on a pesticide product. So, our workgroup right now is looking at options.

We will continue the pilot for another year as we explore our different options for paths forward, which may include rulemaking. That determination has not been finalized yet, but that's certainly on the table and being discussed.

The other piece of our pilot coming out of this workgroup is a factual statement. This initially was allowing statements such as dye free, fragrance free,

which are very easily determined based on the submission on labels. That has been very successful. In fact, it's been so successful that the workgroup is recommending that the program just adopt that as an operating principle. We will be checking, and there is an easy mechanism to do so. It is information that is valued by the public, so we are going to, absent any resounding no from you, we will be proceeding with that.

Then, other statements about corporate commitment to sustainability or to use of less toxic ingredients or the like, we also have had a very positive experience with. We have issued a disclaimer language, essentially two registrants, saying if you put it on your web site, it's part of the label, any claims in that regard to the corporate commitment, that could be enforced again if it were abused.

It was acknowledged, actually, at our workgroup meeting yesterday, that, in fact, an enforcement action has been taken against the company whose web site did contain inappropriate assertions, and they would not remove it. So, these things are followed up on. Again, we're going to institutionalize that. So, these items will no longer be a part of the pilot.

Other areas that we have been pursuing are use of biodegradability, the allowance of statements as to

whether or not all of the ingredients in pesticide products are biodegradable or whether a surfactant used in the formulation of a pesticide product is biodegradable. We've had two surfactants that have made it through the DFE screen and then our process internally. They have been allowed to make those statements on their product labels.

The USDA program regarding promoting biobased ingredients, we have had a lot of interest initially in companies being allowed to use that. We were reluctant at first because we were afraid that the consumer may be confused by yet another logo being on a pesticide product label. So, we agreed to allow it in a pilot fashion with a disclaimer at the bottom essentially stating that it does not indicate anything as to the safety of the product. Just by virtue of having a logo doesn't mean it's safe, or safer.

There's a lot going on in this workgroup around the DFE logo and the transition to safer choice. If you're interested in any more information, please let me know. I'm Monell.Marty@EPA.gov. I'll be happy to include you in further conversations about it. That's it.

MR. HOUSENGER: All right, take note, other presenters.

Phil Villanueva is going to talk to us about SmartLabels.

MR. VILLANUEVA: I appreciate this opportunity to share with you an update with our SmartLabel initiative. By show of hands, could I see those of you in the audience that are already familiar with this program, so that I can focus more on the updates. Okay, it looks like a majority of folks. So, I'm not going to spend a whole lot of time on the initial slides, then.

Most of you are familiar that we're undertaking an effort to get our master pesticide labels in a structured format. I have a couple slides to kind of illustrate exactly what that means. It's mainly to address some of the pain points that we have with reviewing the labels and also implementing that information into our risk assessments.

It's part of our vision to have instantaneous access to quality information. We think that will be a large step in improving the quality of the label information that we receive. It is inclusive of all EPA registered products. So, we're working with a group of folks that have conventional pesticide labels, biopesticide labels, and antimicrobials, home use as well products.

We're building on previous work that the FDA

has already done. They have pharmaceutical labels that are submitted to them in a structured format. We're going to continue to work with FDA. We've been working with them closely over the last year or so.

So, some of our label pain points -- I'm not going to spend a lot of time on here. It's a very manual process to extract the label information out of there to support our risk assessment process. Sometimes the label information is unclear or duplicative, certainly inconsistent across different types of labels, and results in various interpretations of the same information.

We're very limited in our ability to query across label types that may have something in common that we're interested in looking at. Here is just a brief illustration of kind of the difference between unstructured information. Typically, even if it's in electronic format, a lot of the information is unstructured, meaning there's no simple way to extract the information out of there, besides a manual kind of copy and paste.

An example of that would be maybe collecting the address information for a pesticide label for the company that's registering it. A very simple illustration of structured data would be getting those

individual fields that would be important for us. That's a very simple example here, but it allows us to kind of grab those bits of information that are easily tagged and importing those into our existing information systems.

So, we'll be looking at getting stuff more complicated than that into our system. For example, this one is a little bit closer to home. Currently, our master labels are unstructured. They are available in PPLS's electronic documents. Sometimes they're scanned. More recently, we've been working very hard to make sure that all of our documents that are in PPLS are actually the PDF versions that are electronically signed to more easily manually extract the information.

Here's an example of two different bits of language that kind of indicate the same thing. Really, what you're interested in in a structured format is being able to capture the mode of action, that it kills whatever the target pest is. So, that's a nice example of how we can capture structured information that can support our risk assessment decisions.

So, we've been working on a pilot. We were really ambitious last year and thought that we'd be able to get through this really quickly. It ended up being something that's very complicated and very hard for us to do. We have several folks working from across all of our

divisions on this initiative. We've also reached out to the registrants so that they can help us to develop what that data model will look like.

So, since December 2014, we've been gathering feedback from the registrants. They are listed up here. We kept it to nine participants, so it's pretty limited, but we think we've kind of come across the whole sector of pesticide products, and also different sizes of companies, too. That's been very important.

Back in December, we basically went through what we're calling the data model, kind of what it looks like. Those were basically Word documents and Excel tables, just to kind of show the granularity of the information that we're hoping to collect for these master labels. So, that was a brief overview in December.

We came back in February, after asking them to go away in December and kind of enter a sample master label into that data model. We got a lot of feedback. Not all of it was good, but it was a lot of feedback. We took that into account. After those meetings, we set up webinars for April and May. Actually, they're probably still meeting upstairs, the team, with the pilot registrants. We're getting a lot of positive feedback from them.

Here's an example of some of the feedback that

we got in December and February. As you can see, it was a very labor-intensive data entry exercise. Our response to that was really we were testing out the data model. This was not the data entry mechanism. In fact, that's coming in the future.

Certain fields were not applicable to antimicrobial products. So, our response to that is that those fields will not be available in our data entry mechanism once you get to it. So, we're working with the registrants to come up with what we call like our validation, our business rules, so that if that's the type of product that you're entering, then those fields just would not show up.

Overly complicated, we are working to simplify that. I'll say something about that briefly. It seemed that some fields were new, but actually, there's nothing new that's required in there. We're just trying to structure and standardize that format.

So, here's some of the pain points. I'm not going to go through that. These are the pain points we covered earlier. Basically, we have a strategy for addressing each one of those pain points. So, here's just a quick list. You have these slides in your documents, so you'll be able to review it at your leisure. You can see some of the benefits and the

different parties that will benefit from addressing these pain points.

So, we've had really good feedback today, actually came downstairs. The second round we developed are guidance document a little bit more to help kind of hold the hands of the registrants as they enter in their master label information. They said it was much easier, much less time consuming.

Part of the way that we simplified the process is that we actually split out. You can see this phased approached. We split out the label sections so that we're collecting data elements and vocabularies. We're providing guidance documents. All that is for the label sections themselves. There is limited structured information that is gathered in that part.

We're going to pilot the X form, which is our web-based data entry mechanism. That's coming up in two weeks. So, we'll be working with them via webinar so they actually get to feel what this data entry mechanism is like. So far they've had to work with Word documents.

In September, we're targeting the use table which is a harder piece of information to rachet down on. It's very complicated. There's a lot of information that we want to collect. Also, we found, again from our feedback from the registrants, that it was kind of

combining two different aspects of their business process. They have the folks that kind of develop the labels, what you actually see on the label, and then they also have their risk assessment folks that are more familiar with the use tables and what would be particularly useful for risk assessment. So, we're kind of splitting those two pieces apart right now. We're hoping to bring those back together, but it's a phased approach that kind of tackles those separately so we can deal with the same set of folks for each one of those sections.

We're going to continue to collaborate with the states industry and FDA. We've done a number of outreach efforts. Last month, we went to the all-star meeting. We have SFIREG contacts. We've been updating some of our state partners individually as well.

So, I don't want to take any more time. There's more information on the web site. These are the project leads, in addition to myself.

MR. HOUSENGER: Thanks, Phil.

The next update is regarding a couple rules we're doing to further protect farmworkers and pesticide handlers. Kevin Keaney from our Field and External Affairs Division is going to give that update.

MR. KEANEY: When the worker protection changes

went out for public comment, we had a table on our web site that outlined the existing provisions and then the proposed changes relative to those existing positions. Those that didn't dutifully make a copy of that when it went out, I'll put some of these on the table and distribute them. When we go final, we'll have another table that will do the same but indicate the final position relative to our assessment of comments.

As you noted in the blurb I put in your packet, there were an enormous amount of comments. There was quite a bit of heavy lifting from my staff, relatively small staff, to deal with that and then decide and work through as a team what we would do as to the reaction of the comments, maintain our position as proposed or change our position.

There were a lot of useful comments. There were, of course, a lot of surveys, check off the box types of things that weren't particularly helpful for us, but there were a lot of useful comments relative to the ease of implementation or the ease of enforcement, or lack of it, by what we were proposing. So, we did change a number of our positions as a result of the valuable comments we got.

We put together a response of comments document. We have rewritten the regulatory text and the

preamble justification for our changes. The regulatory process within the agency is to put it through final agency review, which has the other offices that have interest in it, to concur or concur with comments.

That package is in the process now. It's in an expedited process. We do then send the package to USDA. We send it to Sheryl Kunickis' group. That package has gone there. When we get an indication it's been received by the secretary's office, Sheryl's particular review would take place. It has a minimum of 15 days review.

Then, at some point down the line, we'll be sending it to the Office of Management and Budget. If they maintain their schedule, we maintain our schedule, it should be coming out final at the end of August or the beginning of September.

There's a phased implementation. We've developed and will continue to evolve a plan, a strategy for how to implement, and how to communicate, and how to engage a variety of stakeholders we have in this exercise, so everyone understands what we are trying to do, what the regulation actually sets up in its final form.

There would be various segments we would focus on, obviously, because the obligations would vary, whether you're an agricultural employer, whether you're a

worker, a handler, or an applicator. So, there will be a fairly extensive engagement over a year or so as we are moving towards complete implementation.

So, that's pretty much what's going on and will be going on with the ag worker protection regulation. We are also amending an older regulation, the pesticide applicator certification regulation, that tries to establish competency standards for the applicators of restricted use pesticides. That has been sent to OMB, the package that will go out for public comment.

We anticipate, if everybody keeps to the schedule, that that will go out for public comment in July. It will go out for a minimum of 90 days and usually gets petitioned for an additional period. So, it's quite likely to be out for public comment for 120 days beginning sometime in July.

So, we'll be doing a lot of engagement, a lot of webinar, a lot of communication, again like we did with the worker regulation so that people understand what we're trying to get at with this proposal and how they can best comment productively on the proposal to help us work through, again, the choice of what we proposed as final or variations, depending on the value of the comments that we receive.

Two very significant regulations covering a

very large population of agricultural labor and the current applicators are numbering in the millions, certified applicators. Obviously, the worker population in agriculture covered by the regulation is in the millions as well.

There is a provision in the certification regulation that others can apply restricted use pesticides under the supervision of a certified applicator. We, frankly, don't have a real way to determine that number, but it's a significant number of those that are applying under the supervision of a certified applicator. So, that adds to the population that would be affected by both of these regulations, because very often those that are applying under the supervision, called handlers, are in that pool under the agricultural worker protection regulation.

So, we are trying to address safety precautions and the safety training that would be appropriate for those that apply under the supervision. Currently, there's no provisions to do that. As I said, it's a wide-ranging pair of regulations, all addressed to, essentially, pesticide worker safety. I'll take no questions later.

MR. HOUSENGER: Smart.

Our next speaker is Jeff Dawson from the Health

Effects Division. He's going to update us on spray drift and volatilization policy.

MR. DAWSON: Thank you. It's a pleasure to be here. Just a brief update about where we are on the spray drift and volatilization policies. I just remind everybody that the spray drift policies, there were two documents that were put out. One was related to human health, and the other was related to ecological risk assessment. Then we put out a volatilization policy, which was really a screen of the conventional chemicals where we identified some subset of those chemicals that we need to do some additional work for.

These comment periods are both in 2014. We envision that we will go forward with these in the registration review process. We also envision that this will be a living document kind of approach where as we get additional information, we can make refinements to these policies. That's what we'll do as we move forward into the future and through registration review.

Some of the immediate goals for 2015, we want to finish response to comments documents for all these documents that we put out. We also have some technical review of additional data that we need to complete. We're, of course, working on revisions to the polices based on the information that was submitted in the review

process.

We're also working on implementation plans, particularly focusing on the volatilization and some of the next steps associated with that. We're also thinking about ways to continue stakeholder involvement and lines of communication as we move forward. This will be helpful with the living document approach.

Then, there's some related issues. For example, you're going to hear just after me a discussion of the drift reduction technology issue. That certainly plays into the policy and the overall implementation of the policy for spray drift.

Just a couple quick overviews of what we're looking at and what we're trying to work through at this point in time. For spray drift, we basically received about 5,600 comments. They raised several science-related topics and also some policy-related topics. The science issues really predominantly focused on how we're doing the drift calculations themselves. For example, we've been made aware and had additional data submitted that we need to look at to potentially refine how we're doing the drift estimates.

There are also some comments about scope related to different kinds of use situations, for example, forestry uses, particularly in the Pacific

Northwest. It's a little bit different there because of the terrain and the application methods. So, we're thinking about ways to better address that in the updated policies.

Also, related to mosquito control and the potential for exposures from mosquito control operations. Policy topics on spray drift really are related to continued stakeholder involvement and having open lines of communication. Some issues related to stewardship, for example, we want to implement drift reduction technology, but how do we do that and how do we work through, for example, development of label language to have continuity and enforceability and all those issues through the process.

Also related to implementation, this is an example. One of the options that could come out of this process is the implementation of buffers under certain circumstances. So, how do we implement buffers in the best, most effective way possible? I would perhaps point to the process that we use for soil fumigants as maybe a framework, starting point, for how we might do that.

A little bit on volatilization, we screened all the conventional chemicals. Approximately 70 of them, and I'll air quote this, failed the screen, which basically means that we need to get some more information

to refine how the potential risk picture looks for those. When we did the screen, we did it using the methods that we laid out in our 2009 process that we took to the SAP that year. We used the best available information that we had. All this information is in a particular docket for volatilization.

So, now we're looking at ways to refine and better inform the process, particularly for the ones that we identify potential issues with. That could be, for example, getting better inhalation toxicity data, better use information, and better constructure information around how we would predict the emissions or the flux, which is really the exposure component of that analysis.

Then, kind of the policy-related topics are, what processes are we going to use to get to the next steps. For example, in some cases, we may want to issue data call-ins or there might be just information that the impacted registrants look at the analysis they will have and just provide it to us.

Then, the other thing that's important here is, again, continued communication and stakeholder involvement. Thank you.

MR. HOUSENGER: Thanks, Jeff.

Anne Overstreet isn't here, so Tracy Lantz is going to give us an update on drift reduction technology.

MS. LANTZ: Thank you, Jack.

Just a real quick updated today. OPP has received the first application for a DRT star rating for a series of products. This manufacturer is the first of several interested in developing and submitting data to participate in a DRT star-rated program since the program officially launched in the fall of 2014.

FEAD and EFED plan to meet with the applicant to finalize the submission package and discuss some technical questions, and then we plan to brief management with a time line for review and assessing this star rating.

We have also developed a template for DRT submission, including guidelines for formatting and analysis of spray drift data needed to assign the actual rating. We have, as of today, posted that template on our DRT web site to provide guidance to these applicants.

In an effort to increase outreach and participation in this program, we've made presentations to state, local extension services, and industry groups, and these presentations are ongoing. Questions raised include implementation, enforceability, and timing of DRT technologies appearing on labels.

To find more information on the DRT program, you can view our website at www2.epa.gov/reducing-

pesticide-drift. Thank you.

MR. HOUSENGER: Thanks, Tracy.

The next update is on the repellency graphic. Martha Shimkin from FEAD is going to give that.

MS. SHIMKIN: So, the repellency awareness graphic is a voluntary program that will give approved use to registrants of tick and mosquito repellants, a standardized graphic that would depict how long that skin-applied repellant would work. Its goal is to provide clear information to consumers so that they can have confidence in the use of repellants and how long they would work against ticks and mosquitos.

We started working on this voluntary project about five years ago, and we did come to the PPDC and worked with the comparative safety statements and public health workgroups under the PPDC, and benefitted from your input, and insight, and advice as we developed this program. We launched it in 2013 with publication of a guidance. Our last update to the PPDC last summer, I think it was, is that we are open for business. We are still open for business. That's today's update.

We have seen interest from registrants in applying for and getting approval of this repellency awareness graphic. We have not yet approved any uses, but we hope to be able to see this graphic being used on

products possibly as soon as 2016.

We want to see the use of this graphic. We know that from our research that we did, it will very likely increase consumer confidence in the repellence against ticks and mosquitos, which would increase consumer use of those repellents and, therefore, increase their protection from vector-borne diseases. That is the update. Thank you.

MR. HOUSENGER: Thanks, Martha.

Next update is on glyphosate, which has been in the news recently quite a bit. Neil Anderson from PRD is going to give us an update.

MR. ANDERSON: Thanks, Jack. So, as Jack mentioned, glyphosate has been in the news a little bit lately, I guess from our perspective, where we are in the reevaluation cycle for glyphosate. That's why I'd like to talk a little bit about it this afternoon.

The registration review for glyphosate began a number of years ago now with the initial docket opening where we published our preliminary work plan and additional documents which identified the types of assessments that we've previously conducted for glyphosate and the anticipated plan for the registration review cycle for glyphosate.

We followed that with an issuance of the data

call-in to registrants identifying or requiring submission of a handful of data requirements, both on the ecological side of the exposure potential from glyphosate, but also on the human health side.

The registrants have completed all the data that we required them to conduct, and have submitted that information to the agency. We have been working over the last couple years reviewing all the information, as well as the entirety of all the other information that's available for glyphosate that's become available, either through public literature or other studies that have been conducted around the world. Our team here has been very actively reviewing all that information and preparing the risk assessments, the registration review risk assessments, for glyphosate.

Along those lines, there will be released in the next couple months the risk assessments for public comment. There will be an ecological risk assessment which will be a comprehensive review of all the potential uses of glyphosate and their potential impact of the exposures from glyphosate on the various taxa that could be exposed from exposure.

This assessment will not include an endangered species risk assessment, however. There will also be the human health risk assessment, which will include a full

review and evaluation of the existing body of toxicity data available for glyphosate and will present the agency's estimates of the risks associated from exposures for humans.

In addition to those assessments, we anticipate putting out a document which discusses the issues for weed resistence to glyphosate as they've developed within the United States. There will be an evaluation, if you will, of the extent or the amount of acreage and weed species that have developed resistence to glyphosate, as well as present a number of potential resistence management tactics that may be employed to combat resistence.

The agency has been coordinating our reevaluation with glyphosate with Canada's pest management regulatory agency. We've been collaborating throughout the entire process and coordinated even the data requirements, as well as review of the data as they've become available to us.

So, there is more information available on our review. In the handout that was provided, the web site is listed there where you can get more information about that.

One of the other things that's been, I guess, in the news for glyphosate and just briefly mentioned

here is about the correlation between glyphosate use and the potential impacts on monarch butterflies. We received a petition last year from the Natural Resources Defense Council to review and evaluate this potential impact.

We are conducting a review. As part of the ecological risk assessment, there will be a portion, if you will, that will be looking at that potential exposure and impact on monarchs as well as other invertebrate species.

We are cooperating with the other government agencies in the overall review as part of kind of a larger global effort on the impacts on pollinators. Monarchs are going to be considered as a part of that. We are cooperating with the Department of Interior and our international partners in North America, Canada, and Mexico.

As we are going to be looking at this particular issue, we're really not going to remain focused just on glyphosate. The particular issue as it's been brought up is how glyphosate and other herbicides have the ability to control the milk weed plant, which is a vital resource for monarchs. So, it's not unique to just glyphosate; it's actually across many herbicides that are used in agriculture and in other areas.

So, our review will be holistic across the potential impact from herbicides use on various landscapes and how that may potentially impact populations of monarch butterflies. We'll be responding to the NRDC petition this summer. I guess that's basically it as it refers to glyphosate right now.

MR. HOUSENGER: Okay, thanks, Neil.

Our final update comes from Bo Davis from Registration Division regarding comparative efficacy claims.

MR. DAVIS: Good afternoon. So, the Registration Division currently has in house a PRIA action where a company is requesting that we add comparative claims to the label. The claims imply in one way or another that their product is more efficacious than another product.

The agency has historically not allowed comparative efficacy claims on labels. Therefore, if we end up approving this action, it will be precedent setting, and it will also open the door for other companies to submit similar types of actions.

Since initially receiving the action, we've had multiple internal meetings with upper management, product managers and also efficacy reviewers. The discussions have not only been focused on the action in house but

also have been more broad in about how we should handle and review these types of actions. From the discussions, we've come up with a list of questions and also some initial concerns. It's these questions and concerns that we will eventually like some feedback and some guidance on.

On the question side, the first question that is most prevalent is what type of data would we like to see. Currently, we only require the submission of efficacy data for public health pests and structural pests. We do have guidelines for those that give some recommendations and guidance on how to conduct the trials.

However, they are very much focused on just determining if the product is efficacious enough to be on the market. We do not currently have guidelines or guidance for comparing two products that are already registered and comparing their efficacy.

Along the same lines, we also have questions regarding how to define topics. For instance, better, how much higher does the percent mortality need to be before you can say your product is better than another product? Speed of kill, what's the difference in speed of kill before you can say your product is faster than another product? What's the difference in residual

activity before you can say your product lasts longer than another product? So, you can see that the experimental design of whatever is submitted is very specific to whatever the claim is.

On the concern side, we have several concerns, initial concerns. The first is if we start receiving actions like this, how will we handle them for products that we historically have not required efficacy data for? For instance, herbicides, fungicides, and then also insecticides that are labeled only for pests that are not public health or structural.

Another question that we have is, how will we handle "me-too" registrations? An example I'd like to give would be let's say we stamp a label with a comparative efficacy claim. Then, after that, five other companies come in and "me-too" that registration. So, they also have the claim. And then all of those products are also "me-too'd" by other companies. Now the claim is out on multiple different products.

How do we handle situations if a company comes in and provides efficacy data where the outcome is contradictory to the original submission? So, the question is, does that mean all the labels out there are misbranded? If so, we need a process in place to be able to handle that.

There's also questions on how that will impact the states. We broached the subject at the last SFIREG meeting. After thinking about it for a day or so, they came back to us with similar concerns, questions of what type of data would we need and how would we make the determination of is the claim false or misleading.

Finally, meetings with upper management. One idea that was thrown out is do we need some sort of external review or third party verification. If so, who would that be? Perhaps the Federal Trade Commission. If we do go down that road, we'll need to have dialogue with them and then develop an MOU.

So, that's where we're at right now, more questions than answers.

MR. HOUSENGER: Well, that's a mess.

So, this brings us to the public comment portion of our program. We have one person who has signed up. I haven't seen Julie. Oh, there she is. Julie Spagnoli representing herself.

MS. SPAGNOLI: I just wanted to make a little comment regarding mosquito control. When I was a girl growing up in Minnesota, mosquito was considered the state bird. The best day of summer was when the mosquito truck came through. We were excited, the mosquito truck is here.

I now live in southeast Mississippi. In addition to mosquitos, now I'm learning to live in harmony with fire ants and black widow spiders, but that's life.

I was a little bit concerned about the description of mosquito products as a problem being they can be used anywhere, and that that's somehow problematic. Mosquito-control products are used where they're needed to protect people from mosquitos. For example, no mosquito-control products are used in the Florida Everglades where there's millions of mosquitos being born, but they are used in Coastal Florida where those mosquitos go. That's where the products are used, where people live and where they need to be protected.

So, the need to be applied anywhere is really necessary because you don't know where that need might arise. Natural events, such as floods and hurricanes, can result in mosquito populations that weren't previously there.

For example, in the State of Mississippi, right after Katrina, there was a sudden explosion of mosquitos, populations of mosquitos, at the same time people were living in temporary housing, including tents, where they didn't have protection from those mosquitos. As a result, emergency funding was granted to 49 counties in

the State of Mississippi for mosquito control in the areas that had been declared disaster areas. So, these were not areas that had previously been treated for mosquitos, but as a result of a natural disaster, suddenly there was an emergency need.

I actually wish you could hear the story from Dr. Jerome Goddard. He's the medical entomologist at Mississippi State University. He's much more entertaining. If you've ever heard him speak, he's the best person ever to hear speak on public health pests.

What happens in the case of a product that's only limited to use in the two or three counties where it was routinely used and you have a natural disaster or this kind of a thing, floods in the Midwest or hurricanes in the South?

So, mosquito-transmitted diseases are truly a serious issue. We know millions outside the U.S. die from malaria and other diseases. But even within the U.S., I think we had a wake-up call with West Nile Virus. In 1999, there were 62 cases of West Nile Virus, all in the State of New York. In the year 2000, that had expanded to New Jersey and Connecticut. Up until the last few years now, it is in 47 states and the District of Columbia, reported cases of West Nile Virus resulting in thousands of cases and hundreds of deaths.

It doesn't take that long for a mosquito-transmitted disease to reach national proportions. Though there's still no vaccine for West Nile Virus, now you look at diseases like Eastern Equine Encephalitis which, while it's still very rare, has a mortality rate of around 30 percent, either mortality or severe brain damage. So, even while it's still very rare, when it does happen, it has to be addressed, because the consequences are so high.

Now we have Dengue and Chikungunya. Dengue is not a new disease. It affects a lot of proportion of the world, but we have now seen cases in the United States. It's also known as Break Bone Fever because the pain associated with the disease is so strong that it makes you feel like your bones are broken. So, Chikungunya is, likewise, a fever and joint pain.

Neither of these diseases have any vaccine. The only real method of trying to keep them away is by controlling mosquitos, or repellents are useful. Really, repellents in conjunction with reducing mosquito populations is a way to try to keep these diseases at bay.

So, the fact that these diseases are maybe only seen in a few localities within a couple of states, it

really isn't any reassurance because we see what happened with West Nile Virus. It was a few cases in one state, and a few years later it's across the country.

So, the bottom line is that in mosquito control, we're looking for new global tools. We heard about the Gates Foundation efforts. That's good, but we also need to look at maintaining the tools that we have, especially for controlling resistence. So, I think as we look at how we're reassessing these products, I think we really need to look at some flexibility in how we assess mosquito-controlled products to make sure that we don't inadvertently lose some of the most valuable tools that we have for controlling mosquitos.

That's it, thank you.

MR. HOUSENGER: Thanks, Julie.

Are there any public comments from the phone? I guess not.

Any other public comments before we conclude?

MR. GRAGG: This is Richard Gragg from Florida A&M. I am just going to send my comments on the e-mail to Dea.

MR. HOUSENGER: You don't want to tell us now?

MR. GRAGG: I guess I could. I just had some comments from this afternoon up to now. There are just three.

I'm saying that I understand the reason and logistics of the state-based protection plans, but from what I heard on the discussion, it seems to be that EPA should consider some baseline uniform requirements for all state plans. That may assist in gathering data on the universal BMPs, and it also may present an opportunity to collect incident data as it relates to applicators and pollinators.

Then, for the web page discussion, I went on the web page. I think there needs to be some more visibility as it relates to environmental justice and the significant EPA policy actions tools and guidance that has taken place. I just think that's lacking on the revised web site. I think it would be beneficial for both EPA and the EJ stakeholders.

Then, my last comment is really a question. In what role does mosquito control play in this whole issue around pollinators and pesticides?

MR. HOUSENGER: All right, thank you very much.

MR. GRAGG: Okay, thank you.

MR. HOUSENGER: Anyone else? If not, we'll convene tomorrow at 9:00 a.m. and hear about school IPM. Have a good evening.

(Whereupon, the meeting was adjourned.

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