UNITED STATES

ENVIRONMENTAL PROTECTION AGENCY

PESTICIDE PROGRAM DIALOGUE COMMITTEE MEETING

DAY ONE

May 18-19, 2016

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 to the spring PPDC meeting. Before I go any further and talk about what we're going to be doing, I'd like to turn it over to Jim Jones. I think most people know him. He's been here for not quite as long as I have, but a long, long time. I know he's been busy on the Toxics side of things, so we're happy to have him here.

So, Jim, take it away.

MR. JONES: Thanks, Jack. It's always good to be with this group. But yes, set your Google alert to toxic reform today. There might be some interesting stuff happening there. That's where I'm going to have to run off to at 9:30 to work on some issues in that space.

So, welcome, everybody. It's good to see all of you. I was thinking as I was coming in this morning that I'm beginning the last six or seven months of my tenure here and working on these issues. I was thinking about the PPDC and its history. I think it's probably about 20 years old, thereabouts, maybe a little older than that.

I was a branch chief in Registration when it started under Dan Barollo's tenure. I thought he was ahead of his time in that respect. It was the best practice he brought from New York State, and I think this is the kind of advisory FACA that has served this organization really well for 20 years.

Over that period of time, we've had a lot of assistant administrators. They've come and gone, various stripes, Republicans and Democrats. We've had a series of office directors, some really good, some not so good, come and gone. I'll talk about myself in the not-so-good category. Hundreds of hard-working, dedicated employees who have worked in this office. I've been really fortunate to have been a part of it at multiple different aspects of this program for many years.

I will say the one consistent thing that has, in my experience working in and with this program over that period of time, and I'm sure it was before then, and I'm sure it's going to be after then, is the degree to which hard-working individuals at all levels of the organization are doing their best to do their jobs to protect public health in the environment and make smart

decisions for the United States as it relates to pesticide use.

That theme has run consistently, no matter who the president is, who the administrator is, who the assistant administrator is, who the office director is. It's basically sort of the core of the program. Making decisions in this space inevitably comes back to science. There's just no way to make decisions without embracing the science.

Our understanding of chemicals has changed pretty significantly over that period of time. This program has always embraced it and has always put that as a forefront of decisionmaking. I just say that because I hear a lot in the world out there of just how political we are.

I'm sure you're not going to believe the only political appointee in the room, but I've been here for a long time. I've worked with a lot of people. What I've experienced in that period of time is a consistent embracing of sound science to make really important decisions. Like I said, I've seen it play out through administrations of every stripe, different personalities,

and I’m pretty confident that that embracing is going to be here long after I am, and this leadership team is.

The other reason I mentioned that is I think it’s important to acknowledge that although it’s an extraordinarily hard-working and dedicated group of people, sometimes we make some mistakes. Sometimes those mistakes nobody ever notices at all -- most of the time that’s the case -- and sometimes they’re glaring in their nature. It’s not necessarily because of a mistake, per se, but it’s about what the mistake involves.

I’m referring now to the inadvertent release of some documents a couple of weeks ago. Ultimately, there’s all kinds of investigations going on around it. I’m hear to tell you they were the mistakes of some hard-working individuals who thought they were supposed to be posting something that they were not supposed to be posting. There was no conspiracy around it. It was an honest mistake by some honest individuals. The reason why the documents shouldn’t have been posted is because we weren’t done yet.

But I recognize why that can easily be thought of -- the context around the mistake can be easily

construed into being somebody got their finger on the scale, or that there's some other nefarious motivation behind it. Time will tell, as there are enough independent entities, not just us looking into it, looking at what happened. I'm confident that when they're done with their evaluation, they will see it is what I'm describing to you today. I thought that was just important to sort of put that out there, because I'm sure it's on the minds of many people in this room.

Again, one of the themes that I routinely speak to at this meeting over the many years I've had an opportunity to is how critically important it is to have an open government. But I recognize how hard it is to participate in an open government, especially in an issue as complicated as these issues are. They're not really amenable to hearing about something for 10 minutes and being able to figure out what the solution is.

I say that in recognition to the incredible amount of time and energy all of you put into participating what is an open government forum. It isn't just the day and a half that you're here today and tomorrow; it's all of the time in between these meetings

that you spend trying to stay on top of the issues that are most important to the healthy functioning of a pesticide regulatory program.

I recognize how labor intensive that is for each and every one of you. I just want to thank you because you can't have a participatory government without individuals like yourselves who are willing to roll up your sleeves and really dig into very, very complicated issues to give us your best advice.

So, thank you for all that you have done and all that you are going to do. As usual, the pesticide program has got an incredibly relevant agenda, some of the really challenging issues that wouldn't just resonate around a room like this, people who are really inside the issues, but would be relevant to anybody who reads the newspapers in the United States. That's often the way the issues that we deal with are.

So, again, thanks very much. Sorry, but I will have to leave around 9:30, but thanks, Jack.

MR. HOUSENGER: All right, thanks, Jim.

So, we've taken the advice of the PPDC, and we've kind of made some changes to the agenda. The first

one is that we sent out some updates early on, I think last week, and they're in the packets. There's three updates, School IPM, WPS Implementation, and Cumulative Risk Assessment. So, you have those. We've allotted some time to discuss those if there are questions, but we didn't want to make formal presentations on them. We wanted to give you information in advance.

We also have fewer topics, so there's more time for discussion. As you go down the agenda, I think you'll see some of the topics that will probably create a lot of discussion, pollinators, ESA, chlorpyrifos, which seems to get a lot of attention, incidents, resistance management, international activities. These were all suggestions made at the last PPDC that people wanted to hear more about or suggestions that we've received through e-mails and so on.

And, of course, Zika, which you read about every day. Zika is coming to the mainland soon, so Marty is going to talk about that. We've put in a lot of time and effort on Zika, as have a lot of other federal agencies. We'll bring you up to speed on our part of it.

We have a new audio system, so you're going to

have to share. There's one for every two people. I don't want any fights. I guess we can have up to six people talk at one time. I have a button. If I don't like what you're saying, I can just cut you off. I think I may use that. So, turn up your tent cards when you want to be called on. We also have a teleconference line that is on global mute. So, we will control the muting and unmuting. So, don't unmute your phone unless we ask you to.

There's a public comment session at the conclusion of each day. You can sign up to speak. Public comments should be limited to two or three minutes each. Sign up at the registration table.

Let's start with the introductions. Oh, no, not yet.

So, since the last PPDC where we announced that Bill Jordan was leaving, there's been -- and Bill is here today. I thought he was leaving, but he seems to keep coming back. So, with Bill's absence, Rick Keigwin was promoted to Bill's old spot, the deputy office director. Replacing Rick in PRD is Yu-Ting Guilaran. Replacing Yu-Ting in BEAD is acting Winnie Miller. Don

Brady left.

I'm not sure why everybody is leaving once I become office director, but it seems to be a trend. Don Brady retired. He had 42 years in, so he thought it was time to leave. We're rotating the deputies. Anita Pease is currently acting EFED director. Jim Coles will be after Anita's four-month stint. Also, Marty Monell has told us that she is retiring. That will happen at the end of June. Susan Lewis, RD Director, has announced her retirement.

Since the last PPDC, we've brought in Delores Barber from Department of Homeland Security to head up ITRMD. The only other one I think is Michael Hardy has accepted a promotional detail in OECA, so he'll be leaving -- oh, OARM, sorry. So, he'll be leaving for a year. Maybe it's time to go. So, that's that.

Since the last PPDC, I just wanted to talk a little bit about some of the highlights that OPP has had. These aren't all of our accomplishments. In terms of new AIs registered, RD has two new import tolerance decisions and three proposed decisions on new AIs, halauxifen,

dicamba and yesterday, sulfoxiflor.

BPPD has registered eight new biologicals; they've denied three. AD has registered two new AIs. One is partial ETO, ethylene oxide replacement, which is good news. So, we've got 12 decisions so far, and more to come.

In terms of registration review, PRD has opened 33 dockets and issued 14 draft risk assessments. AD one docket, one draft risk assessment; BPPD six dockets and no risk assessments. So, we're making good progress on registration review as well.

Like I said, Zika has consumed a lot of our time. We've issued a couple section 18s. One involved the bait station, involving low-hazard pesticidal ingredient. Another to treat bed nets with an insecticide. We've got a couple more requests pending. We've also fast tracked 75 amendments and 15 chemistry amendments that will help provide available product to meet the demand over the summer for Zika.

WPS rule, we talked about it last PPDC. But, since then, it actually issued on November 2nd. It is effective on January 2nd, 2017. We've also issued crop

grouping number 4 that expands and sets, creates new crop groups, including leafy crops, brassicas, and some tropicals and subtropicals.

We had an SAP meeting in April on chlorpyrifos. We'll be talking about chlorpyrifos a little later on the agenda. You'll hear about today's new PRNs, pesticide regulation notices, for resistance management that we're getting ready to issue.

We also reached an agreement with the registrants of BT Corn, measures that are designed to not eliminate but delay resistance to the corn rootworm. We released biological opinions in April. In December, we put on the internet 12,000 or so pages that backed up those assessments. But those are the first three in a pilot of five coming out of the National Academy recommendations on how to proceed on ESA.

Pollinators, we released the imidacloprid draft risk assessment in January. I've already gone over the personnel changes. So, just a few of the highlights.

So, why don't we start with the introductions of everyone. I'm Jack Housenger. I'm Director of the Office of Pesticide Programs.

MR. KEIGWIN: Rick Keigwin, Deputy Director for Programs, Office of Pesticide Programs.

MS. BURD: Lori Ann Burd, Center for Biological Diversity.

MR. BUHLER: Wayne Buhler from North Carolina State University, representing the American Association of Pesticide Safety Educators.

MS. CLEVELAND: Cheryl Cleveland, BASF.

MR. LAME: Marc Lame, Indiana University School of Public Environmental Affairs, representing the National Environmental Health Association.

MR. WHITE: Mike White, Council of Producers and Distributors of Agrotechnology.

MS. RUIZ: Virginia Ruiz, Farmworker Justice.

MR. KUNKEL: Dan Kunkel, Associate Director, IR-4 Program.

MR. SANCHEZ: Valentin Sanchez, Oregon Law Center.

MR. GRAGG: Richard Gragg, Florida A&M University School of the Environment.

MS. D'AMATO: I'm Annie D'Amato, representing Beyond Pesticides.

MR. WHITTINGTON: Andy Whittington, Mississippi Farm Bureau Federation for American Farm Bureau Federation.

MR. McLAURIN: My name is Allen McLaurin, representing the National Cotton Council, and also a cotton producer from North Carolina.

MR. DELANEY: Tom Delaney, Georgia Urban Ag Council, which is the lawn and landscaping side of industry.

MS. SELVAGGIO: Sharon Selvaggio, Northwest Center for Alternatives to Pesticides.

MS. BISHOP: Pat Bishop, People for the Ethical Treatment of Animals.

MR. TAYLOR: Donnie Taylor, Agricultural Retailers Association here in Washington, D.C.

MS. WILSON: Nina Wilson, representing the Biopesticide Industry Alliance.

MR. HOUTMAN: Bruce Houtman, Dow Agrosciences.

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

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

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

MS. GILDEN: Robyn Gilden, University of Maryland School of Nursing, representing the Alliance of Nurses for Healthy Environments.

MR. COY: Steven Coy, representing the American Honey Producers Association.

MS. LIEBMAN: Hi, Amy Liebman from the Migrant Clinicians Network.

MR. McALLISTER: Ray McAllister with CropLife America.

MS. CODE: Aimee Code with the Xerces Society for Invertebrate Conservation.

MR. ROGERS: Jeff Rogers, Virginia Department of Agriculture, representing the Association of American Pest Control Officials.

MS. PALMER: Cynthia Palmer, American Bird Conservancy.

MS. STUDLIEN: Susan Studlien. I work in Region 1 of EPA up in Boston. My region is serving a coordinator function between our headquarters office here in Washington and the 10 EPA regions.

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

MR. JONES: I'm Jim Jones, Assistant Administrator for Chemical Safety and Pollution Prevention at EPA.

MS. MONELL: Marty Monell, Deputy Director, OPP.

MR. HOUSENGER: Okay. So, our first agenda item is the topic updates. We have various people within -- oh, I'm sorry, the phone. I guess we have to unmute them to hear them. For the members on the phone? Thank you, Marty. I don't know what I'm going to do without Marty.

MS. MONNEL: Get a maid.

MR. HOUSENGER: You can tell she's a short-timer.

No members on the phone?

MR. GJEVRE: This is Eric Gjevre, Coeur d'Alene Tribe, representing the Tribal Pesticide Program Council.

MR. HOUSENGER: All right, thank you.

Now onto topic updates. I guess we'll just open it up for questions, since these were provided in written

form. So, maybe we can have the relevant people from our organization up here to answer questions.

Marc

MARC: Thanks, Jack. Of course, I want to talk about the school integrated pest management. I do have a question on that. I want to recognize, or acknowledge, that over almost 20 years, there's been tremendous progress. It's been slow, but tremendous progress on this. So, I'm gratified. As a parent and as a taxpayer, I'm gratified. I do believe that the Agency has pretty well, at least out of headquarters, developed a good diffusion process, which I hope they continue.

My question goes to the coordination, or my concern of the lack of coordination, with the regions, realizing that this is a really difficult situation, you know, trying to coordinate with the regions and that kind of thing.

So, as a university administrative coordinating facility it's like herding cats, and I suspect you have the same problem with regions. But I do feel that if -- I won't say anything about the northeast, but I do think that if you want to reach your goal, which I think is

entirely achievable, that there probably does need to be an increase in coordination with the regions. I'd like to know what plans there are for that. So, Bob?

MR. McNALLY: Thanks, Marc Bob McNally, the Director of the Biopesticide Division. Susan can elaborate on this. School IPM is still one of the regional priorities this year. So, we essentially have a person in each region who spends part of their time helping to disseminate information on school IPM.

Obviously, the regions have been under pressure with resource cutbacks, so they're balancing a bunch of initiatives, including school IPM. So, the Center of Expertise in Dallas and Frank's staff here in D.C. work on a pretty consistent basis with the regions to try to disseminate information on school IPM, try to implement what we call a wholesale approach to school IPM, which is not necessarily going out to every school, but maybe going to meetings of school administrators in Boston, let's say, or in Massachusetts, or working with the PTA groups out there. So, that's the intent; that's the plan.

I don't know, Susan, if you want to elaborate

on some of your own experiences in New England.

SUSAN: Well, first of all, I want to commend Bob and his group. The Center of Expertise, they have been outstanding at providing monthly updates to all of the regions. We post those on a Share Point site for everyone to see.

I think what the regions have done is pretty much what Bob has indicated in terms of trying to -- and this is certainly true in my region -- trying to meet with large groups as opposed to individual schools or sites, and to get the word out that way. We've done that with respect to the roundtable that's going to be held next week here in Washington.

So, I think, actually, the current approach to regional work has been really quite good. I think the Center is very, very active. They have produced lots of valuable products in terms of outreach that is currently being used by all of the regions. Is that helpful?

MR. HOUSENGER: Robin, is your question on school IPM?

ROBYN: I'd just like to echo Marc's congratulations on all the hard work that EPA has done

and the work group has done. I had two questions. I see a lot of nursing collaboration, so I'm very happy about that. I just wanted to ask how the prior nursing conference interaction has gone.

Also, I noticed Dea had sent out an e-mail with some logistic information, and she also had sent some recommendations of topics for work groups that would be discussed here. I see a formation of the public health subcommittee, but I know that several of us have been interested in forming an official subcommittee on IPM, but I didn't see that make the list. So, if you could comment on that, please?

BOB: Thank you, Robyn. Frank probably could talk a little bit more about the individual interactions with the nurses. I will say this, that we've worked with them for the last two or three years, and they've been among the more forceful spokespeople for the importance of the school IPM approach. So, we really applaud their interactions and appreciate their help.

Frank, maybe some of the day to day stuff you could cover.

FRANK: Yes, we've had, I think, an ongoing and

productive relationship with the National Association of School Nurses over the years. I think, Robyn, you've helped introduce us to some other nursing groups. As we led up to this roundtable, we've had discussions with other organizations that we're just becoming familiar with.

Bob and I had a conference call recently with the State Nurses Association, the organizations of nurse consultants who work at the state level on nursing issues, not just in the schools but across the board, and recruiting them for the roundtable.

That was an organization that we had not had familiarity with. Actually, one of our regional school IPM coordinators tipped us off to this group and made introductions on our behalf. So, as we go down the road of the roundtable that we're having next week, I think our network is growing, and we're having, I guess, increased interaction within the nursing community as a whole. I think it's been very productive.

BOB: Your second question, I think maybe there's time in the agenda later. I think your question is, should there be an IPM PPDC work group. I think

we've heard that suggestion. I think the management is considering the ways to handle those kind of new work groups.

MR. HOUSENGER: Virginia?

VIRGINIA: Good morning. My question is similar to Marc's around the issue of the worker protection standard. I want to thank OPP's headquarter's staff for meeting with stakeholders. I just wanted to ask about that sort of outreach at the regional levels on the update.

There is a lot of information about training for regional regulatory partners, but I would like to hear a little bit more about communication with other stakeholders, in particular, farmworker organizations at the regional level and perhaps more information about how people on the ground can pursue more communication or make those contacts with the region.

MR. KEANEY: Well, as you can see by one of the things that was distributed to you, my staff, really small staff, is pretty aggressively involved in outreach and communication and on a number of levels. It did make sense to begin with the state regulatory folks

and the regional folks so they could fully understand what the changes entailed and how they could deal with the work that's coming their way.

But we have been pretty aggressively soliciting folks that are interested in getting webinars or getting walkthroughs on Power Points as to what's entailed in the worker protection regulation, and what the implications are for those that are service providers or training materials, developers, and so forth.

So, we have a number of grants, multi-year grants that we are going to be using to help us develop the necessary changes to training materials and to build sort of the suite of materials that would be necessary for the state regulators and the folks in which the basic burden falls, that's the agricultural producers.

So, we are going to develop an updated "how to comply" manual, a very useful guide for inspectors, and work with NGOs through some of our cooperative agreements to update the basic suite of training materials that will be necessary. That's ongoing.

There's a phased in limitation period which is going to be fairly intense, us doing work to meet the

various deadlines we have. But as long as this branch exists, we'll be involved in outreach and communication with the regions, and the states, and the NGOs, or any other stakeholder group.

VIRGINIA: Just to follow up. The regions themselves, can you tell me a little bit more about is there personnel or staff at some of the regions or all of the regions?

MR. KEANEY: There's a regional coordinator in each region, work protection focused or applicator/certification focused. Many times the same person.

VIRGINIA: Thank you.

MR. KEANEY: Same people.

MR. HOUSENGER: Annie.

ANNIE: Yes. I'm just jumping back to school IPM. A comment and a question. One, I just wanted to say, you know, we support IPM as a decision making process, but just wanted to reiterate that the best IPM plans are those that really eliminate toxic inputs. We've seen a lot of success in our work using products just on the 25B list, as well as those approved in

organics. So, we really feel that IPM programs don't need chemical inputs to be successful.

I also had a question on your gold star schools. We're just wondering if you have any data on the schools getting gold stars, as far as like how many there are out of how many schools, and what exactly constitutes gold star status under your program?

FRANK: I just want to ask a clarifying question. Are you talking about IPM star certification that the IPM Institute provides for schools?

ANNIE: Yes.

FRANK: I don't have the statistics. That's a program that's run by the IPM Institute. It's one of the programs that's out there to certify schools that have fairly robust IPM programs out there. I think their web site has pretty comprehensive information up to date on an array of schools that have gotten certified through their program. But it's one that we don't actively work with them on that program.

BOB: To elaborate on that, if you look on the handout, we are instituting our own

program for recognizing -- an awards program that will kick off later in the year. So, I'm not sure if you're confusing the two, but Tom Green's effort is separate and apart from EPA activities. We plan to have a program of our own that would commence in the next year or so to recognize schools at various levels of accomplishment.

ANNIE: Okay, great. Well, I'll follow that closely, then.

MR. KEANEY: I'd like to make another point about the worker protection. As I mentioned, we do have grantees that we're working with. One of the grantees is cited in University of California-Davis. They are going to be establishing a fairly elaborate repository for training materials as we develop them. So, they'll have an online site where people can have access to the various training materials for their own, use.

We are building a fairly robust version of our web site in which we'll have interpretive guidance materials, Q&A materials, and any number of fact sheets posted relative to the changed regulation.

MR. HOUSENGER: Ray.

RAY: I have a series of questions about the school IPM programs. The handout here mentions the $500,000 for grants. Are those funds coming from the PRIA set-aside?

FRANK: No, these were not PRIA-related grants.

RAY: They're separate from that?

FRANK: Yes.

RAY: Apart from those grants, what's the total budget of EPA for the school IPM program, given the FTEs and partial FTEs, among the --

BOB: Well, the FTE part, that's essentially, Ray, the program in terms of the funding. We have about four FTEs that are Center of Expertise in Dallas who are doing school IPM, and Frank, part of his time as the branch chief managing that branch. That's essentially it. As I mentioned to Susan, there is a staff person in each region who devotes some of his or her time to school IPM.

RAY: What's that total amount among the regions?

BOB: Well, I think there's one

FTE per region.

SUSAN: There is. Yes, every region has one FTE. And, you're right, at this point in time, because of the shrinkage of resources, sometimes the person combines school IPM with one other program area.

RAY: So, there's maybe 8 to 12 FTEs total?

BOB: Probably less than that. I think there's probably 8 to 12 people working on it. Some of them, as Susan alluded to, are not spending their whole time because of other pressing budget priorities.

RAY: Do you have an objective measure for what EPA is getting for its investment in school IPM?

BOB: That's been looked at before. It's very hard, I think, to somehow measure it quantitatively. Part of what we're constrained by, and we think it's appropriate, is going into schools to try to figure out what the baseline level is for schools across the country. We really don't want to do that.

One thing the roundtable is doing that we have next week is we're working with the school administrators, the school superintendents, the school board, to try to have them sort of at the national level

send a message that this is important to consider implementing as a way to deal with your pest problems. So, we hope to work with them to get a sense of how it's going through their organizations to see how successful this is going to be over the next two or three years.

RAY: Is that message coming back from the other direction? Are they telling you it's important or are you telling them it's important?

BOB: I think we all share it. That's why they're endorsing the principles.

RAY: In the context of pollinator protection, which has occupied more of my time, I know the Agency is looking very closely at metrics of the state-managed pollinator protection plans. It's a hard issue to come to grips with. I would encourage you to continue that approach also for the school IPM program. Find some objective metrics that demonstrate what we're all, as a society, as an agency, as schools are getting out of that investment.

BOB: We'll take a look at that. Some at the table can elaborate on it. But individual school districts and schools have looked at that and

they've seen a decrease in pest pressure and decrease in expenditures for pesticides. But it's all very hit or miss. There really isn't sort of a national effort, as you're suggesting, to pull that together and look at metrics to see how the program is doing.

MR. HOUSENGER: Amy.

AMY: Hi. I just want to say that we're very pleased to have the revised worker protection standard and want to commend the Office of Pesticide Programs for starting this rather aggressive effort to make sure that it's implemented accordingly.

I'm wondering if you could expand just a little bit and talk about what the role of EPA is in the lead federal inner-agency task force, and what other agencies are doing, and how to engage them?

MR. KEANEY: Well, generally, we are working with other agencies, Department of Labor, HHS, and HUD, mainly. It's an effort to leverage resources, obviously, and use their various venues to send the basic messages that we're trying to send through this regulation.

So, we develop handouts and we develop things

that could be distributed to folks that might be affected by the regulation, for instance, in the Migrant Head Start Program or Migrant Health Program. They can distribute that material to help get the messages through a number of different channels into the populations that would be affected by the regulation.

Did that not answer your question?

AMY: That's good, thank you.

MR. HOUSENGER: Bob.

BOB: So, I have a question, too. I have opinions, but I'm going to not share those. I'm just curious. So, I think it's a not a new issue. I started in 1989 working at NPMA, and they had passed a school IPM law in Michigan in 1988. They passed one in Texas in '89. Thirty-eight other states have passed laws since then. I think this is a little bit of what Ray was getting at.

It seems to me like it would be useful -- and I'm not sure I've ever seen it -- to know what percentage of schools, what percent of students, what programs work, what programs don't work, are things the Agency is doing, you know, having an impact, are state laws regulatory

approaches having an impact? You think there's a chance that some of that grant money could be used to develop those kind of baseline metrics?

BOB: Frank can maybe elaborate in a second on how people are doing. What we found, Bob, is there's not necessarily always a correlation between a state having a law and necessarily effective implementation. The money this year has already been allocated to the projects that are listed on the one pager, but that's something we can look at.

I think, Frank, the numbers we've heard anecdotally is that the number of schools doing some type of school IPM program across the country has increased over the past four or five years. These are all somewhat anecdotal. There's not a firm metric for my 25 percent to maybe upwards of 45 percent of school districts doing some type of IPM program.

Now, is that the gold star that was alluded to earlier that Tom Green had? Probably not. There could be more baseline efforts to improve school IPM implementation.

Is that your sense, Frank, in terms of the

numbers anecdotally?

FRANK: Yes. I think Mark may want to elaborate on this at some point, too, because I think he's done some work along with Dawn Gouge at the University of Arizona with the national school IPM working group, looking at assessing that in different schools. I don't believe it's been done in a scientifically robust way, but it's something that we have talked about here. There are challenges with us being allowed to go census schools to get that information and to be able to enable a school with fundings, another group to do that basically on our behalf.

But it's an area that I think deserves future consideration and discussion, Bob. I agree with you there. I do want to give Mark a chance to respond, because I think he's been involved in some of the measurement work in the past directly.

MARC: Thank you, Frank. By the way, welcome back. It's nice to see you again, Robert. In your absence, actually, in the last couple years, I did present some program evaluation with regard to states that are implementing integrated pest management as

opposed to having it as a policy, because there is a big difference between implementation and policy. So, that is ongoing.

In any quality control/quality assurance program, program evaluation needs to occur and continue to occur. So, your question, both yours and Ray's, are good questions.

I would say that the work group spent its first two years on metrics and has developed a number of metrics that have been alluded to both in terms of cost reduction, reduction of applications, reduction of pest pressures, and things like that. I know that that is ongoing, and it should be ongoing, particularly if there is taxpayer money going into it. So, I applaud your questions. I think that's a good thing.

But the metrics have been -- actually, we've probably spent too much time on metrics for awhile. But we've certainly done it and could certainly answer any of those questions, at least I could. But everyone knows that I would go on and on about that.

I do have a comment with regard to something that I brought up before. With regard to -- well, I'll

step back again to the regulations of the states that have laws. Almost all of those laws are pesticide centered because that's where they're allowed to be measured, and that's where the laws are. So, I don't have an objection to that.

But I do feel that if one is to measure integrated pest management, you can't measure it by pesticide centric laws. So, that is a problem in itself. So, that's why more recently EPA has even looked at laws from health departments concerning waste, water, cleanliness, clutter, that kind of thing.

Those are probably more key to integrated pest management with regard to conducive conditions than pesticides are. Of course, your professionals are all part of that. So, that's an important thing. That's a fairly new release from the Agency, rather well done, I would say.

So, my suggestion or concern is that, with all due respect, when it comes to having monthly updates with the regions, it's good, and it's critical, on the one hand. On the other hand, there's a difference between talking about things and doing things.

So, I would suggest, at least as an amendment to this update, or if there are any other future reports, and I'm not sure there will be, and that's up to you guys, that there's a report or a listing of regional activities, rather than regional meetings, meetings they're going to go to, or will go to, or participate in, or might participate in, actual activities of what's being done.

I think the Center can say, yes, this is what we're doing. But I do think, again, that there needs to be that coordination with the regions to do that in conjunction with a strategic plan that has already been developed. That's just a management thing that I would suggest to a graduate student, as well as anyone else.

So, if we can have either an amendment to this update or if there are future updates, I would suggest that something like that be done.

SUSAN: Can I mention right now we do have monthly updates by the regions on their activities that we do post on our Share Point site that's available to all of the regions and the headquarter folks. Maybe, Bob, there's some way we can make that available

externally as well. But we do do monthly updates of activities, yes.

FRANK: Susan, we can add some of that. We do try to highlight some of these in our --

SUSAN: Yes, in your updates.

FRANK: -- (inaudible) on a regular basis. But we can try to compile those.

SUSAN: Yes, we can try to weave them more closely together. Would that work?

MARC: Yes. It would be helpful anyway.

SUSAN: Sure, happy to do that.

MR. HOUSENGER: Andy.

ANDY: My question is related to WPS. If you want to exhaust the IPM out, I'll hold my question until after. Is that okay or do you want me to go?

MR. HOUSENGER: You can go. We're all over the place.

ANDY: So, my question is related to the Train the Trainer schedule. I see Region 4 is August 2016. Are the state-lead agencies going to be able to train way before they actually get trained? From August until

November, it's virtually impossible to reach the people that actually need the training because they're in the field harvesting. We don't schedule meetings during that period of time, just because you're not able to reach them.

So, if we're restricted to this August '16 training -- we're looking at trying to get everybody trained from the second week of November before the January 2nd deadline. So, will all of the materials be available when we actually -- we probably need them end of June and then the month of July, which is the easiest time to reach the people that actually need to be trained.

MR. KEANEY: There's a phased implementation, I think, in -- I don't know what August you're referring to, but a great deal of the regulation provisions go into effect in '17, the start of '17. A lot of the training material, a lot of the training aspects, the change in trainings, is January '18. Train the Trainer programs would be approved by us and our regional staff.

We're putting out probably this week or next week a description of the process that could be used to

submit Train the Trainer programs to us for approval and, therefore, build towards training materials. We'll be providing basic training materials through our grants relationships. We'll also be in the business of approving other training materials as appropriate to be used for the training under the regulation.

ANDY: Right. So, I'm looking at the priority training for regulatory partners.

MR. KEANEY: Yes.

ANDY: And then, if you flip it over, it says August 2016 training for Region 4 states. I read that as the state-lead agencies in Region 4 would not be trained until August?

MR. KEANEY: No, we've had general trainings. We had invites out to what's called the PREP courses we do for the state regulatory agencies. We've had one. We'll have a second next month that will bring all the folks that can attend those to have the basic training. But then, there's additional training for whoever might not have been at those PREPs as far as the regional staffs, the state staffs in those regions.

ANDY: All right, thank you.

MR. KEANEY: As I said, we're in a pretty aggressive training and outreach exercise. There's open invitations for anyone or association or any stakeholder group that wants to have a work-through with our folks on the regulation and the implications for the regulation.

MR. HOUSENGER: Cynthia.

CYNTHIA: So, since we're all over the map, as you say, I'd like to step down to Item C, if that's okay, Cumulative Risk Assessment. We appreciate the one-pager on risk assessments, and I look forward to studying the new documents that came out in April.

It seems that neonicotinoids are a perfect candidate for cumulative risk assessment, given a similar mode of action and the fact that multiples are used simultaneously. When the American Bird Conservancy and the Harvard School of Public Health last summer tested congressional dining hall food, we found that most foods had multiple neonicotinoid residues, and some had as many as five different neonicotinoids.

So, my question is, what can we expect in terms of cumulative risk assessment for the neonicotinoids

class? Thank you.

MS. VOGEL: So, I'm Dana Vogel. I'm the Director of the Health Effects Division. This is related to human health risk assessment, but we have put the screening policy out for -- it was commented on, and we received comments back, and then putting out our response.

Part of what we're doing through registration review, neonics is a class of chemicals that we'll be doing in registration review. The cumulative (inaudible) screening guidance to get through that class is the point of that guidance, to figure out how we get through -- under FQPA, how we do cumulative risk assessments for the classes that we need to in a more efficient way than we've done it in the past. But yes, we do recognize the neonics, and that will be done in registration review.

MR. HOUSENGER: Valentin.

VALENTIN: I have two questions, but first of all, I want to recognize the work that has been put into improving WPS. The one thing that I saw or the one issue that we currently have is that the outreach materials that were created for the old WPS were inadequate and

sometimes hard to understand for the farmworker population. So, as we move into developing effective outreach materials for the improved WPS, I just want to really encourage you to make sure that the materials that are created are really adequate or easy to understand for the farmworker population.

You mentioned entering into cooperative agreements with two different institutions. My question is, for the UC Davis agreement, will they be determining in which language some of the materials will be in or is that something that EPA will decide?

Second question is, are you thinking of allocating additional resources aside from the two cooperative agreements that have been entered into?

MR. KEANEY: As you mentioned, we had a five-year cooperative agreement with a combination of UC Davis and Oregon State. They'll be reaching out to various NGO groups and have representation, So, that for any material for workers is obviously appropriate language level and culturally sensitive as needed.

As far as the language, everything will be in English and Spanish and then in other languages. The

existing regulation materials, I think it was 12 languages we ended up translating to. That would be decided by a combination of us and stakeholder groups that alert us to various pockets of languages that might exist. We would then create the materials specific to the language, since the training is by regulation, to be conveyed in a manner that's understood. That's the basic level, language that's understood.

But we do have other grants, as you asked. We have a long term agreement with the Association of Farmwork Opportunities that does basic safety training. We are updating -- they will be with us updating their material to be appropriate to the current regulation. All that material, as I said, is going to be posted in a web site at UC Davis. So, there will be a repository of training materials as we develop them there for use by anyone.

MR. HOUSENGER: Aimee.

AIMEE: So, I'm also interested in cumulative risk assessment. I had put that as one of the things I was hoping we would talk about, more for the ecological cumulative risk assessment than human health. Watching

as endangered species act evaluations have been undertaken, they do consider cumulative risk assessment not just the way we look at it in OPP, where it's just like modes of action, but actually looking at other stressors as well. I'm very interested in finding out if EPA is going to be moving in that kind of direction where you'd be looking at other stressors.

For example, pollinators, there's concerns with disease and fungicides and neonicotinoids possibly interacting, increasing risk. So, are these stressors something that might be considered in cumulative risk assessment over time?

MS. PEASE: I'm Anita Pease. I'm the Acting Director of the Environmental Fate and Effects Division. That's a good question. It's something that we'll be addressing in the biological opinions. There is a section that will be devoted to evaluating the cumulative effects not only of the actions related to the federal action of the pesticide registration, but also any other actions that might impact species other stressors. They're all be integrated into the final jeopardy determinations.

I think Patrice might be talking a little bit about that later today.

AIMEE: I guess I'm also curious if that's something that might happen in registration decisions as well. Is that something that might overlay that we could actually be looking at for pollinators? We're in the middle of risk assessments for pollinators right now. So, I don't know if someone else could --

MS. PEASE: I think on the ecological side, that's the evolving science, and we're not quite there yet. So, we're working towards that. But right now, our evaluations will not be including that cumulative evaluation.

DANA VOGEL: Just one thing to add. At an agency level, separate from what we do in OPP, there is a lot of work going on cumulative risk assessment and trying to understand better the impacts of chemical and non-chemical stressors. So, that is an area of research. I think it's an evolving science that's going on. But I think in line kind of what Anita said, we're not quite there yet in figuring out exactly how to do it, but there is a lot of work at the Agency level

going on.

MR. HOUSENGER: Cheryl.

CHERYL: So, the update says that some changes were based on the public comments for the cumulative. I mean, I think when we made our comments back last year, it was a reasonable approach. We want to screen first before we get down into a lot of details that may not be necessary.

The concern I had, technically, was that if you take a single chemical assessment which is highly unrefined and you take one that is somewhat refined, and you slap them together, and you don't get a good answer, the way the guidance was written at that point, you could still kick into the formal without taking advantage of some quick refinements that you may already be able to do. So, it wasn't described as quite tiered in that original posting.

So, my question is, what changes were made based on the public comments? Particularly, has that one been addressed?

MS. VOGEL: This is Dana Vogel. The management lead for this is my acting associate

director -- there's a lot of acting around, as you can tell -- Billy Smith. He's been the kind of lead for the technical part of this, especially sheparding along the response to comments. I'm going to let him answer your question.

MR. SMITH: Right. It is a good question. It was a valid point. We've not changed the actual tiering levels, but we have taken that into account within the tiers. I don't know if it was specifically your comment, but specifically we had things like, you know, can you take into account for same crop treated, can you take into account PDP data, potentially.

So, we did try to focus a little bit more on particularly -- I think it's a little bit easier on the dietary exposure side. If they didn't, as you said, you know, take, however they are initially and throw them together, and if it doesn't pass at that point, maybe trying to put them on a same level playing field on the exposure side. So, to answer your question, yes, we did that.

CHERYL: That would be important because that would be a way to avoid additional tox tests, etcetera,

etcetera. So, yes.

MR. HOUSENGER: Donnie.

DONNIE: I'm going to kind of build on what Andy was asking about around worker protection standards. Could you kind of give me an idea of what your outreach program looks like, give you confidence that everybody will be aware of these changes by January 1? So, that's kind of the first aspect.

I also appreciate you working with OSHA, especially around the respirator issue. Are there other areas that you're working with OSHA to make sure that those two don't disagree with each other. So, when inspections do occur, that EPA is not telling them one thing and OSHA is telling them something different that kind of occurs today?

And then, last but not least, are you willing to share your compliance training materials so we make sure we know what to be ready for during inspections?

MR. KEANEY: Yes. As I said, we're in the process of developing key compliance materials, like the How to Comply Manual that exists. We'll update that. Then, there's an Inspector Guidance document that, you

know, we develop. I thought in the earlier regulation, it was something called a Quick Reference Guide that was quite useful. We'll duplicate that with relative to the current regulations. So, that will be available.

The OSHA, we've got specific focused fact sheets on relative to the respirator and the process of fit testing and what's meant by medical evaluation and so forth. So, there will be a lot of specific focus on that with information that will be up on our website and available and in our training with the state regulators and the regional people. That's a big focus.

What was the first question you asked?

DONNIE: Outreach, can you give me an outline of your outreach program? You were confident that everybody would be aware of this by --

MR. KEANEY: Well, I thought the thing that was sent to you or that you had is a basic outline. We are pretty aggressively beginning with the regional people that are tasked with being the location for worker protection information are the regions. Then, the state regulators.

We do have, as I said, a process. We bring

people together for a week's training, the pesticide regulatory -- PREP. Acronyms are good, but you can forget what they mean. It's a state regulatory people training session. We had a week of that in May that was well attended by the state regulators. We're having another one at the end of next month that will do the same thing. It's ongoing. We'll be in an ongoing process all through this phased implementation. Well, for the life of the regulation, really, but pretty intensely front loaded into this phased implementation activity up until '18.

DONNIE: My question is more around the next level. What's your outreach program to the producer growers, those people that are impacted, not the regulators?

MR. KEANEY: We will reach out and provide webinars and Power Point walkthroughs. We are in the process of setting up a contract with an outreach firm that would do a variety of things to reach into that community with informational presentations or PSAs or any number of things like that. But we haven't got that contract in place yet. We're verging on that. That

would be, again, a multi exercise for continued communication. So, anyone you know who would like to get an ear full, we can give that to them.

DONNIE: I've got at least one audience for you, but I'll talk with you later.

MR. KEANEY: Yes.

MR. HOUSENGER: Aimee.

AIMEE: Just as a follow-up question, I recognize these are evolving issues on cumulative risk assessment and ecological risk assessment. It's not easy. So, one, I'm curious. Conversations are happening. I'm curious a little bit more about is there anything more than conversations, something concrete that I can look at, timelines, or ideas, or goals?

Then, adding a layer to it also, I gave an example of disease, a chemical or non-chemical interaction. I'm also curious synergies. I know that's something that we've talked a lot about between different active ingredients that might be used jointly or where the exposure might be joint. I'm curious about how EPA is responding to that issue as well on an ecological sense.

MS. PEASE: Hi, Anita Pease again. So, I'll address your question on synergies first. So, we recognize it. That's an evolving issue. Mixtures are really a challenging issue for us to tackle at this point in time. We are looking at the open literature. Any available data on mixtures, we evaluate it qualitatively.

We did get recommendations from the National Academy of Science on how to evaluate mixtures. They suggested that we assume additivity, which we're doing in the ecological risk assessments. I'll talk a little bit more about that in my presentation on ESA, about how we're looking at mixtures.

Again, you know, we're not there yet. We don't have a quantitative method, but we are seriously looking at it, and we are working with the Services on ways to quantify that.

AIMEE: I should just clarify that I'm curious not just for ESA biological opinions but also registration review and evaluation. So, if it's not true for both of them, that would just be helpful for me.

MS. PEASE: Sure. No, we're doing the same thing for registration review. We do a thorough review

of the open literature. We are discussing all the data that we have on mixtures, synergistic, antagonistic, and additive effects.

MR. HOUSENGER: Cheryl.

CHERYL: So, whoever was the acting director, he didn't really finish answering my question, which was, were there any other changes? The reason for asking that has to do with the WPS, because apparently, there was some big change that happened in WPS at the last minute that created a lot of confusion, which was around the designated representative provision. That's not outlined on the sheet here. So, I'd like to hear what that change was about and why it was made, because there are some people that are concerned about it. Then, I'd like to hear if there were additional changes to the cumulative policy.

MR. KEANEY: That provision designated agent is if the worker feels, for whatever reason, unwilling to ask for the necessary information that should be provided, then they can have a designated agent do that for them if they feel retaliation or whatever. Whatever misgivings they have, they can have a designated

agent request the specific information that needs to be provided. We've put up a lot of Q&As on the web site and fact sheets on the web sites. It doesn't look like that's an answer.

CHERYL: I guess the question was, what was the impetus for that? Apparently, it's not super clear as to how that works.

MR. KEANEY: The impetus was information we got through comments and through engagements with NGO organizations that felt that a lot of workers feel intimidated, feel in a lesser position as far as their ability to ask for information that the regulation says they should be entitled to.

MR. SMITH: And then, to just address your question on the cumulative, there really wasn't a lot of significant changes. There were some language changes where we added some language about the schematic review. We got a number of comments about that.

We sort of addressed that in the accompanying response to comments/documents. We've added language in to address those comments. But substantial changes? No, there wasn't anything really outside of the question

you've already asked sort of putting them on the same level playing field on the exposure side.

MR. HOUSENGER: Ray.

RAY: On the WPS, following up on Cheryl's question, can a designated agent represent an agricultural worker anonymously?

MR. KEANEY: Can they represent -- well, they're asking specific information. If you're asking an employer for specific information that's key to a work period or, you know, a geographic location, ultimately, if it leads to an enforcement action, they can't maintain anonymity at that point.

RAY: Anonymity of the worker representative?

MR. KEANEY: The worker representative?

RAY: Yes, the worker who is represented.

MR. KEANEY: The initial request can be anonymous, that they would like the information for X day or X month and so forth. They have to provide enough specifics so that it is relevant to whenever the worker was there doing whatever he was doing.

RAY: If that worker is not identified, that's a real problem.

MR. KEANEY: Ultimately, he would be identified.

RAY: Well, it should be right up front.

MR. KEANEY: Well, there has to be certainty that the person was employed there, yes.

MR. HOUSENGER: Amy.

AMY: I just want to follow up on this conversation, just to underscore a couple of the points that Kevin is making about the vulnerability of a population that is picking, harvesting, and planting our crops. These are hard workers. They want to work.

The EPA has an obligation to protect them. This designated agent is incredibly important because sometimes workers -- it's not a matter of feel; they are intimidated. They have been intimidated. They need someone else to assist them in obtaining information about the pesticides they are exposed to.

So, we're watching it very closely as well, but we feel it's very important as a part of the WPS functioning accordingly.

MR. HOUSENGER: Andy.

ANDY: Are there any definitions that define

who can be a designated representative? Are there limitations on what can be used with the information that is collected from the producer?

MR. KEANEY: There is description in the regulation of what types of identification the representative has to provide, yes. What use can they make of it? The same sort of use that anyone could make of that information. What were you getting at with the question of what use could they make of it?

ANDY: It just seems that pretty much anyone that wants to can seek out someone that works on a farm and want to be his designated representative and can get a lot of information, and there’s no restriction on what that information could be used for, or where it could be used, or for what purpose it could be used.

MR. KEANEY: The regulation specifically describes what information should be posted and available. That’s the type of information that they would get. It’s nothing different than what already exists in the current regulation. Well, there’s some added information that we’ve got in the change, but it’s required to be posted and made available.

MR. HOUSENGER: Virginia.

VIRGINIA: Just to clarify, in the proposed regulation draft, the regulation did have a provision about a designated representative who could assist a worker to obtain information that's already in the central posting in the event that a worker is incapacitated.

The final regulation retained that provision but also added additional steps that a worker would have to go through to designate that representative. So, there were some changes, but it only made it a little bit specified as to how that process would occur and steps a worker had to go through to designate that representative.

MR. HOUSENGER: Amy. Andy. All right, are there any other questions regarding any of the three topics? Anyone on the phone that's a member of the PPDC?

(No response.)

MR. HOUSENGER: All right, hearing none, let's take a break. It's a little early, so let's do quarter of.

(A brief recess was taken.)

MR. HOUSENGER: Okay, let's get going on our next topic, chlorpyrifos. There's been a lot of questions. We recently went to an SAP meeting on it. Dana Vogel, the Director of the Health Effects Division, is going to lead us in this session.

Dana.

MS. VOGEL: Good morning, everyone. All right, so part two of chlorpyrifos. Since the first part at PPDC was so much fun, we thought we'd do it again. So, we're going to give you a little bit more. This presentation I'm trying to go back a little bit and give you some of the background in regulatory history. Then we'll talk about the most recent science advisory panel that we had just recently in April. Then we'll talk about after the SAP what our next steps are moving forward.

Just a few slides on background. I just want to go over at a very broad level that chlorpyrifos is a very widely used OP insecticide. It's used in over 40 states and on nearly 50 crops. So, it's very widely used.

So, regulatory history, there is a bit of

regulatory history here. So, in 2000, all homeowner residential uses were eliminated except for those that really don't present much exposure, any exposure at all, are very self contained.

In 2006, we completed a cumulative risk assessment for the OPs. Of course, chlorpyrifos was a part of it. We determined that there were no risks of concern. They didn't exceed our level of concern.

In 2009, we began registration review. We moved chlorpyrifos up in the schedule because of its importance and because of some cutting edge science issues that are surrounding chlorpyrifos.

So, as you can imagine, there has been, or you're probably aware, there's been a lot of science work done on chlorpyrifos. We've taken many issues to many different SAPs. This slide briefly summarizes some of the or most of the SAPs we've had, starting in 2008, on a new way of looking at experimental lab tox data on animals and epidemiology studies. That was in 2008 when we first brought those issues.

In 2009, we looked at potential for volatilization exposure, how bystanders might be exposed

through potential volatilization of the pesticides like chlorpyrifos.

In 2010, which is very important, we brought the framework for how to incorporate epidemiological and incident data into human health risk assessment and really presented a conceptual framework for how we would use that in risk assessment, and followed a systematic approach, this microview approach, and utilizing a weight of evidence as well. So, that was back in 2010.

In 2011, we brought the PBPK model for chlorpyrifos and its linkage to CARES.

Then, in 2012, again we revisited some of the major science issues concerning the health effects of chlorpyrifos, that again including epidemiological data. Subsequent to that SAP, we did do a paper review, a federal peer review panel of some of the MRI findings that were in the epi data to get a better understanding of those and how we could look at those and what they actually meant.

So, the main point here is that we have done a lot of significant science work over the years at tackling different issues early of chlorpyrifos.

So, I'm going to step back a little bit to 2007 because it's relevant to the conversation on chlorpyrifos. In 2007, NRDC and PANNA submitted a petition to EPA to revoke all tolerances and cancel all registrations due to neurotox and neurodevelopmental concerns, including with children, farm workers from spray drift, and volatilization. Part of that petition was citing some of the epidemiological data and some of the concerns for neurodevelopmental risks.

So, as we mentioned before, a lot of these issues are cutting edge science issues that we took to the SAP because they're very important issues that were moving the science forward, and we needed some external peer review to respond to different issues brought up in the petition.

Between 2008 and 2012, we again, as I showed you in a previous slide, we took these to a variety of SAP meetings.

So, moving forward, petitioners brought suit to us most recently in 2014 to the 9th Circuit Court seeking to compel either a denial or a proposed or final tolerance revocation. In June 2015, the 9th Circuit

ordered EPA to inform them of our plans to respond to the petition. So, this is just kind of going through the history of the petition.

On June 30th, we reversed our provisional response and indicated our intention to issue our proposed rule revoking all tolerances by April 15th. So, we've set a schedule in place at that point for responding to the petition. We also said at that point we're setting our schedule to try to establish a schedule for getting and answering all the remaining science questions.

Part of that, as we previously identified, the outstanding remaining science questions are some with drinking water concerns. So, this response is really based on our 2014 human health risk assessment and the results of that that I'll speak a little bit more about in a few slides. But our response in June really was driven by the results of the 2014 risk assessment and the risks of concern that were identified from that assessment.

In August, the 9th Circuit Court rejected our time line and ordered EPA to either deny the petition or

issue a proposed or final revocation by the end of October in 2015. So, we issued a proposal to revoke all chlorpyrifos tolerances on the day before the deadline. Then, EPA also informed the court that it expects to issue a final rule by December 2016, as was their request.

So, risk assessment history, I'm going to give you kind of an idea of the different risk assessments we've done over the years for chlorpyrifos and really focus in on what was done with the 2014 and the results of the 2014 risk assessment.

So, you can see our preliminary human health risk assessment was issued in 2011. In 2012, we issued our spray drift assessment and mitigation around spray drift resulting from those concerns. In 2013, we issued a draft volatilization assessment, which indicates no risks were identified. Then, in December of 2014, we issued the revised human health assessment.

So, what we're doing here is we're responding to different points of the petition. At the same time, we're, in parallel, working on registration review for the OP pesticide chlorpyrifos.

So, in the 2014 risk assessment, we retained some of the important points. Some of them to take away are that we retained the 10X factor because of neurodevelopmental concerns. That was largely driven by, not completely but largely driven by the epidemiological data and the weight of evidence that we've done around that.

There was also in that risk assessment identified risks to workers with the specific individuals of concern and who we assess in our assessment of pregnant workers. The potential was posed for drinking water in certain areas of the country, so we identified that in the 2014 assessment.

Subsequent to 2014, we've been doing more work on the revised drinking water assessment, as well as some other science issues, which I'll talk about in a few slides. As I mentioned before, there were no new risks identified from food or to bystanders from either spray drift or volatilization.

So, for the 2014 risk assessment, I just wanted to briefly touch on the different key guidance documents that we looked at and adhered to to put that assessment

together; the NRC report on default factors, as well as data derived extrapolation factors, which is an EPA document, and also our 2006 approaches to how to use PBPK models for risk assessment. So, those are the key documents we've used. As you can see, they've been peer reviewed, and there's been numerous publications.

So, back to the 2014 risk assessment, we did use red blood cell cholinesterase inhibition as the critical fact for determining the point of departure. We used the PBPK model to derive human specific points of departure for different age groups, routes, and durations. We also used the model to derive intra-species factors for some life stages, but not for women of child-bearing age, because at that point, the model we were using wasn't capable of assessing or accounting for pregnancy.

We also, as I mentioned before, retained the FQPA factor based on the uncertainty in the dose-response relationship as it relates to the neurodevelopmental effects that could be potentially seen in children. That concern comes from the epidemiological data. One of the main studies but not the only one is the Columbia study

that you've probably heard spoken of.

So, because the epidemiological data is such an important and spoken of point for the chlorpyrifos risk assessment, I thought I would go through just a little bit of detail on the epi studies. So, the main epi studies that we're using are three prospective birth cohorts that examine environmental exposure and adverse health outcomes. That's the Columbia cohort, which is New York City, Mount Sinai, which is also in New York, and CHAMACOS, which is in California, so three different cohorts funded by EPA and NIEHS.

So, if we think about these studies, I think, there is certain information that's available in the Columbia study that is not available through the other two studies. At the same time, they all kind of lead you in the same direction. They all kind of support each other. So, what we're relying upon and what we took from the SAP was mainly some of the quantitative ways to use the Columbia study. All three cohorts kind of work together and pointed us in a direction that we felt we needed to pursue to address the concern for neurodevelopmental effects.

So, with the epidemiological data, we have done some work over time to get at some supplementary analysis that may inform our regulatory needs. We did have a group that went to Columbia and met with the researchers in 2013 to discuss some of our specific information needs. You can see what those are here.

We were not at that point in time able to get -- we do not have the raw data. I know that has been a question at the last PPDC. We did not have the raw data, but we have pursued it in a few ways. This is one way we've pursued it. We'll talk a little bit about the other ways we pursued it kind of when we get to some subsequent slides. So, that's just an important point to make.

The weight of evidence, so there is no clear mode of action or adverse outcome pathway for chlorpyrifos and neurodevelopmental. But the data suggests that these chemicals, chlorpyrifos and its oxon are biologically active and may affect the developing brain. There are uncertainties that remain, but they are diminished in the context of the similarity between the different data that we have. So, there was in the 2014,

and prior to that, a kind of impetus for all of the SAPs we've done on the epi data, a concern for long-term neurodevelopmental effects. We're trying to figure out how to best evaluate.

So, I'm going to skip forward and kind of talk about the 2012 SAP, as that led us to the work we did in between the 2012 and the 2016 SAP. So, there are a couple quotes here just to outline or highlight from 2012 where the panel did in 2012 agree that our epidemiological review was thorough and accurate. They also concurred with the 2008 SAP and concluded that chlorpyrifos likely plays a role in impacting neurodevelopmental outcomes, as examined in all three cohorts. They went through the strengths of the studies and identified some strengths.

This is also an important point to make. They acknowledged some of the limitations in the studies. One of those being the exposure measure, based on how the exposure measure and what exposure measures were collected. We're in general agreement that the data, as it stood at that point in time and based on the analysis we had done at that time, was not sufficient to derive a

point of departure.

However, they also encouraged us to find ways to use the epidemiological data, in particular the Columbia study -- when you see CCCEH, that's the Columbia study -- to inform how it can be used in the risk assessment. They also encouraged us to make use of the PBPK model.

Given these recommendations of the 2012 SAP, we did some significant science work after that to kind of look at their recommendations and incorporate what they had told us to the best of our ability and to the best way we could use science in the support of a way to that point.

So, that leads us to what we took to the 2016 SAP. So, what we did for the 2016 SAP, the main points that we took, were we used the PBPK model and we used our standardized EPA/OPP exposure assessment approaches. One example of that might be the residential SOPs of how we assess what residential exposures people might get from a pesticide use in the residential environment or in and around their home. We used those two together to more fully characterize how the women in the Columbia cohort

likely were exposed, our best estimate of how they were exposed, knowing that that data wasn't collected in the Columbia study.

As I mentioned, the residential SOPs and the other exposure assessment approaches we used and paired with the PBPK model have all been peer reviewed as well. The results provide -- this is our assumption and what we brought to the SAP -- that we wanted to bring this together to support how we were using the cord blood to to determine a point of departure. So, that was really one of the main points we brought to the SAP. Can we use the cord blood data? That was available in the Columbia study to establish a point of departure and use that data in a quantitative way.

We also, as part of the SAP to illustrate the science we had done, we did case studies to show how the PBPK model could be used to predict internal dose from existing chlorpyrifos exposures.

So, for those of you who weren't at the SAP and don't know this, it was a very lively discussion. There were a lot of differing opinions, I think, amongst the panel. Because of that, they acknowledged -- I would say

one of the things I took away from it was the statement that they wished us good luck in figuring out how to use it and what to do. But they expressed and understood this is a big scientific challenge that EPA faces, and it's not cut, and dry, and straightforward.

So, because of all that and because we heard a lot of different things thrown at us as far as whether or not -- there was significant discussion of whether or not it's appropriate to quantitatively use the data to set a point of departure. I think we, in general, heard they disagreed with that approach, but they offered some other approaches.

Because it's not very clear, we're going to have to wait and see the written report of the SAP before we can fully understand what their guidance is to us. The rules for an SAP is that the report has to be to us within 90 days of the meeting. So, we're expecting that report to be out in mid-July.

So, along with that, our next steps are one, wait for the written report so we have a really full understanding of what the SAP is going to be recommending to us, because there were a lot of differing opinions

expressed around the table during the meeting.

We've also tried to follow up again based on what we heard at the SAP, and we've heard from other parties as well. Pursuing getting the raw data both by contacting Columbia and also by contacting CDC who did some of the analysis of that data. So, we have done that.

The next step will be for us to check in, as we're required to, in June with the 9th Circuit Court on our status. And we included some links to some of the most relevant documents in the presentation, if you want to, they are there for you.

Any questions?

MR. HOUSENGER: Robyn.

ROBYN: Thank you. Great presentation. Just a couple questions. On slide 9, is the first bullet supposed to be 10X instead of 1X?

MS. VOGEL: I think that was the older assessment. I think it's just a typo. I think it was a 1X at that point in 2011.

ROBYN: Okay. So, it was a 1X, and then you said it was retained, but you actually mean it was

changed.

MS. VOGEL: So, at that point in 2011, the uncertainty factor was 1X. It has since then been changed.

ROBYN: So, in 2014 --

MS. VOGEL: There's a 10X.

ROBYN: Right.

MS. VOGEL: Yes.

ROBIN: But the way it reads now is 10X was retained, but you don't say when it was changed from 1X. It's just that on this slide --

MS. VOGEL: I mean, I think -- when did it change?

CHERYL: It's the language of retaining an FQPA factor. When it's 10X, you retain it. When it's 1X, you've reduced it.

MS. VOGEL: I think she wants to know when we made the change, at what point after 2011, I'm guessing.

ROBYN: Right.

MS. VOGEL: At what point after 2011 did we change it from 1X. Cheryl is absolutely right, that's the language of FQPA. We retain it when it's a 10 and

reduce it when it’s a 1.

ROBYN: I just want to know the date.

MS. VOGEL: Yes, sure.

MS. LOWITT: This is Anna Lowitt. So, between 2011 and 2014, the big milestones in between, there would have been several SAP reviews on the PBPK model. On the 2012 big review we did on the animal behavior data and the epidemiology data along with the federal paper review we did on the MRI results and the metrics used to evaluate the children in the cohort. So, based on all of those external peer reviews leading up to the 2014, the results of all those peer reviews led us to retain the 10X.

ROBIN: Okay, so 2014.

MS. LOWITT: So, between 2011 and 2014, we did a lot of science work but no updated risk assessments.

ROBYN: Okay, thank you. And then, what is the barrier to getting the raw data from either Columbia or CDC?

MS. VOGEL: The barriers? So, I can’t speak to the people that have the data, but we have requested it. I think one of the concerns I’ve heard is the potential -- because this data is epidemiological data, it’s based

on humans. There is partially a concern over personal identifiable information, as well as we've had discussions back and forth as to whether or not we can have access to it.

MR. HOUSENGER: We continue to try to get that data. In fact, I sent a letter to Dean, I think, Freed (phonetic) and the Mailman's School of Public Health in Columbia. I haven't heard. I wrote her back and she said that they're working on a response. So, that's one avenue.

The other avenue is with CDC. I contacted Pat Bracey (phonetic). His initial response was that they didn't have it, but it was unclear what they didn't have. I don't know if they didn't have the results of the raw data or he was speaking more in terms of personal information. I asked for clarification of that, and it's still going back and forth.

ROBYN: Well, it is possible to get de-identified raw data.

MR. HOUSENGER: Right, right.

ROBYN: They can just take off the public --

MR. HOUSENGER: That was my question back to

him. I said, I don't need the personal identification.

ROBYN: The private health information.

MR. HOUSENGER: For both of them.

ROBYN: Aren't you one of the funders of this particular study or was it all NIH? What right does that give you to get the data?

MS. VOGEL: We have pursued that.

MR. HOUSENGER: There's some question about if Columbia used any federal funds for the pesticide portion of this. They're claiming that it was segregated and they used private funds for that.

Gabrielle.

GABRIELLE: First a question and then sort of an observation comment question. One question is, California Department of Pesticide Regulation also did chlorpyrifos human health risk assessments. It came out the end of December this past year. They used the epi study. But what I found was striking was they did not find any drinking water concerns.

Now, I know in the version of the human health risk assessment that became publicly available and that we provided comments on last year, you know, almonds

alone exceeded the drinking water standards. We only grow in California. So, I'm just curious, how are you looking at what DPR has done versus what EPA has done. That's my question.

MS. VOGEL: So, we have seen California's risk assessment. I mean, as far as the drinking water goes, the drinking water assessment, what was presented in the 2014, we said there was additional work to do. We have been working on some refined drinking water assessments. It gets more refined, and we're down to like water shed type levels.

So, there is additional work that's being done on the drinking water to refine it. At that point in time, I think we even said in the risk assessment or shortly thereafter that we knew there was additional work to be done on the drinking water assessment.

GABRIELLE: Partly it's because California has some additional regulations in place. That's part of the reason DPR came to a different outcome.

MS. VOGEL: Right, and they're California. We're looking at the --

GABRIELLE: Yes, that's the other country,

California, I know. I've been to many of these meetings when they talked about the other countries. It was Canada and California.

Anyway, my question and my observation is, for chlorpyrifos, we have registration review, which would have a certain time frame for it. We have lawsuit driven deadlines for the Endangered Species Act, which I believe by the end of next year it needs to be all said and done. Now we have this lawsuit driven process for determining whether to revoke or cancel the food uses of chlorpyrifos. We have Jim Jones saying it's time to fundamentally be the driver for EPA's OPP's decision.

As I listen to this, A, I'm totally confused how you're going to get -- I mean, the ESA process is a whole year longer with the legal deadlines than your current legal deadlines for the food uses. All of this has some really complicated science behind it.

I mean, what you're talking about -- the reason there's been so much discussion is this is the first time OPP is using epidemiologic data this way. There is a lot of question marks about whether the policy really has been established. So, it's being established through

doing it. That means it needs time for back and forth.

You have the SAP saying we have some things we think you can do, but we're not quite -- you're saying, hey, I heard a lot of feedback, but it was confusing. There's no way, absolutely no way you can do a good job on the science in six months to make that decision by the end of this year.

So, I just am trying to figure out, you know, between these three different time lines and time to do a good job on the science -- I mean, on the ESA side, there's a whole bunch of new -- the volume 1 things, and I know you guys tried to prep us for that. Again, having the time to really look at all of this.

Ron was just asking me, you know, how long have you been doing this. I realize it's been almost 19 years since the first PPDC I ever attended in the audience. It's kind of a scary thought.

You know, when we do new science, it takes time for all the sides to sort of argue with each other and for EPA to work their way through it. So, all I can say, and this is really a plea, is at that June meeting, you go back to the judge and say, look, the SAP is saying

we've got a lot of work to do, PPDC is saying we've got a lot of work to do. We cannot meet these deadlines if we are to follow the junction of doing good science.

So, from a big picture policy question, I'm struggling at how these legal deadlines are to jive with, in my experience, a transparent public process, the way I put it, muddle our way through to figuring out how to make it work. Again, meaning all sides have had their say, have argued with each other. I always say EPA has done their job when we're equally unhappy.

I mean, this is really difficult, I understand, but somewhere along the way someone has to have the guts to go back to the judge and say, this -- because there's legal theory and there's scientific reality and good public policy reality. Where is that conversation?

MR. HOUSENGER: I think that's how we ended up with our deadlines, but thanks for those thoughts. I think we were saying to the court, this is very hard science, and we ended up with a mandated deadline.

Cheryl.

CHERYL: I have to echo some of what Gabrielle said. I was kind of disconcerted that the whole first

part of this presentation is all about the deadlines and the lawsuits. We do want to hear about the science.

I'm glad, Dana, that you represented having read snippets of the document that came out from the transcript. It was very clear that you didn't get consensus (inaudible) was exactly what was here. I did think that the statement that said that the PBPK model was much stronger, at least one person did, said that it had more faith in the PBPK model than some of these other studies is important to pay attention to.

So, I mean, you've heard this before, but it seems like the cart is before the horse a little bit here, because it's being driven by these legal things. Also, if you go to your last slide on the next steps, we're still talking about getting the fundamental data. We're still talking about whether or not you can get access to the data, whether CDC can come up with some information. It seems like that would be the starting point. Now we're kind of doing it backwards. It's a bit of a double standard.

Sorry, I have to complain, but if a registrant came to you and said, yes, we've got this study and yes,

the data is there but you can't see it, there's no way you would give credence to it. So, I don't understand what is continuing to compel you to go after this one study.

MS. VOGEL: I think, you know, as we've taken this issue to variety of SAPs -- and, Ann, I'll let you chime in as well -- this is epidemiological data. It's not the same as animal data. It just isn't. In itself it's a different entity. It does present information that presents an uncertainty for us and a potential for neurodevelopmental effects on children that we need to look at. So, I think all the data together, all the epidemiological data together presents a picture, something that we need to look into. I think we have to.

MS. LOWITT: So, just to add to that, I think it's important to take two or three steps back from it's only one study question. Remember, as Dana described, we've been actually at this for a very long time. There has been more public process on these three epidemiology studies since 2008. We've been to the SAP multiple times on these issues. It's not just one single study.

There is one study that happened to have

measured chlorpyrifos in cord blood, which makes it uniquely important for chlorpyrifos. But there are two other cohorts, one funded by a combination of federal dollars and private dollars. So, there are actually three cohorts that represent three individual separate physical locations, three different sets of mothers and children, three different sets of investigators who have looked at the same types of measures, and infants and children across the same period of time. Those three cohorts have observed the same trajectory of the same outcomes across the three cohorts.

It's not just a single piece of information; it is a body of evidence. There's the epidemiology. In our 2015 review, Dana didn't really talk about it, expands our epidemiology and how it's beyond the three cohorts. When we bring in international cohorts, we bring in additional cases, control studies. The same trajectory continues.

If you look at -- there are hundreds, if not thousands, of studies on chlorpyrifos and also other OPs looking at developmental neurotoxicity in animals, non-guideline studies looking at outcomes in adult animals

that are exposed during gestation and early post-natal. There are hundreds, if not thousands, of studies looking at the mechanistic underpinning of the effects of OPs on brain development. This is not just a single piece of information; this is a body of evidence based on many lines of evidence.

So, the analysis that we took to the SAP in April focused on that one piece of the cord blood for chlorpyrifos, because we happened to have a very robust multi-compartment, multi-route PBPK model that we can use to begin to understand what happened to the women and the children at the level of internal dose and to bring that on the level playing field with today's exposure. We don't have that tool for any other OP. We will not be able to do that kind of analysis for other OPs.

So, the SAP was about the cord blood and how we could use it, but we cannot lose sight of the totality of the evidence and how far we've been since 2008 and all the peer reviews, the 2008, the 2012, the federal peer review, the PBPK models, the 2015 updated literature review. This is not a new conversation.

MR. HOUSENGER: Louis.

LOUIS: It appears clear to me that there's two issues that you're dealing with. You're dealing with legal issues and scientific issues. I believe it's part of the pursuit of science that you want to go out to the raw data, you know, from the sources you mentioned.

Those of us at universities know how sensitive it is to release data that involves different personalities. With that said, if federal dollars were used for any part of that research, I don't really understand there's such a problem getting that.

The question I have, in the event that in the end you don't get that raw data, what are your plans of how you proceed beyond that? How is that likely to impact on the legal issues that you have to address, or are they not related?

MS. VOGEL: I think we are pursuing the raw data. We're hoping to get it, and hopefully that will inform us. We are waiting for the SAP report to see exactly what their recommendations are going to be. We have done to this point a lot of work around how do we best use the data that we have from the published literature that exists, using the data that we have to

the fullest extent that we can.

I'm not sure I can really say much more than that. Anna, do you want to add anything?

MS. LOWITT: I wish OGC was here because they could add some to that. I won't pretend to know the details, but our understanding is that there's no federal statute that requires that we have that data. Our understanding is that this issue has been litigated in the courts, and the Agency is not required to have raw data to make a regulatory action. That's litigation that would have occurred across other EPA programs.

Our sister programs in other offices, such as water and air and solid waste, et cetera, regularly make regulations on open literature and sometimes have the raw data and sometimes they don't.

MR. HOUSENGER: Annie.

ANNIE: Yes, thank you. I'm just wondering, given the clear neurotoxic dangers associated with chlorpyrifos, if the Agency could speak to its decision to revoke tolerances as opposed to going through a full cancellation procedure for the label allowed uses? Also, will the procedure you're pursuing, will that process

remove label uses?

MR. HOUSENGER: So, if we revoke the tolerances, it would be basically -- you'd be producing adulterated food if you still used the product on the crops and had residues. So, even though we'd have to go through a cancellation to get rid of them off the books, I don't think anybody would be applying it.

Does that answer your question?

ANNIE: I guess. I mean, I guess we're just wondering like will there be a full cancellation down the line, then, or are you just going to stick with this revoking of tolerances?

MR. HOUSENGER: I think that's getting farther down the line than we're currently at right now. I mean, I think we'd cross that bridge when we got to it. I don't know -- that's predetermining the outcome of the hearing. I'm not ready to do that yet.

ANNIE: Okay. So, then, when you revoke the tolerances, will the label uses be removed?

MR. HOUSENGER: Well, that would be the ideal situation. If you're producing adulterated food, I think it would be a fairly easy cancellation if the registrant

didn’t remove those uses. There’d be no benefits in creating adulterated food. I’m not sure why growers would go out and use it.

ANNIE: Right, okay. Thank you.

MR. HOUSENGER: Cynthia.

CYNTHIA: So, to take Annie’s question a step further, given the serious neurotoxic implications, especially for children, the ESA findings of 97 percent of CCs affected, and the many years of scientific deliberations that simply can’t be fast tracked, wouldn’t it make sense to temporarily suspend the use while these studies and further deliberations are underway? What would it take to do a temporary suspension?

MR. HOUSENGER: All right. I think what you’re talking about is emergency suspension under our law, which would require us to make a determination of imminent hazard to get it off the market immediately. Again, I think we’ve gone to the SAP. We’re going to wait until we see what the SAP says in terms of where they’re coming out. If you were at the SAP, it was very undecided, to say the least. So, we want to see the report before we figure out our next steps here.

Ray.

RAY: The standard in FFDCA is that the administrator may establish or relieve and affect the tolerance for a pesticide chemical residue in or on a food only if the administrator determines that the tolerance is safe. In the case of chlorpyrifos, EPA has made repeated determinations that the tolerances are safe and has removed the FQPA safety factor. Anna's description of the body of evidence is a very large body of evidence upon which these decisions were based.

The standard further states that the administrator shall modify or revoke a tolerance if the administrator determines it is not safe. Now, you're proposing to revoke those tolerances. Has a specific determination reversing previous decisions been made that says those tolerances are not safe?

MR. HOUSENGER: I don't know where you're going with this.

RAY: The law obligates you to make a determination that they are not safe in order to revoke the tolerance.

MR. HOUSENGER: Right. That's what we're in

the process of determining whether we can make a safety finding or not, just like we do on all of our chemicals.

MS. VOGEL: There were risks of concern identified in the 2014 risk assessment, which is what that was based on. I mean, there were risks of concern for workers, for drinking water.

MR. HOUSENGER: Right, using the 2014 risk assessment.

MS. VOGEL: Right.

MR. HOUSENGER: We couldn’t make a safety finding.

MS. VOGEL: Right.

MR. HOUSENGER: Lori.

Lori: I just want to commend the Agency for its commitment to meeting these deadlines. These deadlines were established in recognition of the fact that urgent action is needed on this potent neurotoxin. We don’t have a lot of time to lose on this. We’ve seen the effects. We’ve seen the large body of data out there. So, I just want to commend you for taking this action.

MR. HOUSENGER: Are there any other questions

on chlorpyrifos? Any questions from PPDC members on the phone?

(No response.)

MR. HOUSENGER: I don't think I hear any. Maybe we can break for lunch early and come back at 1:00. You can't say we dodged the easy topics right off the bat. So, it's kind of like the SAP meeting; I think people are all over the place in terms of their opinions, but we do appreciate the comments and discussion.

So, let's come back at 1:00, and we can start on another fun topic, ESA.

(A luncheon recess was taken.)

AFTERNOON SESSION

MR. HOUSENGER: -- headed up by Anita Pease and Patrice Ashfield from Fish and Wildlife. Take it away.

MS. PEASE: Hi, everyone. This is Anita Pease, Acting Director, Environmental Fates and Effects Division. I'm going to be tag teaming this presentation with Patrice Ashfield, who is sitting in for Gina Shultz. Patrice is the Branch Chief for National Consultation from Fish and Wildlife Service Headquarters.

Also, in your packets there are slides. I think there's an additional piece of paper after that packet of ESA slides that has Patrice's slides, the Fish and Wildlife Service step 3 slide on that. So, just a little logistical thing to start.

So, in terms of today's topics, I'll give you a little bit of background. I know a lot of you are familiar with this topic, very passionate about it. I'll provide you a summary of the draft biological evaluations that we just released, try and take that public webinar that we just gave and condense it down into about 10 or 15 minutes.

Talk a little bit about the tool development, some of the tools and models we've developed along the way. We'll discuss a path forward, and then I'll turn it over to Patrice who will talk about step 3 and the biological opinion and the activities associated with that effort.

So, it's been three years since the NAS report came out. It was released in April of 2013, and they provided us recommendations on how to assess the risk of pesticides between endangered species. When we began this work, all these agencies, EPA, National Marine Fisheries, US Fish and Wildlife Service, and USDA, agreed that we would do this collaboratively, that work would be based on a partnership. We also agreed that we would develop a common method, so it wouldn't be EPA's method and Service's method. We would just have a joint method.

So, right after that report came out in April, we released an interim scientific and technical method in November of 2013, kind of a white paper of those interim methods. It's available on our web site. It's a link provided on the slide.

Since then, you know, it's been about three

years, we've been continuing to develop that interim method, to refine it, to put some more meat on the bones. We've had four interagency workshops. Those have been week long workshops. We're staffed with the Services, USDA and EPA. Technical and management staffs have gotten together and tried to work out some of these issues. We've had four external ESA stakeholder workshops.

We've really been on the road at a bunch of scientific conferences, American Chemical Society, CPAC. We presented to this group, as well as SFIREG. We've been to CropLife America. So, we've really made a concerted effort to try and be as transparent as possible regarding the method development and where we are at that point in time along the road to developing these methods.

We also acknowledge that, you know, once we develop these methods, that we would need to test them out in the context of an actual consultation. So, that's what we're doing right now. These are pilot biological evaluations. We recognize that some of these methods are going to have to be changed based on stakeholder comments and feedback that we get along the way.

What we said is that once we've vetted the

methods, we would use a day forward approach in applying those methods, implementing them in the context of our other regulatory actions. So, we acknowledge that, just like all science that evolves, this is an iterative process, and this will evolve just like science evolves in other topic areas.

So, I think the last time we met was in October. At that point in time, we were just getting ready to release a subset of the draft biological evaluations. So, what we did was in December of 2015, we released the problem formulations, all the exposure and effects data, and the analysis plans for the three chemicals, chlorpyrifos, malathion and diazinon. We put those on our web site, so those have been out about four months before we released the full entire draft biological evaluations.

The draft BEs were released on April 6th, and the web site links are provided for those materials. I'll provide a couple screen shots of what the web site looks like, just to take you through a little tutorial on how to navigate it, since it's a lot of material.

Right now, the public comment period is open on

the draft BEs. It will close on June 10th. I'll just get this out now. I'll share the bad news. We have gotten some requests for an extension to the comment period from a number of stakeholders. The request was for additional 120 days.

There's a couple reasons why we're not going to be able to grant that extension. One is that we have some court mandated deadlines or dates that these final biological opinions need to be completed for these three chemicals, December of 2017. There are two more chemicals after this, carbaryl and methomyl. They're a year behind. If we grant that 120-day extension period, we will not meet these court mandated dates.

So, we're not going to be able to grant that extension. Additionally, you know, we thoughtfully put the materials out in December of 2015 to give people an additional four months to look at some of the data and the analysis. A large volume of material was posted at that time. So, that's why.

You can imagine that if we did grant this extension, there is a ripple effect forward on all the deliverables and the deadlines that we're working under.

So, we're going to forge ahead, and we're expecting that the comment period will close on June 10th. Again, the final biological opinions are due for these three chemicals in December of 2017. Before those go out, they will be released in draft, and there will be a public comment period associated with the draft biological opinions as well.

So, once we released these draft BEs, we thought, you know, okay, we can take a breath now, but that's never really the case, right. So, since we released these in April, we've presented a number of different occasions.

We had a public webinar on May 5th where we had a couple hours we devoted to this. We had an hour presentation from technical staff on the methods that we used to develop the draft BEs. We also gave a tutorial on how to navigate the web site. Then we opened up for questions for about an additional hour. I believe we had about 180 people on that call, so there was a lot of interest on that call.

I just want to let you know that we will be posting the slides and recordings from that session, as

well as a list of acronyms, because, you know, we love to use acronyms. That should be out in the next couple weeks on our website.

In addition, we have developed a bunch of new models and tools that I'll talk about. At the ecological modeling public meeting that we held on May 9th, we had some presentations on those models, and we also had demonstrations actually walking through the tools. So, we have been out and trying to release and communicate these tools.

So, this is a screen shot of what it will look like. So, if you go to our endangered species protection page, you'll want to click on the link for the NAS report recommendations. Then, once you click on that, you'll land on this page.

So, what you can get from this page, it has a link to the NAS report. You can actually get the interim approaches that we developed in November 2013. Then, there are hyperlinks for each of the BEs for the three chemicals, as well as a separate hyperlink that will take you to all of our provisional models and tools.

So, if you click on malathion, for example,

this is what it looks like if you click on that page. So, the first thing you'll see is a list of document revisions since the December 2015 posting. So, this is really like an errata sheet of everything we've added since December of 2015. It also gives a brief description of if we have taken a document that we've posted in 2015 and revised it slightly, it describes what exactly those revisions were, and also provides a list of all the new materials.

This document is instructions for commenting on the draft BEs. This is also located in the docket. So, this is a little bit different than the normal way we post risk assessments. Normally, we post them to a docket, but this was so large, we had to put it on a web site. But the instructions are on the docket.

Basically, if you want to post comments or provide us with comments, you'll provide them in writing to the docket. But this document provides instructions on how to comment, where to comment. It also lists a number of topic areas where we're specifically soliciting comments from the public. These are challenge areas for us, so that's articulated in that document as well.

Then you'll see the hyperlinks to the different chapters, the draft BEs, and associated documents. So, basically, the attachments, I believe, are methods that are common for all three chemicals. So, you'll see the same attachments repeated on each of the draft BEs for the different chemicals.

The appendices are information that's specifically relevant for that chemical. Finally, you'll see this yellow icon that says new. That's just to let you know that that's new material since the December 2015 posting.

So, I know you all have seen this before. This is the three-step process, and this is what we're trying to implement. This is based on the NAS report recommendations. So, I'll just walk you through this briefly, and then I'll talk a little bit about some of the methods we use on these various steps. So, basically, we're trying to integrate the problem formulation, exposure, and response analysis, and risk characterization in all three of these steps. That's based on current risk assessment methodology.

So, step one, basically, what we're doing is

we're asking ourselves will the chemical cause an effect, is there a may effect or no effect to the species. This is for individual listed species. If there's no effect, then we're basically done, and there's no need to consult. If we come to a may affect determination, then we move into step two. EPA's biological evaluations encompass steps one and steps two of the three-step process.

So, at step two, we're asking ourselves, is the registration of this pesticide, according to the label, likely or not likely to adversely affect listed species. If it's not likely to adversely affect, what we call NLAA, then we would seek concurrence from the Services, and we would be done with consultations, like an informal consultation.

If we make a likely to adversely affect determination, then we would enter into formal consultation with the Services. That's the point where they would pick it up, and they would write a biological opinion, and that's step three of the process. That's done by Fish and Wildlife Service and National Marine Fisheries.

Then, they would make the jeopardy or adverse modification decision in that step three process. Patrice is going to talk a little bit more about that in her slides.

So, just a little bit more on step one. So, step one, what we're asking here is is there a potential for direct or an indirect effect from the action. Again, the action is the pesticide registration according to the label. So, we're looking at whether or not there's overlap of the action area with the species range information. The species range information has been provided to us from the Services.

The action area is basically the footprint where the pesticide can be used. There's an additional distance that accounts for spray drift and runoff to encompass that action area. So, what we're doing in step one is basically a geospacial analysis of determining whether there's an overlap between the pesticide footprint, which is based right now for agricultural uses on crop land data layer from USDA, as well as nonagricultural data layers that are available for other types of use patterns, and overlaying that information

with the range data that we've gotten from the Services. So, if there's any overlap, then we're automatically into may affect; no overlap, we're at no affect. For most of these species, obviously, there is some type of overlap, and we've moving on to step two.

So, in step two, the question we're asking is is the individual's fitness -- again, these are affects to one individual of a listed species. That's really an important point. I'm going to say that a bunch of times during the presentation. So, is fitness to an individual reduced or is the species essential habitat features affected? Habitat features really relate to its designated critical habitat for those species that have that.

The way that we're doing this in step two is primarily based on a weight of evidence approach. I'll show you in the next slide the matrix that we've created to walk through this analysis. So, what we're doing is we're looking at various lines of evidence that integrate not only exposure for aquatic and terrestrial environments but also the toxicity for direct and indirect effects.

We're also considering incident data, as well as evaluating qualitatively mixtures, and that came up earlier this morning, as well as looking at the abiotic influence on toxicity. So, these are things like does temperature or pH have an influence on the toxicity that we see in the literature.

So, based on this weight of evidence, again, here we're making that not likely or likely to adversely affect determination. If we're at not likely to adversely affect, we'll seek concurrence from the Services. LAA, we move into step three.

So, I think you all have seen this before, but this is our weight of evidence matrix. So, these are our lines of evidence that we're evaluating. We're filling out one of these tables for every single species. We have about 1700 species or so that we evaluated. So, these are our normal endpoints that we would look at, mortality, growth and reproduction, our normal apical endpoints.

In addition to that, we're looking at some sublethal effects like behavioral and sensory effects. We're capturing indirect effects. These are impacts to a

species' food base or its habitat. Then, these last two lines of evidence, these are the qualitative pieces, mixtures and the abiotic or biotic factors on toxicity.

So, for each species, we are going to fill out these cells in the center with information on exposure and effects. Here we're looking at the relevance and the robustness of the information. Then, at the end here, these last two columns on the right, risk and confidence, we're assigning weights of high, medium, and low to confidence in that data, the exposure and effects analysis, as well as the risk estimate. Based on the combination of these weightings of high, medium, and low, we're making either a likely or a not likely to adversely affect determinations.

So, again, I think you all have seen this before, but this is a summary table of the number of species that we evaluated, the number of no affect, not likely to adversely affect, and likely to adversely affect determinations by taxonomic group, by species number.

So, these are the results for chlorpyrifos and malathion. For these, we have a 97 percent determination

likely to adversely affect determination, again for an individual of the listed species. So, when we say 97 percent of the species are being harmed, that's a little bit of an overstatement. This is, again, in effect to one individual of the species. The Services, when they do their biop, will translate that individual into a population level effect, which will provide some more context.

So, for diazinon, it's a little better picture. We have about 80 percent likely to adversely affect determinations. The reason is because for chlorpyrifos and malathion, they have use patterns, wide area use patterns, mosquito site use patterns where they can be used virtually anywhere across the landscapes. No geographical restrictions for certain use patterns for chlorpyrifos and malathion. So, basically, the action area for those chemicals was the entire United States.

For diazinon, this chemical is used on pretty much vegetables and orchards, as well as I think there's a cattle ear tag use. So, the action area is a bit smaller than it is for those other two chemicals. That's the reason for the 80 percent LAA as compared to 97

percent.

At the end of the day, there's still a lot likely to adversely affect determinations. So, why so many? The first reason is these chemicals, they are extremely toxic. They have wide ranging uses across the United States. The other part of it is that the threshold for a likely to adversely affect determination is a very low bar.

We're using a one in a million chance. Mortality is a threshold for acute mortality. We are making some conservative assumptions for exposure. We're looking at the maximum application rates. It's on the label, the maximum number of applications, the minimum days between applications. So, very conservative assumptions for exposure.

Also in that weight of evidence approach that I showed you, when you start comparing those weights, that high, medium, and low weight for risk and confidence, the only way you can get to a not likely to adversely affect, like just looking at those weights, is if you have a high degree of confidence and a low degree of risk for every single line of evidence. Otherwise, in the slides that

we presented in the public webinar, there's a matrix that shows you how the rankings of high, medium, and low get you to NLAA, or likely to adversely affect.

So, you know, we recognize the need to go back and have to look at some of these evaluations. Again, like I said, the likely to adversely affect determination is for a single, individual of a listed species. So, again, you know, looking at the instructions for commenting, we are soliciting comments on some specific areas, actually looking for areas where we can refine these analyses.

So, a little bit on the tool development. I think the last time we met, I had talked to you all about a lot of these tools. Really, this is the good news part of this presentation. Along the way, there's so much data that we're looking at. For the modeling runs, we have tens of thousands of modeling runs. We have toxicity studies. We looked at thousands of toxicity studies for these chemicals. So, we really did make a concerted effort to automate a lot of this work.

So, the tools that we built here will not only serve us well moving forward in the ESA consultations,

but we'll also be able to leverage them for other types of assessments that we complete in the program. I encourage you to go and look on the provisional models page and look at these tools, because they really do take a lot of information aggregated into a way that we can digest it.

So, in the aquatic exposure modeling, you know, we have what's now called the pesticide and water calculator. I think the name has changed several times throughout this process, but this is basically the tool we use to calculate aquatic exposures. We're doing this not only for one type of aquatic habitat, which we typically look at, which is the farm pond, but we've expanded that to nine different types of aquatic habitats in the assessments. So, there's three different habitats for static water, three for flowing water, and three for estuary marine. So, a large, large amount of information.

We've also developed some new scenarios that correspond to the crop land data layer footprint that I mentioned earlier. We've developed some new scenarios for non-agricultural uses as well. Then we have this

post processor that we've developed. This basically allows us to produce graphs and tables that include probability distributions of exposure over time, help characterize the duration and the magnitude of exposure. They also allow the user to compare the estimated exposures to the aquatic thresholds, summarize these exposures by HUC (phonetic), which are the hydrologic, you know, regions of the country, and also by the aquatic habitat pin. They allow us to make the effects determinations for aquatic species.

On the terrestrial side, we have this tool called TED. I think I spoke to you about this the last time we met. This tool basically aggregates our existing terrestrial models. So, it takes T-Rex, and terra plant, and T-Herps, and Ag Drift, and our earthworms-to-gaspy (phonetic) model, and it combines them into one aggregated tool. It also allows us to go beyond our typical exposure route that we evaluate which is dietary exposures, to look at exposures based on drinking water, inhalation, and dermal routes of exposure. So, this tool is actually a great tool because we don't have to do all those separate model runs.

The other thing this tool does is it allows a comparison of estimated exposures to the thresholds for terrestrial species. It estimates the distance from the edge of the field where we wouldn't expect there to be risk of concern. It also provides information on the duration of the time that the residues exceed that threshold. So, it provides a little bit of information on the probability as well.

The TIM and MCnest tools are tools that we've developed to further our avian risk characterization. These are probabilistic tools that are complementary. They look at mortality and fecundity of avian species.

On the effects side, again, as I mentioned, we look at a lot of information. Not only the registrants submitted data, but also all of the data in the open literature. We built a tool called the data array builder, which basically allows you to take all the information and you can segregate it by the type of endpoint or the species. You can look at a lot of information in one single snapshot.

Then, the species sensitivity distribution toolbox allows us to distribute all of the acute

mortality data, along with species sensitivity distribution, to derive a threshold. So, that's another tool that we've developed.

The newest tool that I don't think I talked to you about the last time that we've developed since the last PPDC meeting is called this weight-of-evidence generator. So, this tool basically takes that table that I showed you and it automatically populates the information for exposure and toxicity.

It also incorporates biological information for the species. It calculates the percentage of overlap between the footprint and that species range data. It helps the risk assessor make that high, medium, and low call that eventually leads to the effects determination. So, this tool has been a lifesaver, actually. I'm sure the scientists in the room can attest to that. It really helps to (inaudible) a lot of information very quickly.

So, in terms of the path forward, again, the comment period is going to close on June 10th for these three chemicals. We recognize that, you know, we have built a process that really right now is not sustainable. It took a lot of resources to get where we are. If you

go on the web site, there's thousands and thousands of pages. So, we need to go back and figure out a way to build this process so it's more sustainable so we can use it moving forward.

So, we have developed some smaller interagency subgroups to look at some lessons learned, to go back and do more of a retrospective analysis to see if we can come up with some process efficiencies. It's a little difficult to do this because we don't yet have the biological opinion step three analysis. Once we have that in place, then we can really go back and figure out what did we really use in step three, what didn't we use, what's nice to have, that kind of thing, and figure out where we can trim that way. So, this will be an iterative process.

Right now, our next step, you know, the comment period, as I said, is open. We're going to have a two-day ESA stakeholder workshop. The dates have been set to June 29th and 30th. It will be at the Fish and Wildlife Service building in Falls Church, Virginia. In this meeting, the feedback we heard from stakeholders is our past four ESA workshops, while they were good for

informational exchange, it was kind of a lecture style.

This is going to be different in that we're going to, you know, roll up our sleeves. We're going to have some breakout groups on some different topics, including aquatic modeling, refinements to steps one and two, and also take another look at that weight-of-evidence approach for animals and plants. So, in this meeting, we plan to invite some people that have some specific expertise in these areas so that we can move forward and get some refinements. We're also hoping to develop some charge questions to focus this meeting moving forward.

So, the last slide I have here is just a proposed schedule for chlorpyrifos, diazinon, and malathion. Of course, depending on the volume of public comments we get, which I'm anticipating will be quite a few, we are setting the proposed date to get the final BEs done by the end of this calendar year.

Then, right now, we are starting to work with the Services, as Patrice will describe, on the draft biological opinions. Right now, we have a proposed date of April of 2017 for that. Like I said, these documents

will go out for public comment, just like the draft BEs. Then, that court mandated final biological opinion date for these three chemicals is December 2017.

The next two chemicals we'll be working on will be carbaryl and methomyl. They're about a year behind. So, we're hoping to get draft BEs out for these two chemicals by the end of the calendar year. Then, the final biops are due in December 2018.

So, with that, I'm going to turn it over to Patrice.

MS. ASHFIELD: Thank you, Anita. It's nice to be here today representing the Fish and Wildlife Service. Again, I am the Branch Chief for National Consultations. You know, I thought I would start off just by saying that, as you may or may not know, this is the first opinion of this type that the Service will have ever done, having, you know, to take a look at 1640 species, and I think what is critical habitat around 650 or so. So, obviously, quite an endeavor. With that, this lays out a whole new set of kind of parameters on how we're going to tackle something along these lines.

So, with that, I thought I would walk you

through, you know, an overview of where we're at currently with the biological opinions and give you an update on some of the areas.

For those of you who don't know, biological opinions, set up per our regs, have very specific areas that we will write and address. One of the first things, in order to understand what is going on with our species, and then, in order to take a look at the action and how that action is going to affect that species, is we really need to understand where our species are. You know, you may think, gee, the Fish and Wildlife Service didn't have current range maps for all those species. You know, you might have been surprised by that.

In Section 7, a lot of times we're consulting on some species a lot and other species not so much, and some species not at all. So, one of our first tasks was to lay out a current range map for each of our species. FESTF was actually extremely instrumental in helping us do this. They pulled together draft maps.

Then, we went through an exercise where we reached out to our field offices. We have about 90 field offices across the United States and in Hawaii and Puerto

Rico. They are a field office, those individuals who know those species. Took a look at those range maps and further refined them from what FESTF had done with the draft map.

So, this actually is a huge step forward. I always like to start off with it because it's something we have completed and we now have a range map for every one of our species.

So, one of the first steps in the biological opinion, along with understanding where they are, is to understand what's going on with that species. We call that our status of the species. The status lays out, you know, population numbers, as we know them, specific locations of importance, some of the basic ecological information of that species, and it will also bring in to that beneficial actions that may be occurring that's helping the species population or other stressors that's also affecting that species.

So, with that, over I'm going to say about a year ago, about the time I think we were part way through our mapping exercise, we also started working on having biologists pull together the status of the species

that we currently had, and then also starting to write status of the species for species that we did not have this information.

It was slow going. We had trouble getting enough detailees to be able to help us with this. Once again, FESTF stepped in and is currently assisting us on pulling together the information on the status of the species. So, while that looks a little daunting to see up there that we still have over 900 statuses that have to be completed, I'm optimistic with FESTF's help and some of our detailees that are still working with us that we will get this task done. As you can imagine, it's paramount to understand what is going on with the species as we go through the biological opinion process and be able to assess the effects of the actions.

So, we also need to take a look at the critical habitat. We need a status for the critical habitat. So, again, you can see this one does need some more work. We have over 100 partially done, but again, with FESTF's help, we will get it done.

UNIDENTIFIED MALE: You're using an acronym I don't know.

MS. ASHFIELD: Oh, I'm so sorry.

UNIDENTIFIED MALE: FESTF?

MS. ASHFIELD: Oh, excuse me, FESTF is the FIFRA Endangered Species Task Force. This is my understanding, they're a consortium of representatives from different industries. I'm looking at Anita to make sure I'm saying that correctly. I work a lot with Berna Lynn. She's the coordinator right now. So, like I said, they've been very helpful. I'm sorry to have thrown in an acronym without explaining it. Sometimes you get so used to saying some acronyms that they're almost like words.

So, the next part in our biological opinion will be the project description. Fortunately, because, as Anita had talked about, we worked so closely with NMF (phonetic) and with EPA, we'll be able to lift a lot of the description right out of the BEs and pull that over into our biological opinions. We do need to have our biological opinion be a stand-alone document. It should be something that the general public could pick up, read, and understand what's going on. Of course, we'll always be referring back to the BEs, but the project description

should be able to lay out what we're looking at and why.

There's another part of the biological opinion, which is the baseline, which takes a look at the status of the species within the action area. So, normally, for us, in section 7, a federal agency will have an action, whether it's building an airport, or a highway, or something along those lines. So, when we take a look at the status, we take a look at the status overall.

When we take a look at the baseline, we take a look at the status of that species within the area that is going to be effected. In this case, as Anita was talking about with a couple of these chemicals, the baseline, or maybe I should say, because a couple of them are so ubiquitously used, the status and the baseline are really going to be one in the same. However, for diazinon, because the use isn't quite as widespread, we will have a baseline. Currently, for that, I have a biologist who I've tasked with, and he is working on this to write up this section for the baseline section in the diazinon biological opinion.

Speaking of that, I'll tell you also -- I should have brought this up first -- we have at the Fish

and Wildlife Service here at headquarters beefed up our staff to help us be able to accomplish this task. So, currently, right now, I have eight biologists that are working full time on these opinions. My newest person just came in a couple days ago, but I'm still excited to say that we have eight folks, four of them toxicologists. Some of these folks, through the last two or two-and-a-half years, have been working, as we said, continuously with EPA and NMF. And then, some of my newer folks will be coming up to speed.

So, the meaty part, the effects of the action, this is the tough one. So, now we've laid the stage. We've figured out where the species area. We figured out what is going on with that species, how their status is doing. So, now we're going to be taking a look at the effects of the action. This is where we're going to be working off of what EPA, and Fish and Wildlife Service, and NMF have been working on. But we're going to expand that in our effects.

So, for instance, a lot of the modeling that Anita talked to you about was set up to take a look at is the action likely to adversely affect that one

individual. So, when we take a look at this now, we're going to be working with EPA and modifying some of these models to be taking a look at. So, yes, they have determined that an individual can be adversely affected, but what does this mean to the population.

So, in some of the early work that we've been doing, EPA has been talking about assisting us with being able to take a look at meteorological data, for instance, taking a look at I'm going to be talking to my field offices, taking a look at out of a range, where is that species, are there areas where the species has higher density versus other areas.

For a lot of species, as we know, they're not ubiquitously placed across their range. There's going to be -- I'll use a species I'm familiar with, lease bells verio (phonetic). There could be some drainages where you're going to have higher populations of that species versus other drainages.

So, we're taking a look at how can we add this into the work that we're doing so that we're assessing, you know, clear or more correctly the exposure of these species to the chemicals.

One of the other things that we've been focusing on in all the subgroups that we've been working on is we've taken some representative species and we've spent a lot of time taking a look at lease bells verio or the power sheets skipper link (phonetic). We had a fish species.

So, a lot of time has been focused on that. We're going to take that and extrapolate that, then, across different groups of species. So, for lease bells verio, we'd be able to represent other insectivorous (inaudible), for instance. So, I have right now over at Fish and Wildlife Service, one of the things we're doing is we're taking the 1640 species and grouping them into major taxonomic groups, but then also subgroups. So, for instance, out of our 80 freshwater and muscles, we'll be grouping those into groups that make sense, so that we can then assess a representative out of that subgroup. Then, the others would be extrapolated from that.

So, after we go through this process, we take a look at our status, our baseline, and our effects section. We work on our conclusions. The objective of a biological opinion is to determine whether the action

would jeopardize the continued existence of the species or destroy or adversely modify critical habitat.

So, with that, in the conclusion, we would then be taking a look at these effects for each of these species. If the action does not jeopardize, we would then be figuring out what do we think the take would be pursuant to that action.

So, in simpler terms, back to my airport development, et cetera, you might take two pairs of nat catchers and Steven's kangaroo rat, for instance. We normally do our take statements in, you know, numerical type values. This pesticide consultation may be something we'll be looking at having a different type of take statement pursuant to our new rule that we just passed using surrogacy for incidental take statements.

So, with that, then, is how we conclude our biological opinions. I was trying to think if there's anything -- I think that I've kind of covered that overview of how we're hoping to proceed, some of the things that we have accomplished. As you can see, we have a lot more work for us in our future.

So, I think that covers it for me. I'll pass

it back to you.

MS. PEASE: Questions?

MR. HOUSENGER: Bob.

BOB: This is really just a question. So, that was really interesting and way over my head. So, when you get to a decision, say on the organophosphates, what kinds of things will you do? Will you cancel the product, or are there specific ranges of risk mitigation options? What's the end game look like?

MS. PEASE: So, the end game, we're probably not going to do anything until we get the biological opinion, because that's where, you know, the Services come to their jeopardy conclusion or no jeopardy conclusion. We'll issue what they call reasonable and prudent measures or reasonable and prudent alternatives. So, those are basically the mitigation measures that we would then be responsible for implementing in the context of our pesticide registration.

So, at that point, you know, we hope that before we get that final biological opinion, we will have engaged in some meaningful conversation about what's reasonable and prudent, and what we feasibly do with the

resources we have, and also to engage registrants to the table, so we're not just saying, here it is, you know, go implement it. We've tried that in the past, and it hasn't really worked so well.

So, I mean, I can confer that back to Patrice, but right now, the stage where we're actually doing something about this, the mitigation piece comes when we get the biological opinion.

MS. ASHFIELD: So, as far as the mitigation aspect, you know, we will be working with EPA throughout this entire process. But, you know, this is something to think about. If we are working with EPA and then we can reach out to different companies, if there is some type of mitigation that we can put up front, maybe that might be for a particular species, it might be a larger buffer, or it might be a timing issue, et cetera, if that can be added into the biological opinion as part of the action, then that goes also into our effects. So, then, while we have the impact of species, x number of species are adversely affected pursuant to the chemical, you have the benefit, too, that's being offset.

MS. PEASE: I'll just add one thing to that.

We were able to complete a successful consultation with Fish and Wildlife Services on Rozol and Kaput, which are identifieds. The way that we did that is we used this term called conversation measures. We developed some measures that we included between the draft and the final that basically got us to a no jeopardy opinion.

So, that's the framework, the paradigm that we want to operate under, is that we're having the discussions early on. We're developing options that make sense and integrating those into the biological opinions so it's not just, here, EPA, go do this RPM. You know, we've had conversations about it. That's kind of the framework.

MR. HOUSENGER: Sharon.

SHARON: I have a few questions. Do you want me to ask all of them or ask a couple and then let others go?

MR. HOUSENGER: You can go. Just do them all. Then we won't come back to you.

SHARON: Well, okay, going back, Anita, to when you said that in the BE, you also looked at abiotic

factors, such as temperature, I'm curious about how you incorporated that into the analysis. Did you use temperature under current conditions? Were you looking at the registration review period being 15 years, what you might expect for temperature, for instance, over the next 15 years?

MS. PEASE: Not necessarily. I think we had some data that showed that increased temperature increases toxicity. NFM specifically, Marine Fisheries, has some scientists that are working on this effort. So, they have some publications out that show a direct relationship between increases in temperature and toxicity. So, we tried to integrate that into the analysis. Again, this is a qualitative piece of information that's discussed, but it carries a little bit less weight than some of those other lines of evidence I talked about.

SHARON: Okay. So, the second question, both today and the last time that we met Fish and Wildlife Service has been represented here. I think that's great, and I recognize that Fish and Wildlife Service has over 90 percent of the species on the endangered species list.

I'm just kind of curious, because I haven't seen National Marine Fisheries also represented. I'm curious if they've been as integrated into this process and if they are, you know, I guess, aligned with this approach and everything that you're saying here.

MS. PEASE: So, yes, they've been involved in all the discussions that we've had. All the interagency week long workshops that we've had, they've been involved in those workshops. The interim methods that we developed, we developed in collaboration with Marine Fisheries as well as Fish and Wildlife Service. So, they have been invited to these meetings. We've done some presentations for CropLife America and other meetings where they have been present. Unfortunately, they couldn't be here today, but they've been involved.

SHARON: Okay. So, for the ESA stakeholders workshop that's coming up at the end of June, is that an invite only workshop?

MS. PEASE: That's a good question. So, we struggle with this because we want to balance it. We want to be inclusive, but we also want to invite the people that have the expertise to really help us, you

know, roll up the sleeves and figure some of these challenges out. So, what we're thinking of doing is -- right now, we have a steering committee that's working on the logistics for the workshop.

That steering committee, I think there are some people that are even in this room, but it's not just the government agencies; it's also NGOs, industry groups, and grower groups that are involved on this steering committee. So, we're all putting forward names of people that we think will provide fruitful conversation and provide some expertise.

So, what we're hoping to do is identify some specific folks that we can invite to the breakout groups. Then, with the room that's left over, we would open that up to the public. Then, also, at the beginning and the end of the workshop, we'll have plenary sessions that will be open to the public.

So, the very beginning where we're talking about here's the methods we've used, here's the challenges, here are the charge questions, that will be open to the public. Then, the end session where we're talking about the results of the breakout groups, the

recommendations, the pass forward, that will be open to the public. Then, some of the slots in the breakout rooms would also be open.

SHARON: I think I just have one more. So, EPA has said on various occasions that you'll be using this pilot process as sort of a day forward approach. Recognizing that these are pilot nationwide consultations and this is, you know, a new process for all the agencies involved, and that you've got a schedule not only for these three OPs but also for carbaryl, methomyl -- and then, I believe we've got glyphosate and atrazine coming behind that, maybe a couple others I can't quite remember.

I'm curious because the registration review process continues on. You know, you've got a schedule for that, too. So, this year I think you've got open dockets and draft registration reviews happening for a dozen, I can't quite remember, chemicals.

I recall EPA saying that ultimately and eventually the Endangered Species Act analysis will be incorporated into the registration review process. But when exactly will you integrate that in so that that's a

standard part of the registration review process of all active ingredients?

MS. PEASE: That's the million dollar question. So, I mean, it's a great question. Right now, what we've said is, just like you said, once we get the message vetted, which is what we're doing right now based on putting out these drafts, taking them to the public, getting public comment, having the stakeholder workshop, once we have a method we agree with that we feel is sustainable --

And I don't have a magic ball. I think I'd need a magic eight ball for this question in terms of timing. But once we get there, we will then go back to registration review and we will, you know, carry it forward at that point in time. I don't know when that point in time is going to be, but we're working towards that.

MR. HOUSENGER: Aimee.

AIMEE: So, I'm curious, because you were talking about kind of honing the range information to better understand where populations are currently in order to determine where you're going to have risk most

likely, because you're going to have populations there, you know, of levels that might cause harm overall.

I'm going back to the Endangered Species Act and thinking about protection and to restore those populations. Yet, we've got historic ranges, and then we have current range, and then we have segments within that current range where we have fewer species.

I would like to hear more about your thoughts as to how that honing, which I get it, you don't want to kill the current species that are there, how does that actually then also help us to get to the bigger picture where we want to restore species? Have you thought about that component?

MS. ASHFIELD: So, I think maybe I misspoke a little bit. When I was talking about taking a look or, you know, where we have a current range map of where the species are, I was thinking more of if we could, on some species, it probably wouldn't be all, of having the biologists that are the experts for that species be able to draw like maybe just a gross polygon, for instance, and say, you know, this is where there's a high density of X species here, and there's lower here. Really, that

doesn’t have anything to do with the lower density as less important. It’s more an exposure question.

So, rather than saying that -- going back to my lease bells verio, which is a species that uses riparian corridors, rather than saying these birds are situated across the landscape in a very similar style, they’re actually -- you might have more birds on the Santa Margarita River than you do on the San Diego River, something like that. So, it’s really more of trying to hone the exposure but not the overall need for what the species would need for recovery. So, it’s kind of two different things, as I see it.

AIMEE: So, you have pesticide use throughout the range, and you’re looking at where in that range the populations are. Just talk me through that, because it still feels like they’ve got their whole range. If you’ve got higher use in an area that, you know, is range but it doesn’t have a high population right now, but we’d like to restore them to that area and grow that population, how would what you’re talking about --

MS. ASHFIELD: I think I get it. When we’re assessing -- because, you know, a lot of this is taking a

look at what is the impact of this action to the population. So, how are lease bells verios affected by the use of pesticides adjacent to the habitats where they are, in essence, right?

So, in doing that, if we had a uniform distribution, I think that we would not really get the impact to the species as it is. So, let's say in the drainage, the Santa Margarita, since I've worked this bird, I'm familiar with it, there actually is a lot of farming on Camp Pendleton. There's a lot of agriculture adjacent to some very dense populations of birds.

So, I want to then, if we can, you know, working with, like I said, the experts, if we could then take a look at the exposure, I think you're getting more representative of what's going on. Otherwise, you might take the Margarita and say, well, we have 100 pairs, and the San Diego River has 100 pairs, each river, right, versus that some of these are more important. I think that actually might direct you to working with those rivers that are more important, while not ignoring the rivers that may have lower populations.

In a lot of instances, a lot of reasons why we

see lower densities of our species in some area is just because of lost habitat. Now, in some cases, restoration is possible, in some cases, like Los Angeles River, not so much.

So, I think that was the point I was trying to make. Again, we're still working through all of this. But it was just something we've been talking about.

MR. HOUSENGER: Cynthia.

CYNTHIA: So, I've been trying to follow all this. I just need a couple of clarifications. In the mix of all of this, my kid texted me that they threw up all over the rug. I might have sort of missed a bit here.

So, in the very last slide, you mentioned something about identifying representatives of species, groups, or subgroups. I'm just wondering how we were going to identify the representatives of those groups.

MS. ASHFIELD: So, I've been thinking about -- and again, please take this with a big grain of salt, because this is what we're working on right now. Out of 1640 species, I worry about having an effects section as in depth as we have been working, again like with the lease bells verio or the powershake skipperlings

(phonetic). I don't think that's doable.

So, I use an example that we have 80 species of freshwater muscles. So, some of those muscles, let's say, you find on tertiary streams or some of them you might have a grouping that are found in primary drainages. There's going to be some differences between those muscles, let's say. So, my thought was, those could be broken out into a reasonable, you know, probably -- because the species are similar, then if I have five or six muscles, out of those five or six, we would pick a representative.

We might pick the most endangered. We might pick the species that seems to maybe be the best representative for the other species of muscles. Then we would give a more in-depth affects analysis for that muscle. Then, maybe those others would have to, while they're still may be an effect, it would build off of that representative.

Again, you know, it's something we're thinking of. It's trying to figure out, and if anyone has any other ideas, I'm all ears, of really how to assess. Again, I can't tell you the amount of hours and

biologists and incredible thinking that has gone into trying to figure out how to address something that's so complicated.

CYNTHIA: Right. So, maybe sort of case by case at the beginning.

MS. ASHFIELD: Yes.

CYNTHIA: Second, I wasn't familiar with the acronym either, the FIFRA Endangered Species Task Force. You mentioned it was representatives from industry. I'm just wondering are there NGOs, are there academia, is it a whole range of people involved, or who exactly is this?

MS. PEASE: It's a consortium of registrants. No NGOs. Actually, it's a Federal Endangered Species Task Force. So, Berwin McGehey (phonetic) is the coordinator of that group. They are developing a system called IMS, which is an information management system. So, it's a tool that they're developing of spacial data, biological data on species. They have been extremely helpful in providing a base set of maps to the field offices of the Fish and Wildlife Service field offices that were a starting point for all the work that's happened. So, they had some aggregated data, some nature

serve element occurrence data that was the start of all this work.

CYNTHIA: Okay, thank you.

MR. HOUSENGER: Pat.

PAT: I'd like to know a little bit more about the data you used to determine whether or not there may be effects. You mentioned pesticide toxicity data, open literature. I'm wondering, for example, so you have, say, rodent data for toxicity. Do you apply that data to the universe of mammals, for example, and assume if you're seeing an effect in a rodent, it's going to translate to other mammals?

Certainly, you know, there's evidence that rodent data may not necessarily be greatly represented of human responses in many cases. Similarly, you know, you have reptiles, you have amphibians. You don't often have that kind of data with pesticide testing. You may not have endocrine data for a lot of these types of species. How do you deal with that, and how do you, you know, fill those gaps, so to speak?

MS. PEASE: Good question. I mean, we use a surrogate approach, so obviously we can't test 1600

listed species.

PAT: I wouldn't want you to.

MS. PEASE: Yes, right. So, I mean, we have our guideline requirements that are articulated in 40 CFR Part 158. So, you know, we get data on rodents, and we use that data for mammals. We also look in the open literature. If we have a more relevant species for a particular taxonomic group or a particular listed species, we'll use that data. So, you brought up a good point about reptiles and amphibians. If we don't have amphibian data, aquatic phase amphibian data, we usually use fish as a surrogate. For reptiles, we use birds as a surrogate. But we will go out into the open literature and try and seek out data for taxonomic groups which are underrepresented by the types of tests and guidelines we would normally get. We do that mostly by going out into the open literature and then assigning that.

Recall the weight-of-evidence matrix that I put up? If you look under the effects, there's a column for species surrogacy. That's where we're looking at that, exactly what you're talking about and seeing -- the data that we have, is it really applicable for the species

that we're evaluating? Are we confident in that data or not? Then we do the weights accordingly.

PAT: So, just to follow up, if you have, again, say, the rodent data, how confident are you that that's going to represent, say, a mammal higher up in the food chain, for example, you know, a carnivore or something?

MS. PEASE: I mean, we would have less confidence if we're using a mouse endpoint for a grizzly bear, you know. I mean, you have less confidence. But there also models that incorporate allometric equations that extrapolate based on the body weight of the animal and its diet.

PAT: Okay, thank you.

MR. HOUSENGER: Cheryl.

CHERYL: I just kind of have two questions. One is, an awful lot of work, tremendous amount of work. To get to the end of step two, just kind of a toggle question, you're just kind of toggling, yes or no, go forward.

I'm just wondering if all this work leading up to that, if there's any way to take advantage of it to be

more of a prioritization, because it's kind of like a screening almost, a very conservative screening with a whole lot of work behind it. If you look into these tools, can you do more of a ranking prioritization?

I have a second question, but answer that one first.

MS. PEASE: Again, remember, our benchmark here is an effect to an individual. So, I completely agree with what you're saying. You know, when we built this process, I think we envisioned it would be more of a funnel. So, we take a lot of information, you know. We start with a lot of species. We went our way down to the species that we really care about and we want to spend our resources protecting.

Again, these are pilots. We're building the methods. We acknowledge the need to maybe go back and do some of what you're talking about, because, you know, right now it's just a big tube, and everything is shooting through to step three. So, we recognize the need to do that, and that's what we hope to do in the stakeholder meeting, is identify some areas where we can fine tune, gain some efficiencies. It's going to be an

iterative process.

CHERYL: Okay. The second question is, when you're talking about establishing a baseline or status, that you're also describing this action, this potential action of the approval. You actually have use going on right now. So, as you're describing baseline and status, it sounds to me, from the way you described, you're trying to make a decision do you approve this use or not. But you know for a lot of these cases, it's already happening. So, what's the part of the process that takes into account that your baseline already has this exposure in many cases?

MS. ASHFIELD: Excellent question, one that I've been struggling with. Normally, in section 7, you are addressing the action before it occurs versus while the action is ongoing, as in this case. So, we had one similar consultation on cooling water intake structures where we did a national consultation.

As we know, cooling water intake structures are currently in in work, similar to this. So, the process there, and there was some case law that I'm sorry, I'm not going to be able to pull off the top of my head. But

our solicitors did direct us to take a look at that as if that was part of already a preexisting situation.

So, I think what -- and again, please, everyone, you're hearing it first, almost. We're working on this. I think that we will be taking a look at this with the baseline with the chemical already there. But I have worried about this, and it is a problem, because it isn't like you're saying, okay, now we're adding this new chemical that a species hasn't, you know, had in the environment before.

So, an excellent question and one definitely that I'll be pulling in. I have another resource that I'll mention to everyone. Across the United States, we're broken into eight regions. I have some excellent Section 7 thinkers out there. I will be pulling in that team as we start to hit some of these tough section 7 questions. Also, I do have some solicitors that I can go to to help me with some of these. But, excellent question and one we're thinking about and will be working on.

MR. HOUSENGER: Bruce.

BRUCE: Question, I think, really for Anita.

Step one in your process deals with overlap, the spacial intersection between species, their habitat, and farming. One thing that I know you've updated this panel on in the past is Bulletins Live, a reinvigoration of both Bulletins Live. I'm curious why that spacial information, we now have range maps that are updated. We obviously have a perfect understanding of where farm fields are.

For a process and a time line which are challenging, it seems like streamlining in a refinement opportunity that come from a really closer look at that overlap, that something like a fully deployed Bulletins Live would be very helpful to the process.

I think from a spacial standpoint, you know, we've spent a lot of time looking at this from a midwestern agricultural standpoint. I think automatically 95 percent of American agriculture is out of range. That just seems like an enormously important refinement opportunity for a process --

MS. PEASE: Thanks. I couldn't agree more. In fact, you know, we have this endangered species knowledge base right now that we're working on building. We've included a lot of biological information. One thing that

we are adding is whether species are on or off agricultural fields, I mean, just exactly what you're saying.

I think our vision is to implement protections for species, or maybe even if at step one, if we could think of a way to leverage bulletins to get at what you're suggesting, I think that's a good suggestion. We'll consider it.

MR. HOUSENGER: We're getting close to the time, so Gabrielle is the last one, but Annie now.

ANNIE: Thank you. I just wanted to build on Sharon's question on the integration of agencies. I think that collaboration between agencies has always been a concern for the environmental community. So, I'm just wondering if there has been any systemic changes to ensure the collaboration in creating these biological opinions, especially like if, you know, you were to incorporate the ESA process and integrate it into the registration process. What could we expect as far as more integration between the agencies? I don't know if you've thought that far ahead.

MS. PEASE: Well, I think whatever method we

use moving forward, once we get to a process that's vetted we're going to implement in the context of, you know, registration review and other registration actions, potentially, we're going to need to get there in collaboration with the Services. So, you know, we want them to be involved. I mean, we also recognize the limited resources. I know Patrice said they're hiring staff, but at the end of the day, when you look at the volume of chemicals that move through this program, we do need to figure out a way to prioritize. So, all I can tell you is we're thinking about it, and we're working on it.

I don't know, Patrice, if you want to add anything.

PATRICE: No, I'm good.

ANNIE: Thank you. I just had one other question. Like, there has been some evidence, you know, with atrazine endangering species. So, we were also just wondering if you are going to take any action on atrazine?

MS. PEASE: So, atrazine is one of the chemicals that's up in the cue after we finish these

five. So, I think Sharon mentioned this. So, it's atrazine, glyphosate, simizine, and propazine are the next four chemicals that will be evaluated after we finish these five. Right now, for those four chemicals, we expect to complete final biological evaluations by 2020. Fish and Wildlife has agreed to complete biological opinions for those four chemicals by 2022.

At the same time, atrazine is undergoing a registration review. It's in reg review right now. So, we have been working on a preliminary ecological risk assessment for that chemical as well. I think it was one of the documents that got inadvertently released before its time. So, anyway, we're working on that as well.

ANNIE: Great, thank you.

MR. HOUSENGER: (Inaudible).

GABRIELE: To follow up on the question about -- Anita, you mentioned in terms of doing the risk assessment, you're using the worse case scenario in terms of the label rate, maximum use rates, and so forth. We all know that in general, that's now how these compounds are used in reality.

So, my question is, when you get to the

jeopardy stage, when you're having a conversation back and forth between EPA and the Services, where's the potential to go back and look at okay, so we assumed the worse case scenario, but, you know, this is only used in the summertime, and it doesn't rain, so it's probably not getting into the waterways. Or, it is only used at half the rate typically, not at full rate.

Does that fit at all in these conversations or is that not at all part of the conversation? In every other part of the risk assessment world, looking at that real life has helped refine the risk assessments.

MS. PEASE: Yes, I'm in complete agreement with everything you said. So, let me just say that if you go back to the NAS report, the National Academy basically recommended that we start integrating typical use rate information into step three. We spent a lot of time talking about this at our last interagency workshop. Where is the best place to incorporate, you know, the more realistic use rate information. So, we are having those discussions. I hope that we can bring that information to bear as part of step three. We think it's important to do that.

We also think that if chemical labels say one thing and they're being used another way, there's also an opportunity to potentially change that label to make it, you know, more in line of what's actually happening out in the environment. So, I think it's a balance of those two things.

MS. ASHFIELD: I think if I can just add or maybe reinforce what Anita said. You know, when we're looking at this through the section 7 eyes, we do look at what's the action. The action in how that chemical is going to be used is the label. So, you know, in the future, if those labels could be -- if it says a million pounds, and I'm making a step up, obviously, over 50 acres, but that's not really the use, and it's really half of that or whatever it is, the more refined that could be would help us very much into the future.

It is difficult in the affects analysis, and this has been a lot of the dialogue between the Services and EPA, but it is difficult to say, well, we understand that. This is more the reality, this is what's happening. However, legally, you know, the label says this could happen. So, that's what we feel we need to

look at. So, I think that's a great point and something for folks to be thinking about.

GABRIELE: So, are we anywhere closer to some kind of probabilistic assessment? I mean, I know that's been in the conversation. I don't have any clue where it is for the environmental side.

MS. ASHFIELD: We're definitely talking about that. As a matter of fact, just yesterday I had a great meeting, you know, taking a look at some different factors. We weren't really looking at the labels, per se, or that hasn't been a discussion point yet, you know. But yesterday, yes, I would say on some of the modeling and the work that EPA has been doing, that we're moving in that direction.

MR. HOUSENGER: (Inaudible).

UNIDENTIFIED MALE: Gabriele sort of addressed my question, so I'll pass.

MR. HOUSENGER: Well, then, we're done.

Okay, the next session is broken into two pieces it's so big, pollinator protection activities, Yu-Ting.

MS. GUILARAN: It seems like everybody needed a

break after that session.

MS. PEASE: Wait a minute.

MS. GUILARAN: Just stating an observation. I'm Yu-Ting Guilaran. I'm the Director of Pesticide Re-evaluation Division. Up here with me is Dan Rosenblatt from the Registration Division. You guys already met Anita Pease, Acting Director of EFED.

So, as Jack was talking about, we have two parts on the pollinator protection. The first part, which is what the three of us will be going over, is really more focused on the science piece and also the implementation of the science piece. So, it's really our current thinking on implementing a new bee exposure and effects testing.

After we're done with that piece of it, the last couple slides is to address, I believe, the question that came up from (inaudible) about the schedule for the neonic risk assessment as it's going through the registration review process. So, that's what we're here to do.

So, what's going to happen next is Anita is going to go through the science of it, a little bit about the history, a different guidance that has gone out, and

then what's happening currently. Then we're going to go ahead and launch right into, if there's no question along the way on that, into the implementation.

So, Dan is going to take over the registration, what do new uses or new registration AIs will look like, what are the expectations there, what we're thinking about there. Then, I will cover the registration review piece on our current thinking again and follow then with a Q&A. Then we'll go into the neonic schedule.

So, with that, I'm going to actually turn it over to Anita.

MS. PEASE: Are you guys sick of me yet? So, in terms of the science, this is not unlike any other approach we have for evaluating risk to other taxa. In this particular instance for pollinators, we've developed a number of guidance documents for evaluating the risk to bees.

This really started in earnest in 2011. So, in 2011, we developed our first interim guidance on honey bee data needs. This is really based on evolving science. At that point in time, there was a CPAC Telleston Workshop (phonetic), which is where a number of

experts from all across the globe came together and started talking about ways to develop risk assessment methodologies and develop data for assessing the risks of chemicals to bees.

So, based on that, in 2012, EPA, in collaboration with Health Canada's Pest Management Regulatory Authority and the California Department of Pesticide Regulation, we did a white paper on pollinator risk assessment framework, which we took to a scientific advisory panel.

So, in this particular document, this 2012 document, this laid out the conceptual framework for assessing the risk of pesticides to bees. Prior to that, we'd been using more of a qualitative approach in our risk assessment.

So, based on that SAP review and that white paper, in 2014, we came out with a final EPA guidance on risk assessments for pollinating bees. Again, this was developed in collaboration with Canada and California, the State of California, the State of Canada (just kidding Gabrielle). So, we released his harmonized risk assessment guidance. So, this is being used not only in the U.S. but also in

Canada. We have just translated this document into Spanish, so it's being considered as a NAFTA harmonized guidance as well.

So, right now we're working on a new guidance document which would supercede the 2011 document. So, when this comes out, this will be a guidance on exposure and effects testing for assessing risks to bees. So, we've been working on this. In that guidance document, which we have a draft of right now, we are going to be talking about the regulatory provisions for requiring data. We're going to be talking about the data that's currently codified for bees in 40 CFR Part 158.

We're also going to be talking about some new data needs that we have for toxicity testing for bees. These additional data requirements not only are for toxicity testing but also on the exposure side to get information of residues of chemicals in pollen and nectar to which bees would be exposed.

So, the additional bee toxicity testing guidance, these three tiers really align with the three tiers that are in our 2014 risk assessment guidance. These include laboratory based studies on individual

bees, as well as field based studies on whole colonies, as well as residues in pollen and nectar.

So, I apologize for this slide up front. I know it's extremely busy. So, right now, we have three tests that are on the books right now, are codified, three toxicity tests for bees. These are the ones that are not highlighted in red up here. So, right now, we're requiring a honey bee acute contact test, and these are for adults. We're requiring a residue test on foliage for honey bees, as well as field testing for pollinators.

They're different tiers of data. So, if you look at this table here behind me, you'll see right here these are the tier one studies, tier two, and tier three. So, the need for the higher tier studies, tier two and tier three, is really contingent on the results of the tier one studies.

Right now, moving it forward in registration review with the dockets that are opening now and our data call-ins, we are requiring all of these studies -- these are data needs -- for all pesticides where there's a potential for exposure. So, we're moving beyond just insecticides for any pesticide where diffused outside.

We're going to be calling in these data.

Again, what we would expect is that the tier one data would be submitted, and the tier two and tier three would really be contingent on the results of the tier one. So, it's more of a phased approach.

Important to note also that we are currently underway and beginning to codify these additional data requirements which are highlighted in red. So, for the tier one studies, the additional data needs are an adult oral study. We typically get this data in right now because there is an OECD test guideline for that study. So, we are getting that data routinely right now.

The newer studies are a chronic study for adults and an acute and a chronic study for larvae. So, those are the additional three studies in that tier one. We're calling it, really, like a five pack of data that will be new.

On the tier two side, the studies we'll be asking for, again contingent on the results of tier one, will be residues and pollen and nectar. So, that's an exposure piece -- as well as potentially semi-field tests. These are on colonies. The semi-field tests are

typically either colony feeding studies or tunnel studies. Then, the full field test is that tier three, and that's on the books right now.

So, again, we've started the work on codifying these additional data requirements. That work is underway. I provided a web site link on the slide where there's some further information on that effort. These are going to be codified in what we'll call subpart H of 40 CFR Part 158. Right now, tentatively, this work is going to be completed in 2017.

Also important to note, throughout this process, I know there's been some concern about testing for non-Apis bees, so moving just beyond the honey bees. We are working with our regulatory counterparts, our international colleagues, to develop test guidelines for non-Apis bees. Right now, within that OECD, that international paradigm, there are draft test guidelines for, I believe, acute contact and oral tests for bumblebees. So, we are working on that, and we expect those to be moving along.

So, with that, I will turn it over to Dan.

MR. ROSENBLATT: So, thanks. Again, I'm Dan

Rosenblatt with the Registration Division. I just wanted to give you an update about the reverberations on this topic in the registration or the PRIA realm. So, things are underway. As Anita alluded to, it's our goal to have this promulgated/added formally to the data guidelines to Part 158. In the meantime, registrants, particularly submissions for insecticides, have been walking down this path, you know, stewarding this issue, voluntarily submitting this information.

So, that's been extremely helpful, because, of course, we're operating in FIFRA in a risk benefit realm. So, without this data, you know, I think the uncertainties would be perhaps problematic and perhaps so large that we wouldn't be able to understand properly this issue. So, you'll see this in many of our recent new AI decisions.

It's a moment, too, where we recognize that there's energy to improve things. As Anita said, the science is getting better relative to different life stages and sort of the whole colony implications. So, we recognize this under FIFRA as a potential for a conditional registration. So, you might see that as the

gear is turning in regards to a new AI or perhaps the first outdoor use of a chemical as a conditional registration.

This middle bullet of the items that describe the risk management is, I think, just a reminder, a placeholder, if you will, that the decision landscape has these other factors driving it, too. We would look at the use pattern. We would look at the potential benefit and the alternatives and also the way we might affect mitigations or adjust the label.

The other thing to underscore is, you know, this first sub-bullet. We would utilize the risk assessment methodologies that Anita is alluding to now even now. So, that's perhaps a factor in getting this data in an aggressive manner. So, I think that's sort of mostly what I wanted to cover in terms of the PRIA world.

I think the next slide is back to Yu-Ting.

MS. GUILARAN: So, moving on to the registration review program, just sort of general background information. There's about 460 conventional pesticides subject to reg review. So, as Anita was talking about, the final 2014 guidelines went out. So,

as of January 2015, and I'm kind of reversing this a little bit, we started to ask for the information starting January 2015. So, what that means is all the chemistry that went ahead of it, which is about 250 cases of them, some probably don't have -- and mostly I don't think they would -- what we required in 2014.

So, what we would need to do on those 250 that already went ahead before January 1st was to basically work on the DCI to have it put together and to basically capture the data needs that we are recognizing right now. Again, just to step back just a tiny little bit, I mean, this was really the goal of the reg review program, is a science advance that we would take under consideration to make sure that the science we're using are still protective of the human health and the environment. So, this is really in line with what the purpose of program is.

So, what we're working on right now is that data collection DCI. So, we're trying to get that ready to go through its channel of having OMB review. So, that's for all the 250 cases, or approximately, that would be subject to subsequent DCI, that would require

the suite of pollinator data.

So, for all the registration review chemicals that came after January 1st, there's about 130 of them, I think folks already talked about that. We have done a lot of docket openings. CLA actually invited us to go over and talk to them yesterday. Just to kind of give everybody the information, that we are hoping to complete all the docket openings by the end of this year. So, we have about eight percent left of the 460 chemicals or so.

So, those cases that were opened after January 1st already have the data call-in associated with that. So, that's about 130 cases from that point out into the future. There's about 70 cases that have been cancelled since the beginning of reg review. Our registered use pattern did not result in exposure to bees.

So, that was the reg review program starting basically from 2007, that whole cycle of 2007 to 2022. But there have been new active ingredients that were registered post that time. So, for those between 2008 until today, there are about 43 cases of those. So, as we kind of finish and moving forward, we'll expect to be addressing these 43 as well.

So, you're probably thinking that that's an overwhelming number of cases you're asking in the data in the study. What about lab capacity. So, that is a concern that we have heard, and we share that same concern. So, what we have done is basically thinking about a way of prioritizing the data call-ins. We wouldn't be calling them all at once. There's a way of prioritizing.

So, some of the components that we're thinking about really is related to toxicity mode of action, the exposure. That's the science piece of it. We also want to take the incidents into consideration and also where it was detected in any of the bee samples. Then, also commercially, the commercial pollination with managed bees.

So, let me take a pause here because this kind of ends the segment about the science and implementation, what we're thinking about on that, and take some questions before I go into the neonic schedule, if that's okay, Chair.

MR. HOUSENGER: I guess so. Do we have any questions? Sharon, you've got five?

SHARON: No, just one. I don't know if I'm going to quote this right, but I think yesterday I read that Gina Shultz recently said something like EPA's primary mission really is protection of human health. That represents a departure from what either the past mission was or the way people interpreted our past mission. I saw this week, and I'm not quoting it correctly.

So, I guess this question is for you, Jack. If EPA is prioritizing human health, I think human health is obviously extremely important. But I'm wondering how to interpret a statement like that in light of some of the concerns about the health of pollinators? Are there species in the environment that have some of their own approaches that EPA has developed these approaches for?

MR. HOUSENGER: Who said this? Gina?

SHARON: Yes, if I said it correctly.

MR. HOUSENGER: I think you misheard. I don't want to contradict our administrators, so whatever she said I'm sure is true. No one has ever told me that. We don't approach it like that. We approach human health as adhering to the standard, which is reasonable certainty of no harm, at least for the dietary piece of it. The

eco is a risk benefit determination.

So, I think in the early days when we did re-registration, we didn't do it eco risk quite as rigorous as we could have or should have, but we had to get through that. I think now we're seeing a lot more action to protect non-target species and certainly pollinators. Going back to a discussion earlier, how are you going to make the 2022 deadline for all this?

I think pollinators is a good example. ESA is a good example. Endocrine disruption is a good example of how these issues insert themselves into our periodic re-evaluations and kind of -- when we went through re-registration, we had a target database. Now, all of a sudden we're adding data as we go along. So, it's going to be very hard.

But I think we'll take the mitigation actions that are before us, if needed, and move on with an interim decision and catch up later. I don't think this office sees a difference between human health and eco. I think our job is to make sure that this is safe and doesn't cause unreasonable adverse effects.

Sorry, Gina.

Ray.

RAY: A couple of questions. What is the time frame for incorporating the pollinator data requirements into Part 158? Is that going to be proposed this year? Completion date?

MS. GUILARAN: I think we talked about January 2017.

RAY: Okay, I missed that.

MS. PEASE: I'm sorry, if you go to that web site link, it will go out for public comment, if that's your question. The date for completion we're thinking is going to be sometime in 2017. But it will be released for public comment prior to that.

RAY: Okay. For conducting the suite of studies that will be required for a given compound, what's the anticipated time that that would take?

MS. PEASE: So, you're talking about the tier one studies?

RAY: Yes.

MS. PEASE: So, like I said, we typically get the acute oral and the acute contact. We get those now. So, it's those three additional studies. It's the

acute larval and chronic larval and chronic adult, those three tests. The chronic study is the longest one. The longest of those is the 21-day larval study. The chronic study for adults is 10 days. So, I mean, it takes, you know, under a month to complete those studies, in addition to the ones we currently get now, which are short, short-term studies. You know, they're all laboratory-based studies.

RAY: Some of those studies don't yet have adequate protocols. It's a very active area of research at the moment.

MS. PEASE: Right, understood. I recognize the chronic larval study currently has a draft guideline that's going through OECD right now. I believe it's in its second round of ring testing. There's been a lot of conversation about trying to ensure that we get adequate control of mortality and emergence data from that test.

My understanding is that we have a good handle on it, on the study design elements. We feel that if we submitted a protocol for that study, that it's doable to turn it around. We have acceptable data submitted for the neonics for these tier one requirements.

So, I understand what you're saying. It's not a finalized protocol. We are in the process now, in addition to all that I just described, we are working on a guidance document, internal guidance document to generate a template for that data.

RAY: With the prioritization process, that's going to be necessary for nearly 300 cases. Do you anticipate that this will delay completion of registration review by the 2022 deadline?

MS. GUILARAN: So, I'll just reiterate what Jack said. I'm fairly new to programs. I'm going to caveat my response with that. I feel right now with the reg review, we're constantly struggling between how much information we have so that we can do an interim decision or proposed interim decision to put our thinking out there to start acting on the risks that we have identified so far.

So, I think that has always been -- our intent is that as we find new risks that have emerged, to strike that balance of having enough scientific information and foundation and then to start taking interim action that's needed. Then, knowing that there's other data that's

coming in, as data come in, we'll have to take a look at that again. So, I think that's really the intent of the registration review, is that we take a look at a chemical on a 15-year cycle.

I don't know if that answers your question.

MR. HOUSENGER: We'll say it does.

MS. GUILARAN: Thank you.

MR. HOUSENGER: Aimee.

AIMEE: So, first, I want to from the outside agree with Jack's comment on ecological risk assessment. I started reading risk assessments probably late compared to some folks here, in the late 90s. It's dramatic the difference in what you are evaluating today and the depths in the questions that you're being asked now. So, thank you for that.

Thanks also -- great news on non-Apis bees. You know, we've got 3600 species of bees here in the U.S. The status review for our bumblebees is that about a quarter of them are at risk of extinction, but they're not yet listed on the Endangered Species Act. So, it's great to hear that we're starting to think about those species.

I'd love to see some tier three studies on non-Apis bees. I'd really love to see it if they had Apis bees and non-Apis bees in those same field studies so we could compare relative concerns. But that's down the line. I'm happy with what we have.

My question is really just -- you mentioned 70 cases that were cancelled because they don't have the exposure.

UNIDENTIFIED FEMALE: (Inaudible).

AIMEE: Okay. Well, help me with that. Within it, please help me understand how do we determine no exposure? So, is that --

MS. GUILARAN: Indoor uses.

AIMEE: Just that simple.

MS. GUILARAN: And I think there are a couple of other examples as well. Rick, do you have any more --

AIMEE: So, my question was --

MS. GUILARAN: bait station?

AIMEE: So, those were my questions, if they might still be of concern for solitary ground nesting bees or if maybe it was non-Apis bees, plants that would be attracted to non-Apis bees. That was where I was

curious. The indoor makes perfect sense. So, you said below ground? Was pollinator attractive part of the decision as well?

MR. KEIGWIN: So, things like when I said below ground, I was referring to things like subterranean termite control, so much deeper in the soil than where solitary bees might be.

MR. HOUSENGER: Steven.

STEVEN: So, I have a couple of questions on this last slide. If I didn't have my glasses, I sure wouldn't be able to read this, all the fine print down there.

But the first thing that I want to talk about is the third bullet point there, information regarding bee kill incidents for the pesticides. I know we've discussed this before. The incident reporting system is broken. From the beekeepers, they have very little incentive to report. They have a lot more incentive to not report. So, if you're basing risk assessments or re-registration of a product on a number of incidents that are reported, there's going to be a lot of incidents out there that happened that don't get reported.

MS. GUILARAN: So, just so we're on the same page about what this is, it's trying to deal with the lab capacity. So, we're calling in all this data that we want it to be part -- so, the data will be part of the registration review decision. So, instead of, you know, 300 chemicals that we want to test and different tiers, we want to be able to prioritize which ones we're calling in first. So, the incident is just one of the seven factors that will determine which ones kind of get called in first.

STEVEN: So, if you had a particular product that had a high number of incidents that were reported, that would bump it up the list?

MS. GUILARAN: I mean, you can basically explain it a little bit more, but we basically do a little check.

MS. PEASE: So, right now, all these factors are given equal weight, right or wrong. So, just because an incident wasn't detected for a certain chemical, if it's highly toxic, if it's detected in a beehive matrix, like in dead bees or, you know, pollen and nectar, if the use pattern for the chemical is used on a crop that is

attracted to bees, it’s getting check, check, check for all those items. So, lack of incidents doesn’t mean it won’t be on this list. It’s just one factor of all of these that are considered.

STEVEN: Okay.

MR. HOUSENGER: I think it’s also relative. So, if I’m reporting an incident, I’m not determining whether I report it based on what chemical it is. So, it’s a relative number of incidents. It doesn’t matter that all incidents aren’t reported.

STEVEN: Right. But would it matter if no incidents were reported?

MR. HOUSENGER: Well, then, it wouldn’t be a factor.

MS. PEASE: Let me say one other thing, because we talked about this yesterday. So, we talked about insect growth regulators being a concern. So, we may not have an incident for particular insect growth regulator, but just by virtue of its mode of action, we know it’s going to impact bees, insects. That would raise it up on the priority list.

STEVEN: Okay. My next thing is if I’m

understanding, you've got 43 cases. So, there's new products coming down the line. You're testing for the active ingredients in the tier one testing. In tier two is where you go to the formulated products, is that right?

So, we have concerns that the additional ingredients in the product, other than the active ingredient, can sometimes cause problems that the active ingredient doesn't cause. Then, the current tank mixes and then the 43 new products, the possible tank mixes that they would have could cause some issues.

I mean, I know it's almost an infinite number of combinations, but there's going to be a handful of predominantly used tank mixes that should be relatively easy to look at first.

MS. PEASE: So, I think in the prioritization scheme, we're just trying to get data on the AIs first, just to get that information. Your comment about formulated products being required at the higher tiers but not the lower tiers, if we have information to guess that there's potential effects of the formulated product, we could call in a lower tiered study on a formulated

product. As a special study, we could do that. So, we retain that authority to make that decision.

I'm sorry, what was your other --

STEVEN: Tank mixes.

MS. PEASE: Yes, the tank mixes. I mean, it's an issue, we know, but, like I said, we're trying to prioritize based on active ingredient first. I think we had discussion yesterday about getting registrants to submit data on tank mixes is a difficult thing because, you know, you have different applicants for different products. There's some data comp issues.

So, I think from our perspective, we're trying to get the actives first. If there's anecdotal data on tank mix bee kill information, we'll take that into consideration in the risk assessment.

MR. HOUSENGER: Gabriele.

GABRIELE: One is just clarifying. So, this 2016 guidance, is that already up on the web site or is that something that's an internal document that will be finalized? I'm just trying to figure out where that is. I missed it somewhere.

MS. PEASE: Yes, that's a good question.

Sorry I didn't clarify that. So, right now, it's a draft. We're working on it, and it will be posted on our web site once it becomes final.

GABRIELE: So, is that something for comments or just final -- I mean, I'm trying to understand the process here.

MS. PEASE: No, when we post it, it will be final. It will be describing, basically, all the data that's needed to inform our pollinator risk assessment framework. So, it's really nothing that people haven't heard about before. It's just describing the study design elements, providing information on the codification, you know, work that's underway.

GABRIELE: One question there. This comes back to the lab capacity. At least for honey bees, my understanding, like a summer bee is not the same as a winter bee. Larval development, or if you want to get pollen or nectar, you only have seasonality. So, how does that influence this whole process for when you call in data? Does it affect the time frame for when the data needs to come into your door, because you're looking at, okay, from (inaudible), we have two growing seasons we

can do this in? Is that how that works?

MS. PEASE: So, we recognize there's a lab capacity issue, and we also recognize there's a timing component to some of these studies. So, we'll do our best to prioritize them based on the riskiest, you know, combinations and the chemicals at that point in time. Knowing that there's a need for labs, we've also heard that there's going to be more labs coming on board.

We've heard that there will be some more toxicity testing labs potentially in Florida which has a longer season in which to conduct these studies. Then, I'm also told that there's a lab that is being developed in New Zealand which would provide a whole different time of the year when we could get this information.

MS. GUILARAN: All right, so let's move on to the neonic schedule. So, I'm going to go over the four neonicotinoids. We have imidacloprid, clothianidin, thiamethoxam, and dinotefuran. So, first, folks should know that the preliminary pollinator assessment went out in January. So, the comment period went from January to April. We received over 2000 comments, so we're working on those.

In the meantime, we are targeting for December 2016 to have the draft eco and human health risk assessment. So, this time the eco risk assessment will include both an update to the pollinator assessment with non-ag uses assessed and new data information that would have come in, in addition to the assessment for other taxa. So, it's a complete assessment. So, that will also its own 60-day comment period, and we'll have to address the comments on those.

So, the overall goal for imidacloprid really is by December 2017 that we will have all the information that we need to basically update to the pollinator assessment, incorporating any of the registrant full field of tier three that takes the time to basically design and conduct for specifically cotton and pumpkin. Then, potentially looking at the data to bridge with the residue data to other neonicotinoids.

So, that kind of determines whether or not some of the data that we receive on this particular one can be also used on the other three and then incorporate any additional relevant data at that point or literature studies to basically complete it. So, that's for this

chemical.

For the rest of three down the same schedule, by the end of this year, we were hoping to put out the preliminary pollinator assessment. The pollinator piece is honey bee focused. Then, also, it will have the ag and non-ag uses on it. It will have its own 60-day comment period.

And then, by the end of next year, we will have the draft eco and human health risk assessments associated with these three neonicotinoids. Again, the eco will include pollinator assessments with a pollen nectar residue data and other relevant information, and putting that out for public comment.

So, that’s really generally where these four chemicals are at. Are there any questions?

MR. HOUSENGER: Okay. Seeing none, let’s take a break. Let’s begin again at 3:15. Thank you.

(A brief recess was taken.)

MR. HOUSENGER: Okay. If you look at the agenda, our next session runs from 3:15 to 4:15. Then, Zika runs from 3:45 to 4:45. So, we’ve identified an issue here.

MS. MONELL: With a solution.

MR. HOUSENGER: So, Rick is going to quickly run through the next session and allowing ample time for Marty to do her Zika presentation.

So, Rick.

MR. KEIGWIN: So, we thought about having dueling presentations. Then we decided that we were two Bostonians and we can both speak very quickly. So, that's, I think, the plan.

So, in the interest of efficiency, the first couple of slides are really background slides. You all know about the presidential memorandum that President Obama issued in June of 2014, so I don't really need to go through that.

The next slide just shows all the agencies across the federal government that have been involved in this task force. While EPA, USDA, and Department of Interior contributed probably the lion's share of what you find in the strategy, every single agency that's represented here has played very important roles in helping to develop the overall strategy.

So, it was a year ago tomorrow that we issued

the strategy. You'll recall that the strategy lays out commitments for every federal agency on the task force. It identifies research priorities and research needs that will help to inform future actions that the federal government might take. It discusses a public education plan that has been ongoing throughout all levels of government, including the public school system and the national park system, among other venues, to deliver educational material about pollinator protection.

Then it stressed the important value of the public/private partnerships, that this is not just something that's a federal government problem; it's a national problem, it's an international problem. Everyone can play a role in it.

From the science standpoint, the strategy also reiterates that there are a multitude of factors that are contributing to pollinator decline. But it's not solely varroa mite, it's not solely pesticides, it's not solely lack of forage and nutrition. There are a variety of intersecting factors where we are right now unable to put a specific weight on any of those factors. We know that each of these factors in some way, and certainly in

combination, continue to contribute to pollinator decline.

So, to address this, we outlined three overarching goals. Just to remind you what those were, we've got one related to honeybee losses, one specific to the monarch butterfly populations, and then one to address the forage and nutrition piece regarding federal land.

So, the honeybee piece was to reduce overwintering losses to no more than 15 percent over the course of the next 10 years. The second was to restore monarch butterfly populations to 225 million butterflies by 2020, so, again, within a five-year period. And then, to restore or enhance seven million acres of land for pollinators over the next five years, and to do that through both federal action and public/private partnerships.

This last piece was not meant to say that if we achieve seven million acres of land, enhanced or restored, that we would have solved the nutrition issues. But that was an initial down payment, if you will, and hopefully to stir up interest in others acting on this goal as

well.

So, I thought it would be helpful to just give you a quick rundown of where EPA is at the one-year mark in terms of coming through on our various commitments. So, many of these we talked about in the earlier session as it relates to the first commitment area for EPA, which was to assess the effects of pesticides on bees and other pollinators.

Anita Pease talked earlier this afternoon about the risk assessment guidance that we issued, as well as the guidance for risk assessors on how to utilize the new pollinator exposure and effects study needs. She also talked about the work that we've been doing through OECD and other international fora to develop new test protocols for non-Apis bees.

What we haven't yet highlighted is some collaborative work that we did with Sheryl Kunickis' group, the Office of Pest Management Policy, to revise a publication on the attractiveness of different agricultural crops to pollinating bees. That's a very important piece of work for us. It contributes to how we consider exposure to pesticides in our ecological risk

assessments.

Yu-Ting, Anita, and Dan talked about the work that we've been doing to prioritize the list of chemicals for higher-tiered testing. We also talked about the rulemaking that we've initiated to codify these pollinator data needs into the 158 data requirements.

One of the commitments that we made to ensure that not only did we have the science but that we started to employ it in our different programs, via registration or registration review, is to ensure that these risk assessments were assessing the impacts of pesticide use on bees.

So, from May of 2015 through January of 2016, we've actually issued 45 risk assessments for existing pesticides, looking at the potential effects of those pesticides on bees, utilizing the data that we have in house or literature data that we have.

So, some of these we'll still have to go back and look based upon data needs that were discussed in the earlier session. But again, it's an initial look to ensure that for the data that we have, where necessary, we're beginning to take action to address pollinators.

Then, again, Yu-ting talked about the work that we've been doing with Canada and California on assessing the risks for imidacloprid.

I wanted to give you a brief update on where we are with the acute risk mitigation proposal from May of last year. I'm not going to read this in the interest of time, but the first part of the slide reflects what our proposal was in terms of restrictions for the most acutely toxic pesticides to bees and the role that managed pollinator protection plans can play in helping to reduce stresses from pesticides on pollinators.

We received over 113,000 comments. Granted, many of them were a mass campaign, but that's still a lot of comments to go through, a lot of work, and some really good ideas and thoughtful contributions made during those public comments. We are currently reviewing those comments. We are approaching a point where we can start to make some recommendations internally on how to proceed. We're just not at a point today to be able to share with you where things are at.

But again, just to reflect, the comments that we did receive were very helpful in helping us better

understand what the impacts of what our proposal might be and what some alternative solutions from different points of view might be to move forward.

One of the areas where we did receive general support overall was for the role that managed pollinator protection plan can play in reducing the potential stressors from pesticide exposure. To facilitate that and move that forward, working with USDA, the Honey Bee Health Coalition, and the National Association of State Departments of Agriculture, in March of this year, we held a symposium to sort of flesh out the ideas of MP3s a little bit further. We had about 130 participants attend that session, two-day session. There were representatives from the NGO community, from the beekeeper community, from the grower community, from registrants, from states, from tribes, and from other federal agencies.

The main purpose was to flesh out a little bit more, for example, for those states that already have these plans, how well were they working, what lessons could be learned to be applied in other parts of the country, how might we evaluate how effective

these plans might be, what states have done to engage stakeholders to ensure that it was a thoroughly vetted plan before it was put into place within that state, and then identifying tools for tracking and mapping of successes.

One of the things that was reported is that the vast majority of states, and many tribes, have begun to implement or are in the process of developing or planning to develop an MP3. I think there were less than a handful of states that had not started the process. There were maybe one or two states who had decided they were not going to. I think Alaska, for example, was one that said they probably were not going to develop an MP3.

In the third vein of commitments that EPA made had to do with expediting the registration of new products to control varroa mites. In the past year, we have registered two new active ingredients. One is oxalic acid, which we registered in about a three- to four-month period. That is lightning fast.

This registration shows the benefit of our joint work with Canada because this is a product that was registered in Canada. We basically called up to them and

said, can we have your reviews. We utilized their reviews and made a risk assessment and risk management decision in a very timely manner. USDA actually agreed to serve as the registrant because we could not find someone to serve as the registrant for this particular product. So, this has moved forward quite rapidly.

Another chemical that we registered is actually a biochemical. It is hops beta acid. That product, too, was reviewed in an expedited time frame for the biochemical program under PRIA. To supplement and provide some additional tools to the public, we did publish late last year a list of products that are currently registered to control varroa mites in bees. So, that's the resource that's available. That's the good news of this.

The bad news is that in terms of total registration, there may be only 10 to 12 products. I know when talking to a number of beekeepers, there are some of those products that either are not working or not working well, or there's been resistance developing. Unfortunately, the other piece of the bad news is we don't have any other products in house right now to

expedite. So, there's a critical need for the beekeepers to have products to control this pest that vectors any number of diseases within their hives.

The last area that I wanted to highlight was some of the non-pesticide work that we've done. So, the president charged and challenged all federal agencies to lead by example and to incorporate pollinator habitats into our landscapes around all of our buildings.

So, one of the things that EPA did over the course of the past year is we went to the 17 EPA-owned facilities throughout the country, and we conducted on-site pollinator assessments to see what habitats currently existed, what opportunities there were to enhance those habitats, and/or what pollinator species might already be resident on those.

So, we did an observational study at each of our 17 sites and then identified areas for enhancement. For example, at our laboratory at Research Triangle Park, we found that there was suitable habitat to install some beehives at that campus. At the Atlantic Ecology Division, part of ORD, they've been routinely converting grass areas into meadows and being sure that they

incorporate different flowering plants that flower throughout the year so that they're suitable habitat and forage for pollinators throughout the year. Our Mid-Continental Ecology Division up in Duluth has a prairie that they've been continuing to enhance. So, that's our contribution.

We don't have many acres, but what we decided to do was with the acreage that we had, try to lead by example. We're continuing to look at those. So, our next wave will be to look at those areas where we lease and working with the General Services Administration to see what additional enhancements we can do.

So, what are our next steps? We will be finalizing the acute risk mitigation strategy, hopefully by the end of the year. We want to move forward with implementing the pollinator data requirements as Anita and Dan and Yu-ting discussed. Then, through both our registration and registration review program, assess the impacts of pesticides and pollinators. That's our job. Then, implement risk mitigation as necessary. Then, continue to be promoting these habitat enhancements across EPA's various landscapes.

Quick questions?

MR. HOUSENGER: Cynthia.

CYNTHIA: I appreciate all the efforts on bees. It's a good start. I just want to make sure that there's serious effort to protect other pollinators as well, including the birds. The American Bird Conservancy found that a single coated seed, coated with any neonic is enough to kill a songbird. The worldwide assessment found that other wildlife are affected by these pesticides as well.

I'm wondering specifically with regard to the MP3 plans, since those seem to be sort of at the heart of EPA's approach now, to what extent will these state plans protect birds, bats, beetles, and other pollinators, as well as the very neonic sensitive aquatic invertebrates on which many of these pollinators depend?

MR. KEIGWIN: Thanks, Cynthia. This was actually one of the questions that came up at the symposium. Some states thought that they weren't going to be allowed to consider issues other than managed pollinators as part of their MP3. In fact, we encouraged them that where there was stakeholder interest in broadening beyond managed pollinators, that that was

certainly an opportunity that they could use their MP3s to do.

We do think that the MP3s, even if they don't directly address non-managed pollinators, do have a collateral benefit for other species that might be utilizing that landscape at the same time.

MR. HOUSENGER: Annie.

ANNIE: I have two quick questions. One, I'm wondering what EPA's role in overseeing these state MP3s are going to be. Obviously, with the number of states and just like the various ways that they could be put together, we'd obviously like to see a pretty great role from EPA in making sure they meet like some kind of standardized, you know, requirements.

So, we just want to know what your role is going to be right now. It sounds really kind of collaborative, and states are doing their (inaudible) things. Do you have plans to kind of get everyone on a, you know, baseline of stage?

MR. KEIGWIN: So, in the proposal, we discussed what we thought were the minimum needs for an effective MP3. So, for example, we talked about the need for it to

be developed in a very collaborative process with the stakeholders across the spectrum involved.

We talked about the need for there to be an ability for the agricultural user of the pesticide to be able to communicate with the beekeeper in an effective manner so that discussions about pesticide use could occur. We also talked about the need for there to be reflective measurement on the success of those plans.

So, that's what was in the proposal. In response to comments, we've gotten some additional ideas, so we're thinking about that. The states have already started to think about how do you not only design a plan that's very effective, but how do you measure how well it's working so that you can make adjustments as necessary if it's not working or meeting the goals that were laid out.

ANNIE: So, what do you see EPA is making sure the states comply with the minimum requirements or helping them improve them if they --

MR. KEIGWIN: So, in our proposal, we said that we were not going to require plans and we were not going to approve plans, but that we would play a facilitation

role in their development. Some of the comments that came in suggested that we take a different role. We're not at the point yet to say if we're going to change that. But, in the meantime, these plans are under development. Many states have been coming to us for input on how they might go about designing their plan. We'll continue to play that role, regardless of the outcome.

ANNIE: Okay, thank you. My other question is, I was just wondering what the status of your proposal to limit foliar applications of neonics for managed bees. But is that part of your acute risk mitigation strategy? Is that still on the table?

MR. KEIGWIN: Well, the neonicotinoids already have restrictions on their labels. They're mandatory requirements. The acute risk mitigation proposal is what you're referring to. That's where we're still in the process of going through the comments. But the neonicotinoids now have certain restrictions already for when they can be applied and when they cannot be applied foliarly to blooming crops.

ANNIE: Right. Do you have an estimated date

as to when you'll finish going to through those comments?

MR. KEIGWIN: I think I just said by the end of the year.

ANNIE: Okay, thank you.

MR. HOUSENGER: Steven.

STEVEN: So, I have a comment and a question. The next to last slide, I think you skipped the last bullet point. It says initiated work with state lead agencies to improve consistency in bee kill incident reports. I wasn't going to mention it, but since you failed to mention it, again, the incident report system needs some more looking at.

MR. KEIGWIN: And we'll be having a presentation tomorrow from the incident reporting group on next steps that EPA can take in that regard. But thank you for pointing out that I missed that.

MR. HOUSENGER: Are you part of that incident workgroup?

STEVEN: I get the e-mails, but I have not been able to participate in it.

MR. HOUSENGER: I would encourage you to do so.

STEVEN: So, my question is, does EPA have any

plans for evaluating the effectiveness of these MP3 plans or are you just going to leave that up to the states to individually do that?

MR. KEIGWIN: I think in the note that Jack sent out leading up to this meeting, one of the things that we talked about, and this will be another discussion point for tomorrow, is actually forming a new subgroup under the PPDC that would provide back to EPA advice on this very area. We think that would be an area to get some very valuable input from all of you moving forward in that regard.

MR. HOUSENGER: Lori Ann.

LORI ANN: We were concerned about the Imidacloprid pollinator risk assessment and the fact that it was a honeybee risk assessment, really.

MR. KEIGWIN: Mm-hmm.

LORI ANN: It didn’t talk about our native bees, even though there is significant body of science indicating that they are more -- not significant. There is some science indicating that they are more sensitive and also butterfly bats and all the other creatures. Also, we had some concerns about the body of science that

was explored for that risk assessment. How are you planning on moving forward, or are those concerns going to be addressed in future pollinator risk assessments?

MR. KEIGWIN: So, hopefully, in response to our issuance of the draft risk assessment, you provided us with citations of studies, additional sites that we would look at. We'll take that very seriously and address those comments.

As Yu-ting said earlier this afternoon, we will be revising that risk assessment, but also expanding that risk assessment to include all of the uses for Imidacloprid and also looking at taxa beyond pollinators. So, I think the assessment that comes out later this year would be responsive to the comments that you've submitted.

LORI ANN: But that's for the ecological risk assessment.

MR. KEIGWIN: Right.

LORI ANN: I'm curious will future pollinator risk assessments look at more pollinators?

MR. KEIGWIN: So, our pollinator risk assessment guidance does describe for our risk assessors

how to look at pollinators other than honeybees. We are using honeybees as a surrogate because that's the best data that we have right now. But where there are data in the public literature on non-honeybee species, we are looking at that information at least qualitatively and where we can, where we have the data, quantitatively.

LORI ANN: Thanks, and no offense to the honeybees. I like honey as much as everyone.

MR. HOUSENGER: Ray.

RAY: A couple questions on your slide six. You mentioned that you've developed guidance for the EPA risk assessors.

MR. KEIGWIN: Right.

RAY: Is that guidance public?

MR. KEIGWIN: I think Anita responded to that in her earlier session. So, right now, it's intended for internal use, but it's reflective of the guidance that's already out on the street publicly.

RAY: In the following slide, you mentioned that you issued 45 risk assessments, pollinator risk assessments for existing pesticides.

MR. KEIGWIN: Mm-hmm.

RAY: Are those all in the dockets?

MR. KEIGWIN: They are in the respective chemical dockets for their registration reviews, that's right.

RAY: Is there a list to easily identify which 45 they are?

MR. KEIGWIN: Each quarter, when we put out a request for comments on our draft risk assessments, we provide a list of the chemicals that were issued. We do not have a separate web site that says here's the list of the 45. This is part of the ongoing registration review.

RAY: Will it be clear which one of those have the pollinator risk assessments?

MR. KEIGWIN: Each of them where we have data on pollinators has a component of the risk assessment that looks at pollinators.

MR. HOUSENGER: That doesn't mean that we have the full tier one. It's what we have.

REGINA: Hi, this is California. Do you mind if I ask a question?

MR. HOUSENGER: Are you a member of the PPDC?

REGINA: No, I'm not. This is Regina. I just

wanted clarification. You said tomorrow morning's session is --

MR. HOUSENGER: Regina, we can take public comments, which you would be, at the end of the next session. This is a session just for the PPDC members.

REGINA: Okay, my apologies. Thank you.

MR. HOUSENGER: We'll put you down as public comment.

Wayne.

WAYNE: Rick, I was interested in knowing if I could list the currently approved or available MP3s on the pesticidestewardship.org site? But is there a compilation of them somewhere?

MR. KEIGWIN: I believe AAPCO has them already listed on their site, so you might want to talk to them about linking to their site. I think they are updating that as states or tribes formalize any MP3s.

STEVEN: I'm pretty sure the Pollinator Stewardship Council web site has all the current MP3s listed.

MR. HOUSENGER: Aimee.

AIMEE: Just a quick question I've wondered for

a long time. Well, maybe not a quick question, but a question but a question I've wondered a long time about. So, you talk about qualitative use of data. I review it, and I love all the research that you guys look at. But then, when I go down and I look at the risk characterization, I don't see how you incorporate it, like what are the uncertainty factors or how.

MR. KEIGWIN: So, the non-scientists at the front table -- I mean, I believe it's a weight of evidence approach. It's hard to consider data quantitatively where you don't necessarily have all of the data, but you can consider it. If there are multiple lines of evidence or a high degree of confidence in the data, you can make stronger extrapolations from it. But Anita has now found a mic, as I struggle.

MS. PEASE: I'm trying to move away from the mic, actually. It's a good question. We talked a little bit at the break about this, about the qualitative evaluation, how it factors into the decisionmaking. Like Rick said, it really is a weight of evidence. I mean, more weight is given to the quantitative piece of the risk assessment, but it is factored into the decision.

It may not be completely linear in how it's factored in, but it is factored into the decisionmaking. It's kind of a case-by-case thing, so it's hard to put criteria around it.

AIMEE: So, if you're familiar with the Imidacloprid pollinator risk assessment. The final risk characterization really looked at the population level effects on honeybees. Yet, they talked about numerous other colony level studies for bumblebees that showed risk at lower levels than what the designated level -- I'm hesitating to call it a threshold because you might not call it that, but you have kind of a level at which you see population level effects.

You mentioned and you ranked what was good about it, what was bad about it. But obviously, you stuck with the threshold for the honeybees, even though we saw bumblebee effects at colony levels at lower levels. There wasn't an uncertainty factor. There wasn't anything -- how would that be?

MS. PEASE: So, if you look in our risk assessment framework for bees, I mean, biodiversity is one of the assessment goals. So, that would extend

beyond just honeybees and looking at populations of non-Apis bees as well. So, we do consider it.

You're right, we did look at the bumblebee data, and it showed that Imidacloprid could potentially be more toxic to bumblebees than Apis bees. So, we put that out there in the risk assessment. Again, when we get to the point where we mitigate and we issue an interim decision, all that information will be considered.

MR. HOUSENGER: Mark.

MARK: This is a pretty quick one. So, a lot of what you're doing, which I think is great, is going to end up being public outreach with the monarch and the refugia that is necessary. So, this actually goes to both the Agency and also to Cheryl. Is there a web site of activities that are proposed or in progress for that type of what I would call from my old profession extension work?

MR. KEIGWIN: So, the task force at our meeting just last week, this was actually one of the issues that we discussed, was how do we make more public everything that we're doing and additional opportunities for

engagement via groups or individual citizens. So, it's an important area for us to look into as we go into the second year of implementing the strategy. So, thank you for the support for that, and we'll take that back.

MR. HOUSENGER: Richard.

RICHARD: On your factors associated with bee declines, you mentioned nutrition and urbanization.

MR. KEIGWIN: Right.

RICHARD: But if you could just briefly say how they are factors, what are their impacts. But I didn't hear you mention those in your strategy.

MR. KEIGWIN: I think, for example, the urbanization piece comes in because you're taking landscapes out of potential areas for habitat. So, it contributes to habitat decline. It's not urbanization directly; it's really more of an indirect effect because you have less land available for forage areas.

Does that answer your question?

RICHARD: And the nutrition?

MR. KEIGWIN: Well, the nutrition piece, the land areas serve as the forage base that provides the nutrition to the pollinator species.

RICHARD: So, then you went into the strategies.

MR. KEIGWIN: Right.

RICHARD: And I didn't hear anything specifically on the nutrition and urbanization.

MR. KEIGWIN: So, EPA's area of focus is on the pesticide piece. Since I was only giving you updates on where EPA's pieces were, USDA is a major land manager who contributes to land management through that NRCS program. The U.S. Forest Service is contributing a significant amount of acres to this effort, which will help in these areas. The Department of Interior is probably the largest land manager in the federal government. That's where a lot of those pieces will come in, is through the actions of the land management agencies.

RICHARD: Okay. In these factors, what are the highest contributors?

MR. KEIGWIN: So, we specifically have not ranked them. We don't think that the science is there yet to rank where each of these stressors might lay out. Different people have different perspectives in where they are. But the pollinator research action plan, one

of its goals is to get at a way to ultimately maybe quantitatively try to see where the biggest bang for the buck could be in taking actions. But the body of science suggests right now that each of these factors is contributing. So, to address pollinator health, you really have to tackle each of the stressors.

RICHARD: Okay. I'll just close with I agree, and think, and encourage you to really take advantage of, I would say, the public's willingness to participate in this activity. Thank you.

MR. HOUSENGER: Okay, Ray.

RAY: Just one contribution to your question there about the ranking of these factors. There's a bit of that done in the recent NAS survey in terms of beekeepers ranking the importance of those factors, as well as in the bee informed survey.

MR. KEIGWIN: There is. I don't know that we have any empirical data to back those up. I think it's observational. So, not that that's not important, but I don't think that right now we have any specific empirical data where we could do a quantitative ranking.

RAY: That empirical data would be very helpful

if we collectively could figure out a way to get it.

MR. KEIGWIN: I think the work that the IPBES is doing is trying to figure out how to do it in that regard as well, an international forum through the UN that's looking at this as well.

MR. HOUSENGER: Okay. We have a Zika session and then a couple of comments. So, Marty Monell is going to give us an update on where we are with the Zika virus.

MS. MONELL: Okay. Is Janet McAllister from CDC on the line? You have to pound 6 your phone in order to get unmuted. Okay, well, she's not apparently either able to unmute her line or she's not yet on the line, so I'll get started. Then she can hopefully be available for --

MS. McALLISTER: Marty, I am on the line.

MS. MONELL: Great.

MS. McALLISTER: I'm just not that quick with the unmute.

MS. MONELL: I understand. Well, you don't have to go back on mute at this point. Just don't breathe heavily.

MS. McALLISTER: I'll move the microphone from

in front of my face.

MS. MONELL: Thank you. So, brief background, because you all read the news and watch TV. Right now, I think there's not a day that goes by without some information on Zika, be it international, another country declaring an emergency, or something happening in the Caribbean and/or around the Olympics that are scheduled to occur this summer in Brazil.

So, we talk about Zika as a new phenomenon. In fact, it has been known to exist since 1947, where it was discovered in a tropical forest in Uganda, in Africa. Eventually, it found its way over here to the Americas and became well known and an issue of concern starting in Brazil in 2015. The U.S. has been working aggressively since late '15 and to date to try to address our concerns about this virus and the vector.

So, the president convened a cabinet level meeting in January of 2016, early January, to basically instruct all of the departments and agencies that he expected us to get out ahead of the Zika situation. Having gone through the Ebola crisis a couple years ago, beginning a couple years ago, and then its evolution into

the United States, he did not want to be behind the curve. He wanted to make sure that we got out ahead of it. This is even before we know what we know now.

So, in February of 2016, WHO declared this an international public health emergency. CDC confirmed the linkage -- this was in mid-April, I believe -- confirmed the linkage of the mosquito transmitted virus to brain defects, including microcephaly in newborns. This is significant because I believe it's the first time that an insect carrying a virus has been directly related to birth defects.

The White House, in response to the president's directive in January, started convening regular meetings. The National Security Council acts/speaks for the president and convened the first meeting in early February, where all of the relevant, at that time, departments, U.S. departments and agencies, got together. We were given marching orders.

Within 30 days, we had to come up with a plan for a rapid response in Puerto Rico. The issues there were exponentially becoming obviously problematic. This was coupled with their horrendous infrastructure issues,

financial as well as public health. So, we had to work with other federal agencies to come up with a rapid response plan.

Then, within 60 days, we had to come up with a plan for the southeastern portions of the United States, the continental United States, recognizing that as time goes on, the likelihood of the mosquitos coming to this country, particularly the border states, increases exponentially.

So, basically, EPA's role is to support CDC and other federal agencies in the vector control areas. So, the Health and Human Services Department is the lead for the federal government. But, in fact, CDC is the operational lead, both in terms of the public health issues that arise and the vector control issues that are being pursued.

We have an incredible number of regular meetings now. So, following that first meeting that was convened by the National Security Council, we have weekly Zika sync meetings they call them. At these meetings, CDC updates us on all of the epi data, as well as other agencies, giving reports on what they're doing.

So, for instance, after about a month or so, OSHA shared with us that they had developed some guidelines for workers, workers that may be exposed out in the fields or in handling certain situations, be exposed to mosquitos and how we, as the government, can plan to provide protections for them.

We also have regular meetings that are convened by the National Science and Technology Council. This is also out of the White House. This is to make sure that all research needs are being addressed. So, it runs the gamut from talking about issues of developing a vaccine, developing treatment for the Zika-related cases, to research into optional vector control methodologies.

The Health and Human Services, out of the Office of the Secretary, convenes weekly meetings on the supply chain. This is to make sure that the supply of vector control options is there as we need them. So, we heard that people were stockpiling DEET. What was that going to do to the availability of DEET, particularly in continental United States, once and if it becomes an issue here in the United States.

There’s also been regular meetings on

disinsection of aircraft and marine vessels. I thought it was disinfection, but I was quickly corrected. It's disinsection. This is primarily an issue that impacts the military. The federal government of the United States does not believe it's appropriate or necessary to spray the insides of aircraft or cargo ships to prevent Zika transmission or to prevent mosquitos from coming to this country. The percentages are so low, they're almost insignificant.

That said, there are countries in the world that firmly believe that this work needs to be done, and it's a big deal. So, the State Department is leading that effort. We obviously have a seat at the table because they look to us to supply them with pesticides that can be sprayed inside an airplane. Anyway, so we are involved in those very regular meetings.

They are now looking at future issues around providing travel guidance to people in the United States, assuming we have a locally transmitted Zika situation here. So, that work is being done. So, there's a lot of planning and meetings going on.

For EPA, our regulatory work in support of CDC

has been, as you might imagine, like we do in any public health emergency, like bedbugs, we drop everything to make sure that we pay attention to the high priority actions that are really going to make a difference.

So, for instance, the CDC Foundation, which is an independent sort of an NGO arm to CDC, they are congressionally created. They are able to take donations that CDC as a federal agency could not take. But this foundation can take it and then put them to purposes that serve CDC's interest.

So, the foundation had received many, many donations from companies to put together pregnancy kits, particularly for women in Puerto Rico. In these kits, they wanted to put insect repellant, and condoms, because of the sexual transmission aspect of this virus, bed nets, and so forth.

But companies were reluctant to donate insect repellants unless they had EPA-approved language on the label that said effective against mosquitos that may carry the Zika virus. So, we've been churning those out. We do our reviews as quickly as possible. They're high priority. We've effectively supported that effort to get

these pregnancy kits in Puerto Rico.

The other area that we've been pursuing heavily recently is taking action on unregistered sources, in other words, facilitating those packages so that companies can get their production from those facilities. DEET is an example of that kind of a situation, where there is great concern that that might not be available in the amounts that we will need in this country.

Then, lastly, as an example, is Section 18s. We've thus far granted three Section 18s for CDC to help with their immediate response in Puerto Rico, but it will be available for American Samoa, the Marshall Islands, Virgin Islands, and eventually the United States, should the need arise.

Our sort of second line of effort has been around communication. EPA's Region 2 has a Caribbean office physically located in San Juan, Puerto Rico. Not heavily staffed but certainly very much engaged in the communication work down there in Puerto Rico. I would have to say that our primary focus has been on IPM strategies, source reduction, things that we sort of take for granted, like screens.

Many of the homes down there do not have screens, nor, quite frankly, are they constructed in a way that make it easy to put screens on their homes. CDC is currently working with Home Depot to figure out a way where Home Depot could, through the foundation again, donate screening and labor to get these screens up on the appropriate housing there, particularly for homes of pregnant women.

CDC had tried some indoor residual spraying with a product that we hastened for this particular use. When they did an evaluation of its effectiveness, it was no more effective than the control home that hadn't been sprayed at all. That's in large part because of no screens and no outdoor perimeter controls in place. So, as soon as they left the home, they came right back in again, if they survived.

So, Region 2 also has held two major IPM events in the past couple of months. One was in Puerto Rico, one was in the Virgin Islands. These had been planned before the Zika virus became such an issue there. It was primarily done in reaction, I guess, to the horrible methyl bromide situation in the Virgin Islands a couple

years ago. So, that was essentially a misapplication of pesticides. But they adapted the two opportunities to really get the message out there, not only about source reduction but also about judicious use and appropriate use of pesticides. So, as I said, Region 2 is very active on communication.

We also are involved with CDC in making sure that all of our outreaching communication materials are translated in Spanish, and that they're appropriate descriptions of the pesticide use, in addition to the label language.

EPA in all of the regions and certain headquarter offices have weekly phone calls with Jim Jones. Jim Jones and Tom Burke, Dr. Burke, he's the science advisor to the administrator in EPA. Jim you know. They are technically the EPA leadership for the Zika response for the government. I'm sort of the operational person that gets to go to all the meetings.

Anyway, Jim convenes a conference call weekly as an opportunity for me, basically, to report out on the meetings that I attend and for Susan Jennings, who will be joining us, to report out on what's happening at the

CDC Emergency Operations Center down in Atlanta. That was stood up shortly after the president's directive to the U.S. government. So, we support that emergency operations center by having Susan available. Lately, she's been going there in person once a week. But she's always available by phone. She's the conduit to information about pesticides.

Then, we also talk about the epi data that is updated weekly by CDC. So, I'll just give you the update as of last Friday on the numbers. So, the continental United States, there are 503 confirmed cases of Zika, all travel related. That's up 31 from last week. I mean, it seems to me it's growing. In U.S. territories, we're now at 701 confirmed cases. This is up by 40. Puerto Rico has 671 of those cases. All but three are locally acquired. Sixteen cases in the Virgin Islands and fourteen cases in American Samoa. Those two numbers have not changed much.

Puerto Rican numbers are growing exponentially. We don't have good data on the number of pregnant women involved for Puerto Rico, just because it's very difficult to capture those numbers. We don't have a good

system. We don't really even have a great system in the United States, to tell you the truth. So, the numbers are what they are, but they're growing. So, there's a reason for concern.

The most recent activity that EPA has been sort of leading is a budget proposal for work that we could do. We started this work back when the president submitted a supplemental budget for $1.9 billion -- you hear about it all in the news lately -- to help with the response to Zika. Primarily, it was focused on research and treatment needs.

Although we weren't asked, we saw that there was a role for us to help with funding for EPA-related response activities that could not and would not otherwise be funded. So, we started work with all of our regions. We work with our international and tribal affairs office, we work with Office of Research and Development and the Office of Children's Health Protection in EPA.

Through all of the regions and the program offices, we have put together a package that we plan to submit, once the administrator blesses it, to HHS,

whoever has got the money, for assistance. So, some of the things that we are proposing funding for is screening in Puerto Rico, in particular, but other areas to sponsor some review or studies of the need, particularly in environmental justice communities perhaps, where screens are not available readily to help support that activity.

So, first, get the numbers in terms of the need and then fund an activity to provide the screens. CDC, as I mentioned, is already trying to do that with Home Depot, but we're not sure that that's going to be enough. So, we want the decision makers to have it in their face that screens are really essential.

Another area that we're looking at is tire piles. This is a huge breeding environment for mosquitos. Unfortunately, our agency has not had the resources to address them for years. There was an initiative. They called it the Border 28, Border 2012 Initiative where we worked with the Mexican government and the border states of the United States to address tires and tire problems. I think we managed to somehow deal with 40 million of them, but there are still 80 million tires that we know of in this country that have

been identified by the American Rubber Manufacturers Association.

Again, it's a huge issue, and it's not just on the border areas, it's not just in the tribes, it's everywhere. I think every state probably could identify a tire pile issue. So, we're proposing a pretty significant investment in shredders. That seems to be what the Puerto Rican government is doing, as we speak, with the tire piles that they have. They invested in three shredders, and they're shipping the shredded material to Asia where perhaps there's a use for it. So, we're proposing that we do that here also.

I have no sense of how we'll manage it, but if we get the money, we'll invest it, and we will deal with it. It's clearly an EPA issue. Nobody else in the federal government -- if they've identified it, they're not addressing it. It's waste, so it's something that we have to own and then, of course, the additional funding for IPM approaches, communication materials, and the like.

So, that's mine. I will now turn it over to Janet McAllister from CDC to see if she would like to

augment that.

MS. McALLISTER: Thank you, Marty. I think that you really covered everything quite nicely. So, I just want to reiterate that CDC has been very grateful for all the help that EPA has provided us as we are dealing with the Zika virus. Certainly, challenges will continue to present themselves in the arena trying to control the Zika virus spread. So, both agencies, I think, are in a good place as far as working together and having tools available to us to control mosquitos.

MS. MONELL: I should add that we now have weekly meetings with CDC, just CDC and EPA. It's Lyle Peterson (phonetic), who is heading up the Emergency Operations Center down in Atlanta for CDC, and Jim Jones is leading the effort for EPA in terms of those weekly meetings. So, we're trying to get ourselves as organized as possible because there's just so many issues and so many things, twists and turns, in terms of what's happening here that we have to be on top of. So, it's good.

The communication piece, I think, is probably the most critical, although it doesn't necessarily result

in things, but at least we're all on the same page when we're out there talking about what's going on and what the government is doing.

MR. HOUSENGER: Amy.

AMY: Hi, this is Amy Liebman from the Migrant Clinicians Network. Thank you for the update. I want to commend the Agency for being so proactive and thinking about what's -- because the EPA has a very important role to play which can often not be thought of.

As part of the work I actually do with EPA, the cooperative agreement, I do a lot of work in Puerto Rico. On the ground, it's incredibly scary there. What women of reproductive age are going through is just incredible. One of my concerns that I have is that there's a lot of really important efforts being done in terms of mosquito control, in terms of the education to use DEET and other EPA and CDC approved insect repellant.

I'm wondering what have you guys thought of or talked about in terms of misuse/overuse of these products that can actually cause quite a bit of danger to -- very unintended consequences when you're trying to prevent something that's very scary.

MS. MONELL: We have not directly addressed that, although it's a two-fold issue in terms of it being discussed right now. How should our messaging be with regard to importation of illegal pesticides, because the opportunity is there for that to occur on a big scale, and then the misuse or overapplication of pesticides. Again, that's part of what the Region 2 outreach and communication efforts are designed to do.

Unfortunately, it seems like the only viable sort of meeting place to get information to women in particular is the WIC centers. So, there's sort of a trickiness to that because of the confidentiality issues that that poses. So, the issues are recognized. We're dealing with the government side of it. But in terms of getting the message out to the affected stakeholders, it's not easy, but we've identified it.

AMY: The other point I wanted to make, too, is in terms of there's a lot of education that's being done for the public. But I think there's education that's needed from the clinician side of it, not just in terms of making people aware of this, how to diagnose it, but also from the clinician side in terms of recognizing and

managing the pesticide poisoning piece of this.

MS. MONELL: I'm going to let Janet take this one, but I believe that as a result of the Zika summit that CDC sponsored the first of May, that there are planning efforts going on in the public health departments in every state and territory.

But, Janet, go ahead, why don't you speak to that.

MS. McALLISTER: Yes. That has come up on our radar, that we need to be working closer on the clinician side with education on certainly recognizing insecticide poisoning, but also on using them as a conduit to explain how to apply repellants properly and not just say wear repellants. So, yes, we are working on education materials and a plan to start pushing those out to clinicians.

I do want to also comment on messaging for overuse of insecticides by homeowners. We are working with EPA to make sure that messaging is synchronized and also working with Home Depots and retailers like that to try and get education materials and also making fact sheets as we speak to address homeowners using

insecticides and using them safely to try and start pushing some information out through CDC channels to address misuse issues.

AMY: Thank you. One final point I just wanted to put out there, too, is to encourage the use of the federally qualified health centers as a really important on the ground vehicle to get information out in additional to health departments.

MS. McALLISTER: Thank you. I'm jotting that down. That's why I'm not saying anything.

MR. HOUSENGER: Robyn.

ROBYN: Thank you. I really appreciate the update. Just a few comments. Particularly, if you're interested in messaging, you might want to take a look at the American Nurses Association or the American Public Health Association. I know they have a lot of information out there on how to message about Zika but not create unnecessary hysteria. So, those are good sources of information.

I just want to echo Amy's concern. The pregnant women are the most vulnerable population. Yes, we don't want them to get Zika, but also don't want them

to be overexposed to pesticide.

Then, also for the IPM, I applaud that thought. If you can drain the standing water and take care of all the other issues that promote mosquito growth, then you won't need the pesticides in the first place.

MS. MONELL: One of the interesting things that I heard early on was there is apparently a traditional practice in Puerto Rico. Many of the homes abut cemeteries. There's a practice to have vases of water by the stones, standing water, hundreds and thousands of them.

So, there really is a concerted effort now to educate people about that practice and ceasing it. But who would have thought, you know? It's just something I've not encountered. Thank you, Robyn.

Marc

MARC: Actually, both of my concerns I know are on topics for tomorrow, but your answers will help prepare. One is resistance management, just in general, which is going to come up, particularly with almost every aspect, but I'm real concerned about the netting and the clothing, impregnated clothing in that.

But also, more specifically, and some of you might consider this far fetched, but I would like to know what the official stance is on DDT, because at some point, particularly with public pressure and everything else, DDT is going to come into it. I want to know what the Agency's current stance is on it and what your plan to deal with it is.

MS. MONELL: What year was DDT cancelled? DDT is cancelled.

MARC: I figured you would say that, Marty. Just quickly, I do remember in 1991, a friend of mine, Leon Moore in Arizona, published a paper that the Africanized bee was going to come into the United States. The USDA said they won't because we have a policy that says so.

So, I will say the same thing about DDT and public pressure. Having cancelled it, and I very well knew that, and the fact that this is not bedbugs, this is something way beyond that, the Agency's stance is it's cancelled, no possibility no way?

MS. MONELL: Well, you never say never.

MARC: I recognize that. So, what's plan B,

then?

MS. MONELL: Well, I think that we have to see how and if an emergency arises such that we would even have to consider it under a section 18 or other emergency exemption authority.

MARC: I predict it will come up.

MS. MONELL: Well, I hope you're wrong.

MARC: I do, too.

MS. McALLISTER: This is Janet. Actually, it has come up within people are asking CDC. You may or may not know that the mode of action for DDT is very similar to the mode of action for the pyrethroids. Your comment on insecticide resistance is very timely because there is resistance to the pyrethroids.

So, bringing a chemical back that has the same mode of action is not consistent with insecticide resistance management. We actually need modes of action that are different than DDT and different than the pyrethroids. So, DDT is not being considered in any way, shape, or form as a viable tool to bring back for this particular emergency.

MARC: Janet, this is Marc. I'm glad you're on

the job. I agree with you scientifically all the way. I know about cross resistance. But, you know, we're talking about a possible hysteria and politicians being involved. So, I'm just saying I think the Agency, the group, the task force should have a plan B on this and discuss it rather than say it's not being considered and it's cancelled.

MS. MONELL: Thank you.

Annie.

ANNIE: Thank you. I had a question for you. Just wondering, given what you said about the ineffectiveness of spraying in the places that don't have existing structures like screens and things like that, was that ineffectiveness taken into consideration when you were issuing the section 18 emergency exemption for places like Puerto Rico and others that you mentioned?

MS. MONELL: Well, at least one of the section 18s that was granted was for an outdoor trap, sort of an innovative trap, that will, in conjunction with the indoor residual spraying, will hopefully provide that perimeter protection that was lacking when they did the indoor spraying initially. The indoor spraying was not

accommodated via the section 18 process. That was an already existing use pattern. But the outdoor trap that we recently approved under the section 18 was designed to complement and take care of that perimeter situation.

ANNIE: Okay. Will you consider potentially in the future a section 18 request?

MS. MONELL: Consider?

ANNIE: Just the fact that you said that they're not always effective. Like the indoor spraying, will that just continue to be a consideration?

MS. MONELL: No. I think it's not a simple either or. I think that screens are clearly essential in this equation, then other approaches to the perimeter and perhaps even, depending upon the situation, neighboring homes. Spraying was only done in the homes where there's pregnant women, and they agreed voluntarily to it.

ANNIE: Okay. I just wanted to echo Robyn and even Marc and just commend EPA on what you guys are doing with the pregnancy kits and the Home Depot. I think that's really great. We've always promoted addressing not just the chemical side of things but all the factors that contribute to mosquito spread viruses. We would

also really hate to see the EPA revert to older toxic pesticides like DDT. So, it's great to see that you're taking those other actions. Thank you.

MS. MONELL: Cynthia.

CYNTHIA: Thank you. That was absolutely fascinating, the tires, the disinsections, the DEET stockpiling, the Home Depot screens, the cemetery water, I mean all amazing stuff.

My question, as the mother of two gymnasts, one who is nationally ranked, we live and breathe Olympics. I'm just wondering what special efforts, if any, will EPA be taking to protect U.S. and other gymnasts in Rio.

MS. MONELL: Well, I'm going to defer that question to CDC because they're more actively giving advice to the organizers.

Janet.

MS. McALLISTER: So, some of the activities that we have in play right now with the Olympics Committee revolves really a lot more around having diagnostic testing available, working with local authorities to make sure at least the U.S. delegation is in the best situation that they can be in as far as

having mosquito control available to them while they are down there, and certainly, also, in providing personal protection, things like repellants and nets and the things that we are pushing for individuals to take.

We are in a situation where this is a foreign country, so we can't go in and initiate a lot of things ourselves. But we are working closely with the Olympics Committee to try to address ahead of time as many of the issues that we can have influence over.

MS. MONELL: It's very tricky. Puerto Rico has lost millions and millions of dollars in tourists, as you might imagine. I'm not saying that that's good or bad; it's a reality. The Olympics are an international event that Brazil has invested billions probably to pull off.

So, while it's important that we're mindful, all of the federal government is also mindful that we need to take care of our athletes and make sure that they're properly educated and armed with whatever protective things they need. But to push it too far is just not appropriate. It's a delicate balance going on, as you might imagine.

Richard.

RICHARD: Thank you. I very much enjoyed your presentation. It just got me thinking, how will the EPA deal with the need to use pesticides on the broad scale as a counter to the Zika? How would you deal with that if they are “contraindicated” for the pollinators that we’re dealing with?

MS. MONELL: That’s a very good question, and it is coming up in the context of any efforts at aerial spraying. You see pictures in Brazil and various other contexts of folks going around with foggers, planes coming over with aerial sprays, and so forth. We’re engaging in those discussions now internally because, obviously, the implications are huge.

RICHARD: Thank you.

MR. HOUSENGER: Bob.

BOB: So, two things. One, I took a whole page of notes. It was such a useful presentation.

MS. MONELL: But why is it only one column?

BOB: It’s an OCD problem. It’s a medical issue. Well, you know what, let me just tell you this. Here’s the notes I took from the rest of the day. So, they’re very useful. Thank you for that.

I know this isn't useful, and yet, I feel compelled to do it, which is to say some of the discussion went in a direction I didn't expect it to go in. As somebody who is at least peripherally related to the treatment of these mosquitos, I just wanted to respond to a couple of things that were said.

One, PCOs do not treat indoors for mosquitos, period. I don't know if there's any products registered for that use in the United States. It does not happen. Nobody would do it.

Number two, I don't know of anyone who wants to manufacture or formulate or register DDT. If they did and you were weak enough to register it, I don't know of any PCO that would use it.

Number three, I was a little concerned to hear the focus about the overuse/misuse of pesticides and pesticide poisoning. I'm not aware that that's happened. I mean, if someone that expressed those concerns could -- is that going on?

MS. MONELL: We've not heard of it, but certainly, in light of our experience in the Virgin Islands, with that situation, we're always mindful of it

because that was a tragic event.

BOB: Sure. I guess my take is that happens to be the one thing for which there really is a pretty good infrastructure. The treatment side and the medical response is not so great. I think the enforcement of misuse has done pretty well here in the U.S. That's all.

MS. MONELL: Thank you.

Beth Law.

BETH: I just wanted to say that several CSP member companies donated product and other resources to help fight Zika. In some instances, the registrations weren't exactly -- well, they needed assistance sort of making sure all the paperwork had been done correctly and that the products were properly registered. I can only say that Marty's team and RD acted not only quickly but thoroughly in accordance with their procedures to make sure that everything was in place.

So, it's been quite comforting, actually, to see our federal agencies, EPA and CDC and the CDC Foundation as well, respond so quickly and so professionally to this emergency.

MS. MONELL: Valentin.

VALENTIN: Thank you very much for the information. It's been a very helpful learning experience for me. As you were speaking, and perhaps these questions are for Janet, I was thinking of who are the most vulnerable population when it comes to Zika. I'm thinking about women, migrant farmworkers who live at labor camp, housing being provided by employers. In Oregon, we have over 300 registered labor camps. Sometimes they are living in housing conditions that are in disrepair conditions and oftentimes don't have control of taking steps in preventing being exposed to Zika.

So, my question to Janet is, how are you collaborating with the Department of Labor to equip migrant farmworkers, including guest workers, to equip them with information about Zika?

MS. McALLISTER: That is an excellent question, and I would have to actually reach back to my colleagues in the Global Migration Division here at CDC to see what they are doing on that front. So, I don't have a specific answer to that.

MS. MONELL: Let me just interject here. I probably spoke very, very fast. OSHA has come out with

new guidelines for workers that I believe include migrant workers. They should be on OSHA's web site. It's specifically geared towards workers. We took a look at them in conjunction with obviously our work protection standard revisions and wanted to make sure that it was consistent and just make sure that there was appropriate coverage. Kevin Keaney and his folks found them totally appropriate.

So, I would encourage you to take a look at them. If you see there's an area that's omitted because it wasn't considered, just send me an e-mail.

MS. MONELL: Amy.

AMY: I still am concerned about potential exposure to pesticides on this one. So, I'm wondering, particularly in Puerto Rico, where do we find out, just in terms of the public health thing, what kinds of pesticides are being used, when are they being used, just to make sure that the clinicians that we're working with are aware, just like we like to do in agriculture, aware of the pesticides that are being used in their communities?

MS. MONELL: Well, CDC will speak to that

specifically. I'm sure the information is available. By the way, the CDC Zika web site is the best web site I've ever seen. It's got information that you didn't even think you wanted to know. It's very thorough, very user friendly. They have been working with the territorial government of Puerto Rico on this spring initiative. CDC knows what their contractor is using and where.

I'll let Janet address it as to what they know about the Puerto Rican government's effort on spraying.

MS. McALLISTER: Right. So, as Marty said, the Puerto Rican government really approves what can and cannot be done on the island. So, CDC can make suggestions on tactics to control mosquitos, but it's up to the local government there to approve whether something would be implemented down there.

So, for the targeted indoor residual spraying that has been going on, what they have been using is a deltamethrin product. I believe that they're also using deltamethrin products in the municipalities that own spray trucks. So, to my knowledge, that's really the only chemical that's being used down there right now.

AMY: Thank you.

MS. McALLISTER: As far as something to kill adult mosquitos. They do use some BTI on the island for larval mosquito control.

MS. MONELL: Lori Ann.

LORI ANN: That addressed some of what I was going to say. I have worked on mosquito emergency, nowhere near this magnitude, so I hesitate to compare. But I just want to put out there that working with folks who have significant expertise in mosquitos can be an amazing thing. I was fortunate to work with someone from Xerces who did her PhD on mosquitos.

We had an emergency at a wildlife refuge involving endangered species. That’s why I was involved with it. But it was a public health emergency. Getting to work with someone who is truly a mosquito expert who has all this IPM expertise was an incredible experience and allowed us to achieve amazing results in a very short period of time with BTI.

As we’ve talked about, all these simple solutions, getting people to dump water out of their vases and things like that, I want to make sure that

we are looking to the basics and not forgetting to work with real mosquito experts and working with BTI that we know can be very effective.

MS. MONELL: That’s a wrap.

MR. HOUSENGER: That seems to be it. Time for public comments. Regina are you still on the phone?

REGINA: Hi. Yes I am. It was just a matter of clarification. The first presentation tomorrow morning is incidents, is that all types of incidents or just the bee pollinator incidents reporting?

MR. HOUSENGER: That’s everything. How incidents are captured and reported. It’s everthing, it’s not just bees.

REGINA: OK thank you.

MR. HOUSENGER: That’s it then. We’ll see you tomorrow morning at nine a.m.

(The meeting was adjourned).

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