UNITED STATES

ENVIRONMENTAL PROTECTION AGENCY

PESTICIDE PROGRAM DIALOGUE COMMITTEE MEETING

MAY 2, 2018

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. KEIGWIN: Good morning. Thank you for joining us. Before we get going on the day, I wanted to turn the mic over to Charlotte Bertrand for some opening remarks.

MS. BERTRAND: Good morning, everybody. It's a real pleasure to be here today. The last time I was here, I had just started my position. It's good to see you all again, now that I'm learning a little bit more about the program and the issues.

So I wanted to start by -- and talk a little bit about thanking all of you for your time, and I especially want to welcome and thank the members of the PPDC. We know, I know your time is valuable. We appreciate very much the time that you invest here, the input you provide and your service to the committee. I also want to thank Dea Zimmerman and the Office of the Pesticide Programs staff. I know you all worked extremely hard pulling this together and so it's going to be a great meeting and it's

thanks to all of the work that Dea and the OPP program staff did today to pull the agenda together.

So I'm going to be here briefly this morning. I'll see you all again tomorrow, but I wanted to welcome you here, start the day off, say hello and to give my personal thank you for your time before I turn the reins over to Rick who is the Office of Pesticide Programs director and as you know, the PPDC chair.

So like I said, it's been, I guess I started in October so it's been about six months since I've been acting in my position, but it's definitely not the first time that I've been engaged in dialogues and stakeholder involvement. I've been at the EPA for 21 years, and over the course of those years, it has definitely been my experience that stakeholder input and participation is extremely valuable to us. We can't do this alone. Stakeholder input and participation is something that's not a single event. It's a process.

And so part of that stakeholder input are the federal advisory committees that play a critical

role in providing the valuable input to guide our policy-making at EPA. And federal advisory committees like the PPDC enable us to tap into expertise and in this case with experience in agriculture, labor, public interest, animal protection, business and manufacturing.

So I want to say, I was very impressed. I asked before I came here, I said how long has the PPDC been a federal advisory committee? And I learned this committee was formed in 1995. So what a testament to the value that this committee provides us, that 23 years later we are still sitting at a table and EPA is still benefiting very much from your valuable input.

So I know that OPP following these meetings, we consider your input and your comments on our actions. We know that this is one of our more effective forums for discussion, giving us the opportunity to gather individuals from different perspectives and experience in one room, present issues and updates, field questions and collect valuable and thoughtful feedback.

So I also want to acknowledge that while there's face-to-face meetings, the PPDC extends beyond the input that you're going to provide us today and tomorrow, that twice a year you gather here, but it's not the only time you weigh in on these issues and other issues. So just as you dedicate your valuable time outside these meetings, the reading back on documents to prepare or providing insights on subsequent workgroup meetings, we continue to work on the issues and your input well after this meeting has ended.

So one example that I wanted to draw out is that PPDC's 21st Century toxicology workgroup was established to inform and engage stakeholders early on in OCSPP's approach to evaluating invitro technologies and computational sciences and those will replace and supplement some of the more traditional methods of animal toxicity testing and risk assessments. So in the later years, a workgroup weighed in on goals and metrics for success, and ten years since that workgroup started through the PPDC, OPP is still making great progress

and is continually engaged in this space.

So today you'll hear an update on our progress towards non-animal alternative testing for acute 6-pack studies -- we'll see if I can talk above the sirens -- as well as an update on our pivot to include ecological toxicology studies in this effort. More broadly, these efforts help lay the groundwork for OCSPP's move towards alternatives to animal testing. So that ten years of input really helped and what started ten years ago has really, we're seeing the benefits today.

Last month OCSPP released a draft policy to reduce the use of animals in testing chemicals to evaluate whether they cause an allergic reaction, inflammation or sensitization to the skin. In March OCSPP's Office of Pollution and Prevention and Toxics released a draft of alternative strategies to promote the development and implementation of alternative test methods and strategies to reduce, refine and replace vertebrae animal testing as required under the new TSCA laws. PPDC's role in the early coordination of OCSPP's 21st Century

toxicology efforts was critical in taking our first steps towards these major changes.

So again, I just want to thank the group. Your input is very valuable. Your input is long term and it's helped us shape our policies so it's very much appreciated. I look forward to hearing more about how things are today, I can't stay with you today, and seeing you all again tomorrow.

So with that, let me turn it back over to Rick to walk you through the rest of the agenda and start off a good discussion.

MR. KEIGWIN: Thanks, Charlotte. Really appreciate that.

I wanted to acknowledge before we got going a few new faces here in the Office of Pesticide Programs. The first I wanted to recognize is Ed Messina, who is to Charlotte's right. Ed has joined OPP about two and a half weeks ago now as the acting deputy office director for programs. He joins us from a lot of time at EPA from the Office of Enforcement and Compliance Assurance and several of you may know Ed from his time in OECA. So we're

thrilled to have Ed with us.

We also have with us today Hema Subramanian who is the agency's acting special assistant for agricultural policy. Hema's up there.

And then she could not be with us today but recently Anita Pease has been named the acting director of our antimicrobials division. Anita most recently was the acting deputy director of our biological and economic analysis division and for many years, served in a number of capacities, including the deputy director role in our Environmental Fate and Effects Division. So those are probably our biggest changes here organizationally within the Office of Pesticide Programs since we met last.

If I can just quickly walk everyone through the agenda for today and tomorrow. We're going to -- after we do introductions and some housekeeping, we're going to provide you all with an update on our progress in meeting our obligations under the Pesticide Registration Improvement Act. Steve Schaible who is the PRIA coordinator will lead us

through that.

After the break, we want to share with you our progress in moving some more electronic tools for doing some of our work, so Patricia Parrott from the Field and External Affairs Division will lead a session on what we're currently calling the SmartLabel project, as well as the electronic confidential statement of formula.

Then after lunch, we want to provide you all with some updates and get some input from you all on -- in a couple of areas. One is, actually they both relate to what Charlotte was talking about, part of our efforts to move towards non-animal alternatives for testing chemicals. So we will provide you first with an update on our efforts to reduce and remove certain studies from the Acute 6-pack and then secondly, Kimberly Nesci from our Environmental Fate and Effects Division will give you all an update on some of the new approaches that we're looking at to do something similar on the ecological risk assessment side.

And then we'll end the day today with some

updates on some of the work going on in our biopesticides division regarding novel mosquitos and biopesticides. And then Yu-Ting Guilaran will wrap up the day with a registration review update. And then we will have an opportunity for public comment at the end of the day. Those are -- the members of the public that would like to provide public comment, you should register at the desk that you saw when you came in, please.

Then tomorrow morning, Marietta Echeverria, our director of our Environmental Fate and Effects Division, will give us an Endangered Species Act update and OPP's efforts in that arena. Wynne Miller from our, from our Biological and Economic Analysis Division will be sharing with you all some thoughts that we have on our communications plan on resistance management and we would like to get some input from you there.

And then Arnold Layne will lead as session debriefing us on the progress by the public health workgroup and Julie Spagnolli, who is a workgroup member from that workgroup, will be assisting in

that presentation. And then we'll discuss next steps and possible topics for our fall meeting.

So since our fall meeting, we have had a couple of membership changes. Cynthia Palmer who had been with the American Bird Conservancy has resigned from the committee, and then Rachel Calles, who had been with SC Johnson, and Preston Peck who had been with Toxic Free North Carolina, had moved to new employers that are now either outside the scope of OPP's work or moved to a different viewpoint all together. Cynthia or excuse me, Sylvia Palmer from the Council of Producers and Distributors of Agro Technology has joined the committee, although I believe she's not able to join us here today.

Some other housekeeping issues, hopefully everyone has signed in at the registration desk. If you have not, please do so at the break. In terms of when we turn things over to the committee for feedback, the same system that we've used. Turn up your tent card, make sure the light on your microphone has turned red when it's your turn to

speak and then turn that back off when you are finished with your remarks.

We do have some members of the PPDC that are participating remotely today, so after we've gone around the room for PPDC members to give their remarks or their questions, we will open things up for members who are on the phone. We are controlling the muting and unmuting, so please do not unmute your phone remotely unless we ask you to do so.

We heard the sirens during Charlotte's remarks, so in the event of an emergency over here by Dea, Dea will move first but there is an emergency exit here so that you don't have to go out -- there are other emergency exits but this is the primary one. As I guess as they say on the plane, look for the closest exit door. It may be behind you.

And finally, I just want to say we're really looking forward to today's discussions. We acknowledge that some of the issues that we'll be discussing today, there is not going to be agreement

across the committee. That is fine and we welcome that. We only gain in our deliberations internally from a robust discussion amongst all of the PPDC members and we believe that a range of feedback helps to further inform our decision-making.

So we do appreciate the time that you all are taking out of your very busy days over the next day and a half to be with us, and for many of you who have traveled from out of town, we're really talking about probably a week all together and that really means a lot to us. So thank you.

With that, why don't we do introductions. I will start to my left.

ATTENDEE: Good morning, Arnold Layne, deputy office director for management in the Office of Pesticide Programs.

ATTENDEE: Steve Schaible, Office of Pesticide Programs, PRIA coordinator.

ATTENDEE: Eric Hoffman, Armed Forces Pest Management Board.

ATTENDEE: Charlotte Liang, U.S. Food and Drug Administration, Office of Food Safety.

ATTENDEE: Eric Gjevre, Tribal Pesticide Program Council, Coueur d'Alene tribe.

ATTENDEE: I'm Tim Tucker with the American Beekeeping Federation.

ATTENDEE: Good morning, I'm Amy Liebman with the Migrant Clinicians Network.

ATTENDEE: Donny Taylor with the Ag Retailers Association.

ATTENDEE: Amy Asmus with the Weed Science Society.

ATTENDEE: Charlotte Sanson with ADAMA USA.

ATTENDEE: Steve Bennett with the Household and Commercial Products Association, formerly known as the Consumer Specialty Products Association.

ATTENDEE: Komal Jain with the Biocides panel of the American Chemistry Council.

ATTENDEE: Andrew Thostenson with the American Association of Pesticide Safety Educators.

ATTENDEE: Damon Reabe with the National Agriculture Aviation Association.

ATTENDEE: Liza Fleeson Trossbach, the Association of American Pesticide Control Officials.

ATTENDEE: Jay Vroom, CropLife America.

ATTENDEE: Andy Whittington, Mississippi Farm Bureau Federation.

ATTENDEE: Aaron Hobbs, RISE.

ATTENDEE: Nina Wilson with Gowan representing the Biological Products Industry.

ATTENDEE: Domenic LaJoie with the National Potato Council.

ATTENDEE: Dan Kunkel with the IR-4 Program.

ATTENDEE: Lori Ann Burd, Center For Biological Diversity.

ATTENDEE: Nichelle Harriott, Beyond Pesticides.

ATTENDEE: Jim Fredericks with the National Pest Management Association.

ATTENDEE: Stan Cope, American Mosquito Control Association.

ATTENDEE: Good morning, Leyla McCurdy with the Children's Environmental Health Network.

ATTENDEE: John Gorman, EPA, Region 2.

ATTENDEE: Gina Schultz, Fish and Wildlife Service.

ATTENDEE: Sheryl Kunickis, I'm the director in the Office of Pest Management Policy at the United States Department of Agriculture.

ATTENDEE: Ed Messina, acting deputy office director of --

ATTENDEE: Charlotte Bertrand, acting principal deputy assistant administrator for OCSPP.

MR. KEIGWIN: I indicated we had some members on the phone, so PPDC members who are participating remotely, could you introduce yourselves, please?

(Pause.)

I believe we should have Sharon Selvaggio participating over, via teleconference. Is Sharon available?

(Pause.)

MR. KEIGWIN: Iris erFigueroa, or Pat Bishop?

Perhaps I would check to see if anybody on the phone can hear what we are saying here around the table?

ATTENDEE: Can you hear me now? This is Sharon Selvaggio.

ATTENDEE: Can you hear us now?

MR. KEIGWIN: We can hear you now.

ATTENDEE: Okay, it's Pat Bishop from the Humane Society.

MR. KEIGWIN: Thanks, Pat.

ATTENDEE: Hi, it's Iris Figueroa from Farmworker Justice. Good morning.

MR. KEIGWIN: Good morning, Iris.

ATTENDEE: And Sharon Selvaggio from the Northwest Center for Alternatives to Pesticides.

MR. KEIGWIN: Thanks, Sharon, welcome. I know it's early for you.

ATTENDEE: Yes.

MR. KEIGWIN: So with that, I believe those are the only PPDC members that were participating remotely, okay.

With that, I think we can move on to our first topic which is --

I'd ask Steve Schaible who is our PRIA coordinator to walk us through the presentation. The presentation for this should all be in your materials for the PPDC members. For those

participating remotely, all of the presentations are available on the agency's website for the Pesticide Program Dialogue Committee.

So Steve, let me turn things over to you.

MR. SCHAIBLE: First of all, good morning, and I am going to run you through some of our performance metrics for PRIA through the midyear of our fiscal year 2018. I'm a technological black hole.

So just to run through quickly what I want to talk about, we'll do a brief update on PRIA 4 which would be the next reauthorization of PRIA and we will get into some of the numbers. We'll talk about the PRIA submissions that we've received so far to date, as well as our completion. We'll talk about some of those completions, the negotiation rate of those and our on-time completions.

Then we'll briefly touch on the fees collected but maintenance fees as well as PRIA fees, electronic submissions and our progress in moving towards receiving as much as we can electronically. Electronic label reviews, reviewing things

electronically and then finally the 45/90-day preliminary technical screen under PRIA and sort of what has been the activity and performance under that. And then the last is just points of contact for PRIA, should you have any questions.

So next slide, please.

For the PRIA summary, we are still under PRIA 3. For a while there, we were getting reauthorized on one and two-month increments. With the Consolidated Appropriations Act that passed back in March, we are -- PRIA 3's expiration date was extended through the end of this fiscal year so through September 30, 2018. The PRIA 4 bill that was introduced in the House and passed in the House last March and advanced to the Senate and passed out of the Senate Ag Committee is still pending.

The Farm Bill that was recently reintroduced in the House, HR 2, does include a provision enacting the House version of PRIA 4 should the Farm Bill pass and that would, that version, the House version reauthorized PRIA through fiscal year 2023. The version pending in the Senate, the amended

version in the Senate reauthorizes PRIA through 2020.

Next slide, please.

As far as what we've received and what we've completed, I don't know if you're going to be able to easily look at these numbers but the light blue on the left side is going to be the number of primary applications that have been received. Across the bottom, we have antimicrobial actions, biopesticides, conventionals, inert ingredient actions as well as miscellaneous actions.

The yellow is the number of completed decisions. And so within a decision, there's primary decisions and secondary decisions. The primary decision is basically counting the action once, even if there are a number of associated, for instance, new product registrations associated with that new chemical submission. You send in a new chemical. There is, you know, a technical product and five end use products and there's tolerance decisions, so that's seven PRIA decisions. And so the primary counts that new chemical once instead of

seven times, so just to clarify that.

So the gray is the primary. And then the dark blue are the number of those completed decisions in which there are one or more negotiations of the original PRIA due date. So with that explanation, and again this is through the end of March 31st, so this is the first half of our fiscal year.

For antimicrobials there were 132 primary applications that were received through the first two quarters. There were 173 completions and of those, 139 of those were primary decisions and two of those were involved in negotiation of the PRIA due date. So in the big picture, it looks like we were receiving about as many as we were completing in primary decisions and the negotiation rate is quite low for that.

For biopesticides, there were 74 primary applications submitted. There were 84 primary and secondary decisions completed. 63 of those were primary decisions and there were 12 negotiations.

For the conventional pesticides, there were

419 primary decisions that were submitted -- or received by the agency. There were 517 completions through the first two quarters. 414 of those were primary decisions and there were 136 negotiations of the due date associated.

For inerts, there were 29 applications received, there were 19 completed and all of them were primary decisions. And of those 19, 11 of them involved in negotiations of the PRIA due date.

And finally for the miscellaneous, the lion's share of these miscellaneous actions are going to be requests for gold seal letters, so that's documentation that the product is currently registered with the U.S. EPA and that documentation is sent to other countries. There were 278 miscellaneous categories received, 275 of those -- well, there were 275 completions. All of them were primary decisions. There were no negotiations involved with any of the miscellaneous categories that were completed.

Next slide, please.

This slide talks about our rate of

negotiation and it starts historically, it starts with 2010. We've been under PRIA 3 since 2013. And so you can see up towards the top of this, we're looking at 35 percent, 60 percent, 26 percent, and you can sort of see a trend over time of how the current fiscal year relates to previous fiscal years in terms of negotiations.

I'm going to talk specifically about FY18 only. For the antimicrobials, again, there were two negotiations and that represents 1.2 percent of the total completions that they had for the first two quarters of this year. And that's quite low compared to historic performances here.

So the biopesticide, there were 12 negotiations out of 84 completions for 14 percent negotiation rate. For the conventionals, there were 517 completions and of those, 136 were negotiated, so that's a 26 percent negotiation rate. Again for miscellaneous, there were no negotiations so that's zero percent.

And for the inert ingredients, 11 of the 19 completions involved one or more negotiations. And

so that is 58 percent. And I know that for the inert ingredients, these were first introduced in PRIA 3. I think we have better information now on what are the resources and the timeframes that go into reviewing those inert ingredient applications and PRIA 4 proposes modifications to those timeframes and fees that will hopefully if passed, would hopefully bring these negotiation rates for inerts down lower.

Overall for the office through March, we are at a 15 percent negotiation rate. Last year I think we ended up at 15 percent as well. So we're pretty much within the framework of the last three years of our performance as far as the negotiation rate.

Next slide, please.

Okay. In terms of on-time completions, this is the percentage of our completions on which the PRIA due date or the negotiated due date was met by the agency. So for the antimicrobial division, there were no completions so far this fiscal year which did not meet or beat the PRIA due date. So they're at 100 percent.

For biopesticides, likewise. All of their completions have been before or on the PRIA due date. There have been two completions for the conventionals that did not meet the PRIA due date and so that on-time completion rate is 99.6 percent. For the inerts, there have been no late completions. For miscellaneous, there has been one missed action, a gold seal. And so they're at 99.6.

And so overall for the office, there have been three decisions out of 1,068 that did not meet or beat the PRIA due date, and so our on-time completion rate for the office is 99.7 percent. I will say this is better than we have been experiencing historically and I would say quite commendable, I think, given some of the resource constraints that we're under.

Next slide, please.

These are the fees that have been collected to date for both the PRIA fees and the maintenance fees. The maintenance fees are invoiced in the autumn and the due date for submitting those maintenance fees is in January and then there's some

slow trickle once you get beyond January. These are annual fees that are paid to support registrations with the agency. These fees go to support reevaluation activities, review of new products, amendments that are substantially similar, inert clearances and then IT improvements for the office.

The PRIA fees, of course, are paid at the time of the application, the application is submitted. So to date, well, through April 19th, PRIA fees collections were at $9.58 million, and I actually as of a week later, they were up to 9.8 million. Last year we collected after refunds were taken into account, we collected around 18 million. And so we are on target to collect, you know, assuming you have the same degree of collection in the second half of the year, we're on target to collect 18 million or possibly more.

On the maintenance fee side, the PRIA 3 has a collection target of 27.8 million for the year. Through April 19th and likewise, I checked the numbers as of April 26th, and we've collected 27.76 million in maintenance fees so far. We're pretty

close to the $27.8 million goal or target.

Okay. This next slide has to do with electronic submissions. It was going on three years come September that the portal was made available and that was a secure web-based means by which applicants can submit their applications to the EPA. Prior to that, our electronic submissions involved CD's and DVD's being submitted to the agency. And so this lays out the number of paper submissions we were receiving, the number of submissions on CD or DVD and the number of submissions that are being submitted through the web-based portal.

Likewise, these submissions take into account both PRIA and non-PRIA submissions and they take into account all submissions. So these could be resubmissions of additional information, not just the initial application.

For conventionals, the total number of submissions is 3,855. Of those, 1,943 were submitted on paper. That's 50 percent overall. There were nine submissions on CD or DVD or less than 1 percent, and 1,903 were submitted through the

portal or 49 percent. So half of the submissions are coming in electronically and then half in paper.

And just as an aside, I will say there are certain types of actions that might make sense to submit one way or the other. Especially if you are an infrequent user of the portal, I think that the challenges of getting set up in the portal and understanding the portal and remembering what your password is, you know, I think a lot of people just think it's a one-page gold seal letter request or something, they just go ahead and send it in paper. But I think we are looking to improve the customer experience around the portal in general.

For antimicrobials, the total number of submissions was 1,260. Of those, 402 were in paper or 32 percent. There was one CD or DVD submission, less than 1 percent. And then 68 percent were submitted through the portal.

For biopesticides, there were 542 total submissions. Of those, 250 were in paper, 28 were on CD or DVD and 264 were using the portal. So 46 percent in paper, 5 percent on CD or DVD and 49

percent through the portal.

Overall, we were at 46 percent of our total submissions are submitted on paper, less than 1 percent on CD or DVD, and 53 percent being submitted through the portal. And I think we are seeing still a gradual and slow increase in the use of the portal in terms of overall percentage of our submissions.

Okay. As far as electronic label reviews, there was money set aside in PRIA 3 to -- for EPA to develop certain IT capabilities and one of the specific activities mentioned in the IT set-aside was the development of software and the ability for EPA to review labels electronically. I think in terms of our overall objective of having a fully electronic system of receiving applications, reviewing applications internally and then providing information back to you electronically, it's pretty crucial. So the portal was the first step, stage of that, that we need to be able to receive everything electronically.

The label comparison software is a means by which we can do our work electronically. I think

the idea is that if you are able to use this comparison software, that represents an efficiency for the agency. We're able to complete our work more quickly and therefore, get decisions to you more quickly.

And so this report basically gives us -- so when a reviewer closes out an action, there's a prompt in our system that says, was this label reviewed electronically? Yes, no. If you say no, it has a follow-up pop-up box that talks about if it was not reviewed electronically, what was the reason for that? And it gives the different reasons so that we can understand sort of behaviors of our reviewers and sort of respond to those concerns where they exist.

And if you don't answer anything, that's where you're getting the uncertainty, this range of percentages. If you don't answer, then we -- our numbers are more squishy and there's been a concerted effort, there's actually a report that addresses this range and I think our boundaries have shrunk as a result of that.

So again, this relates to the label review specifically, and I just spoke about the uncertainty. So for RD, for the conventional chemicals, the percent of labels that are reviewed electronically range from 87 percent to 93 percent. For AD, the antimicrobials, it's 89 percent to 95 percent, and for the biopesticides, the percent of labels reviewed electronically is 76 percent to 88 percent.

Okay. Moving on to the preliminary technical screen, this is a tool that was introduced in PRIA 3. Depending on the timeframe, the PRIA timeframe associated with the action, you either have -- the agency has 45 days from the start of the PRIA date or 90 days from the start of the PRIA date to do a preliminary screen of the application. So at the very front end, there's a 21-day completeness screen and that's basically where EPA is just looking to make sure that all the forms are there that are supposed to be there, they're signed. The 11-3 screen is done for the data and your confidentiality page is signed. So these are

basically the very basic things you need to do for us, for the application to be complete.

That occurs in the first 21 days and that precedes the start of the PRIA due date. Once the PRIA due date starts, there's either 45 or 90 days for the agency to get into the actual data, look at the studies, any waiver requests and make a determination on is there enough there in the application that we should, based on this screen, have some certainty that we could conduct a risk assessment and make a regulatory decision.

EPA must complete the screen within that timeframe. And usually if there are deficiencies that are identified, a letter is sent from the agency that's commonly called a ten-day letter. That alerts the applicant of the deficiencies, and the applicant has ten days from the receipt of that letter to provide a response to the agency which addresses the deficiencies that have been identified.

And so I am going to -- and depending on whether that response is adequate or not, we move

ahead with the review because the response addressed the deficiencies. The applicant -- if it does not address the deficiencies, the applicant has the opportunity to withdraw the application or the EPA can reject the application under the preliminary technical screen.

So that's the whole process. So now I want to walk through the pieces of it. This slide has to do with the actions that have been completed the screen. So these numbers aren't going to exactly match up with our completions because some of the screen numbers are things that have, you know, recently been received and so it's a slightly different window of time. This is looking at everything that, for which a screen has been completed.

Likewise, the agency has 45 or 90 days to provide a response to the applicant. If the agency has not done that, then the screen is deemed to have been completed. And so those numbers, so if there was no ten-day letter sent, basically there's no deficiency, those numbers are counted here as well.

For the antimicrobials division, there were 140 screens completed. For biopesticides, there were 88 screens completed through midyear. There were 580 screens completed for RD, 29 for the inerts group and 4 screens completed for miscellaneous. And again, most of the miscellaneous actions that we receive are gold seals. Gold seals have a one-month PRIA timeframe and so there is no preliminary technical screen that occurs for those and so that low number there reflects that the gold seals are not counted.

Okay. And so assuming there is one or more deficiencies that are identified, the agency sends out a ten-day letter. And so for the antimicrobials division, there were nine ten-day letters that were sent out. For biopesticides, there were 43 ten-day letters sent out. 18 for the conventionals in RD, and there were no ten-day letters sent out for the inerts or for miscellaneous actions.

Okay. And then this next slide has to do again with the results. As you can see, most of the responses to the ten-day letters on the previous

slide addressed the deficiencies that were identified. For the registration division, one action out of the -- if I go back, out of the 580 actions that went through the screen, 18 had ten-day letters sent and of those 18, there was one withdrawal as a result of the deficiency not being remedied and there were two rejections.

For the biopesticides, out of a total of 88 screens conducted, there were 43 ten-day letters sent. Of those, there were three withdrawals as a result and there were four rejections. And for the antimicrobials, out of 140 screens completed with nine ten-day letters sent, the deficiencies were adequately addressed in all nine situations.

Here are some of the reasons, and so that we can run a report that lists out all of the reasons for all of the deficiencies, and here are some of the reasons for our rejections and withdrawals and this list quite honestly, having been doing this for two years now, really doesn't change.

So the new product application was found to be not substantially similar, either in the label or

in the formulation of the product to the cited product. There were data deficiencies. Either they were missing data or a rationale for not requiring data was not found to be adequate.

Efficacy data, the efficacy data submitted or not submitted did not support the claims that were on the label. There were uncleared inerts in the formulation or there was missing inert data. In some cases, the inert ingredient is misidentified.

There are data matrix or data compensation issues. The offer to pay wasn't checked, the cited studies, you know, did not support the claims being made. And then finally if there's a bridging argument being made, the bridging argument was found to be unacceptable.

And this last slide is just the PRIA points of contact should you have any PRIA questions. I am at the office level, and I am also helping out the registration division to some degree while that position remains vacant.

Aswathy Balan is also a resource within the registration division for PRIA questions and if you

would like, I can provide that email as a follow-up. Diane Isbell is the contact in the Antimicrobials Division, and Andy Bryceland and Cara Finn are the contacts within the Biopesticides Division. Thank you.

MR. KEIGWIN: Thanks, Steve.

So let me open it up to members of the PPDC who might have questions or comments.

Amy.

MS. LIEBMAN: Good morning. Thank you so much for the update. I have a couple of questions on your update. The first one is that at our last meeting, you talked about the fact that there's about a million dollars that PRIA sets aside in order to address the worker protection implementation activities and I am -- while it's interesting to see your fees and the maintenance fees and all of that, I'm curious as to why you wouldn't have included any update on that. Because there are many members that are interested in what activities are funded by PRIA that are going to worker protection. So that's my first question.

And then the second question that I have is that last time you talked about the Pesticide Education Resource Center or the PERC, which is a PRIA-funded group to help with various worker protection activities. And since our last meeting, a Federal Court ruled that the certified pesticide applicator rule is indeed in effect and that it's unlawful to delay it. And so I'm just wondering what EPA and PERC are doing with the PRIA money to help with a very important worker protection regulation that now is indeed, according to the law, in effect.

MR. SCHAIBLE: Well, first of all, thank you. And yeah, we did not include the worker protection grant in the slides and we will do so going forward. My understanding is that, so yes, there's one million in worker protection that is awarded annually. Then there's 500,000 for the pesticide education and then there is the, what's the third -- and then there's another $500,000, what is the third one? So there's $2 million dollars in the entirety. And is Kevin here or -- okay.

MR. KEIGWIN: Amy, thank you for pointing out that we didn't include that in the slides and we should have. What we will do is we will compile that information today and we will have it available to everybody for tomorrow's meeting.

MS. LIEBMAN: Great, thank you. And then you can, I'd like to hear about the certified protection, certified applicator rule.

MR. KEIGWIN: So do you want me to take that one, Steve?

MR. KEIGWIN: So we have, you pointed out the status of the litigation that was filed against the agency regarding the rule-makings that we had undertaken to change the effective dates. So the effective date of the certification rule is now as it was originally, March of 2017. States have and tribes and other groups that have certification programs have until March of 2020 to submit their revised plans. In the meantime, their plans that have been previously approved are the plans that are in effect, and provided they submit their revised plans by that March 2020 date, their previously

approved plan remains in effect while we go through the process.

We have been working cooperatively with our state regulatory partners and our tribal partners on answering questions relative to what they need to do as they work towards 2020. In the meantime, we are continuing to work through the PERC to help in the development of additional resources.

And then as we announced in December of '20 -- of last year, excuse me, we did announce that we were undertaking a rule-making to reconsider the minimum age provision in the final rule, and we are expecting to issue that proposed rule for public comment later this year. But in the meantime the certification programs, as they have been in place, are the certification programs that entities are working under.

MS. LIEBMAN: And I just want to add, thank you for that update. But what a shame, shame on everybody, at EPA for reducing the minimum age. That's just -- just shameful. You know, I can't believe that a really solid, moderate step forward

in terms of regulation that has such an important piece about a minimum age is now up for discussion, and I'm not sure who supports that. I'm not sure who around this table would support kids being, applying pesticide. I'm not sure why that's good for our environment. I'm not sure why that's good for human beings.

And I think all of us should be scared and the EPA is just certainly failing in its mission and it's certainly failing the people who pick our food and apply pesticides and they happen to be largely underserved minorities.

MR. KEIGWIN: Steve?

MR. BENNETT: Thank you. Looking at the -- the renegotiations, especially with respect to the conventionals, it seems to have shifted noticeably from last year. I think last year was about 29 percent and this year is about 26 percent. I would like to get an idea of what types of factors are driving those, if it's just the types of negotiations have changed, get a better idea of what's driving those, where they're going and how

many are out there.

MR. SCHAIBLE: Okay. Thank you for that question. I think for the negotiations, I think that some of those are us working through a federal register process and I think that we're starting to see some better performance on that. That relates to some of the negotiations. I wouldn't say looking at -- I think that some of this quite honestly is going to be that we are, our resources are less than they were. I think that -- I think that, yeah.

I think we are down around 600 staff right now. I think we were around 40 higher than that at this time last year. I think this is sort of a logical outcome of, you know, attrition and a lag time in our being able to hire up qualified people to fill that position.

MR. BENNETT: I'll do a follow-up then. You're on-time rate went up in light of the, you know, the resource constraints. I'm trying to correlate the two of that perspective.

MR. SCHAIBLE: So on-time means that we met or beat the original PRIA due date or the negotiated

date and so we're on time because we're negotiating.

MR. KEIGWIN: Steve, you look perplexed. Do you have a follow-up?

MR. BENNETT: Yeah, I'm just not -- I'm not sure if the date is reflecting the issue I'm trying to get at, of whether the renegotiations are fully reflecting the reasons why they're negotiated and that's fully reporting, that's reflecting the on-time. Because if you're having issues with the resource constraints but you're on-time rate goes up --

MR. KEIGWIN: Let me try to talk about it a little bit. So when we say that something is on time, we're saying that we met the statutory decision timeframe, with or without a renegotiation, okay. So even if we renegotiate and we meet, we complete the action within that extended period of time through the renegotiation, we're still on time. And so you do have scenarios where your completion rate goes up but your renegotiation rate also goes up.

We've also had a number of scenarios, and we

saw this last year, that our on-time rate went up and our renegotiation rate went down. I'll just add that, you know, when PRIA 3 was designed, we basically had a few hundred more people onboard than we have now and so those timeframes were built off of having onboards that we had at the time. Frankly in my opinion since we are hovering now around 600, that our on-time rate is as high as it is and our renegotiation rate is as low as it is is a testament to the dedication of the staff in the Office of Pesticide Programs to try to meet these timeframes.

And we continue to look for process efficiencies. That's one of the requirements in the statute and we're continuing to look for those. But as Steve was mentioning, the staffing challenges right now have been difficult, and it's been hard to find qualified applicants to come onboard when we have been able to hire.

MR. KEIGWIN: Charlotte, then Nina, then Jay.

MS. SANSON: Thanks, Steve, for the update. And I guess related to the resource constraints that

you're dealing with, would be the experience that a lot of registrants are having with non-PRIA actions in terms of getting those through, through the process. And so I was wondering if you could speak to what the current track record is on non-PRIAs and what can be done to try to help improve that side of things?

MR. SCHAIBLE: Okay. I had not prepared any of the fast track amendment or notification statistics for this meeting, but I had run those numbers in preparation for the last PRIA stakeholder meeting that occurred in early March. And I would say, without remembering the exact numbers, that I think that we do have backlogs for the fast tracks and for the notifications. I think as far as our priority in terms of directing our resources that we are, the PRIA actions have a higher priority than the non-PRIA actions.

That being said, we are looking at ways that we can provide decisions on the fast track actions and the notifications in a timely fashion. We are tracking internally what our performance is around

those and trying to bring those numbers down from what they were.

MR. KEIGWIN: Nina, then Jay.

MS. WILSON: Thanks, Rick. I just wanted to say that probably one of the process improvements that's come about in the last couple years is the technical screen, that I think has done a lot as far as weighing down some of the renegotiations, some of the issues. I mean we'd still like to see less renegotiations but that's helped tremendously, is that technical screen.

MR. KEIGWIN: Thanks, Nina.

Jay?

MR. VROOM: All right. The first thing I would like to say is congratulations to the agency staff for making the kind of progress against the headwinds that you're facing and you've already pointed out a little bit. I think you've understated those headwinds considerably and I would encourage all of us on the PPDC and others to think about ways that we can help contribute to both the operational creativity, some of which you have

internal at EPA and some of the advisory inputs and other stakeholder input help to advance.

But I would like to just spend a little more time at a future meeting really thinking about what more could we be doing from the private sector and the stakeholders around this table and others to come up with creative ideas and processes to help move the process even farther along. I'm disappointed because I think about the kind of discussion that I felt like we had had at the last PPDC meeting about trying to help break the impasse around getting PRIA released. It's still being held hostage in the Senate and I thought there was momentum at the end of that last PPDC meeting last fall to see some progress and I just don't see evidence of that.

A couple of questions that I would like to get your feedback on. One is the omnibus has a restriction on hiring that probably limits your ability to use some of the additional taxpayer funds that were appropriated in the omnibus for OPP. What are the limitations and what are you able to do with

that money so far and through the end of the fiscal year?

There's also an oddity in the existing PRIA, I think is section 4K2, that has tied up about $60 million dollars worth of industry fees. The passage, although the passage of PRIA 4 should release that 60 million, do you have a plan for where those resources could go, assuming that the prohibition on hiring as contained in the omnibus were to go away?

Lastly, I would just say the complexity of what OPP manages is amazing on every level and again, compliments to the team that you've got in place and the comments you made, Rick, earlier, about the staff still having an incentive to get the job done is very much appreciated and ought to be something that the public knows more about.

MR. KEIGWIN: So thanks, Jay. So in terms of your first question regarding some provisions in the omnibus, the agency's operating plan is still under review by the Office of Management and Budget. So I'm somewhat limited in what I can say until that

operating plan has been approved, but we are looking to see how we can maximize the utilization of fees to support bringing onboard additional hires consistent with the requirements in the omnibus.

In terms of the 4K2 provision, I think, you know, in shorthand for those of you who are not familiar with this provision, it's a provision that has been in FIFRA for a number of years. I think it dates back a few decades at least, and in lay terms it essentially means that on the maintenance fee side, to spend a dollar of maintenance fees, you have to pair it with a dollar of appropriated dollars. There's probably some legal nuance and appropriations law nuance but that's how, that's how I describe it to myself.

And so as, as the appropriated dollars have declined in certain years for the office, it's made it more challenging to fully utilize the maintenance fee money, and many of you know, the maintenance fee money is primarily utilized to support the reevaluation program, the registration review program. So we have been accruing balances from

year to year. PRIA 4 would have a provision to remove that requirement to do the one-for-one pairing.

It would also have some language relative to expanding what activities within the office could be funded using maintenance fee dollars. So we are developing a plan. There's also a requirement in the omnibus for us to meet regularly with the appropriations committee staff to work through our plan with them and so those meetings are in the process of getting scheduled.

And then I forget what your third piece was, so. I apologize.

MR. KEIGWIN: Lori Ann, and then Steve, were you coming in for round two? Okay. So Lori Ann and then Amy.

MS. BURD: Thank you. Senators Udall, Harris, Booker and Blumenthal proposed a compromise to PRIA reauthorization that essentially said hands off the worker protection standards and certification of pesticide applicator rules and also asked this office to respond to concerns to the

abrupt face on chlorpyrifos, which we all of course know causes brain damage in children. What, if any, actions have this office taken to respond to their concerns and compromise?

MR. KEIGWIN: So we are in routine contact with Senator Udall's office and we have been providing technical assistance to his office as he has been requesting. And we will continue to do so.

MR. KEIGWIN: You go first and then I can go to the phone.

MS. LIEBMAN: Yeah, I just wanted to clarify that, you know, we used the term "held hostage", PRIA is being held hostage a little while ago in this discussion. And I think that you have to understand a hostage situation really. And it's not. It's simply we have senators who care about kids, who care about the environment and are saying, you mess with the worker protection standard, you mess with some of these rules that are out, important to protect our environment, important to protect our workers, important to protecting our children, we're going to put a hold on it. And it's

just, it's pretty simple.

So I think that the hostage situation is arising in that EPA is messing with these rules and you're putting out, you're going back to it and we're going to see something in the Federal Register that's going to talk about moving the minimum age for when a child can apply pesticides. It's unbelievable. So it's not really a hostage situation. They're just standing up for human rights. They're standing up for kids and they're standing up for our environment.

MR. KEIGWIN: So I thought Amy Asmus just put up her card. But let me first check on the phone.

So Sharon, Iris or Pat, do you have a comment or a question?

IRIS: This is Iris, I do, but I don't know if others do as well.

MR. KEIGWIN: Well, Iris, you've got the mic, so.

MS. FIGUEROA: Thank you. So I just want to Follow up on some of the points that were made by Amy and

Jay and Lori Ann. As a farm worker organization, we obviously are echoing these comments that it's important to receive updates as well on the worker protection component of PRIA. But I think, you know, as has also been brought up, it's really important not just for the current PRIA but for the reauthorization. The whole reason behind the hold, as has been clear from the beginning, was the senators fear that the worker protection rules would be rolled back.

And at the last meeting which Jay referenced, I think to our credit, there was pretty broad consensus about the reasonableness of these provisions that had been identified for discussion as controversial. So we were pretty perplexed when in the letter that was sent to Senator Udall's office, the agency characterized that discussion very differently and then went ahead to, as you mentioned, Rick, have a notice of a proposed rule-making that's going to be happening soon.

So it seems that practically to move forward with that rule-making and expect that the hold is

going to be taken off, when that was exactly the fear that prompted the hold, is not a very realistic proposition and if we don't address that, I don't know how we can move forward.

MR. KEIGWIN: Thanks, Iris.

Amy.

MS. ASMUS: I just want to make a brief comment from the field. I commend you for relooking at the minimum age. We have excellent programs that we work with in the field through 4-H and through FFA programs, and when you move the minimum age to 18, we do a travesty to these kids because they're not allowed to learn in a situation with wonderful organizations like that how to correctly handle, how to correctly apply and to do projects around what they're going to go into the future.

And I don't really think we should repeal it back to 14 or 15, but even to 16 would allow these kids that are in an environment to learn and to get hands-on learning under programs and excellent mentors to teach them how to do it correctly. I think it's very important that we look at repealing

that back, at least to the point where we can properly train and work with and mentor our seniors and juniors in the high school level and in these wonderful programs.

MS. LIEBMAN: But can you clarify about the rule that it's really for hired workers, and that's where our concern is in that we're not talking about 4-H? Could you spend a little bit of time on that?

MR. KEIGWIN: This is when I wish Kevin were here. Many of you may know, Kevin has had to be out of the office for a few weeks.

So when we're talking about certification, we're talking about people first off that are handling restricted use pesticides. It does cover commercial applicators in some states and I would look to Liza to clarify this for me. I believe it also would cover private applicators.

So I mean this is, the Amy Asmus' concern is one that was expressed through various fora. I think it came in in part as a comment in response to regulatory reform. When we do issue the proposed rule, we would invite everyone to submit their

comments and their feedback and their perspectives and that will help to inform the final rule.

MS. LIEBMAN: Just to clarify, that we're looking at the worker protection standard in this rule. Are we or are we not talking about workers that are hired? It's --

MR. KEIGWIN: I mean there is the provision for family farms and family members on family farms under WPS and there's a lower minimum age currently under the finalized WPS rule that went into effect in 2015.

MS. LIEBMAN: So if you have a family member and you choose to have them do it, you're not hiring them, then it's fine, but like if you hire someone, it's not, correct?

MR. KEIGWIN: So as, under the WPS standpoint, I think Amy might be talking a little about certification. I'm not -- but I don't want to put words in her mouth.

MS. ASMUS: A lot of our 4-H kids and our FFA kids come from non-ag families and we really need to encourage their, their interest in ag and

interest in ag fields. And some of them don't have family farms in order to work on, and we really need to encourage them and mentor them at that age. And if they can't touch a third of what we apply, that really takes them out of some of those programs and projects that they're working towards. We can't assume that just because they're a 4-H kid or an FFA kid that they come from a farm family. We really need to grow our pool of workers and we really need to reach out to those kids that are interested in ag and not necessarily growing up on a farm or in an ag family.

MR. KEIGWIN: Okay. Aaron, then Leyla, then Damon.

MR. HOBBS: Thanks. I just want to reinforce the appreciation that we have for the resilience shown by the agency in a very challenging time with the inability for PRIA 4 to be passed. You know, we have talked repeatedly about the challenges as leaders and managers that you're having and just appreciate the dedication that you have, the things that you've done to improve the

program in a challenging political time.

And I guess my concern is all of the issuee that are being discussed are important and need a thoughtful response. And my concern is that two issues have been linked and the result is potentially the burning down of the house. To solve an issue that if the agency isn't properly funded and you don't have the resources you need to do your job, the results would be significantly greater. And so I'm just concerned that the house is burning down with these two issues being linked and it doesn't seem that those folks that are the most engaged there are working towards a solution that allows us to get PRIA moving forward.

So I just wanted to share that concern again, reiterate my appreciation for all the leadership within the program, for what you're doing to keep your teams motivated and focused at a time where attrition seems to be going in the wrong direction for the life of the program, so thank you.

MR. KEIGWIN: Leyla, then Damon.

MS. McCURDY: Thank you. I have a question

for Amy Asmus, actually. It's a three-part question. You said that the 4-H or similar programs are a pathway for young people to get into agriculture and for those kids who may not come from families that are in agriculture, the only way to train them for that type of career is to expose them to pesticides, according to the way you spoke about it.

So around that, here are my questions. How long does it take to train someone? Number one. And these kids, if they come into these programs, how much are they exposed to pesticides? Thirdly, isn't there a way to train them without exposing them to pesticides? There are many, many training programs I know that goes through the routine without having kids touching hazardous materials.

MS. ASMUS: First of all, I would like to say that we operate under the rules of our labels and each of the labels have material safety data sheets go along with them, and we're all trained in protective equipment, PPE, that go along with it. And so these kids, if they're working under, under

those label directions, their exposure to it is minimal. Just like the workers that I put the field, their exposure to it is minimal. All of that safety stuff is listed on the use labels. And when we follow that, we're limiting the exposure to somebody who is 16 or to somebody that's 36. We all want to operate under the same rules and limit exposures to any of these pesticides.

And we do need to train them to use the protective equipment that is listed on the label and to apply them correctly. And if we do that, we work really hard to minimize that exposure to anybody applying pesticides, not just children.

MS. McCURDY: That only answers one of my questions and not really to my satisfaction. Because minimal exposure is still exposure and children are more vulnerable to these types of exposures. I don't need to show a chart to show you why children are more vulnerable, et cetera. So the other piece of my question was why couldn't that training occur without actual exposure, actual exposure, to minimal exposure? Couldn't you do your

training still but not actually have them be near these hazardous materials?

MS. ASMUS: I believe training is a life-long thing. I'm not an educator myself, but I do believe we could give them book knowledge without exposing them. But a lot of the projects that these kids, 4-H kids work on through 4-H and FFA, the application of the chemistry is only a very small part of it. And the same thing with production. We want to teach them the big picture of production and this application is a small part of it. And so what they learn through the application is how to apply it correctly but once they learn and being hands-on and truly involved in a project that this is a portion of, is something you can't teach in a classroom and it's not something that you can teach in a book.

MS. McCURDY: I am not for this thing, training without hands-on. Why can't they just use water as a substitute for pesticide? You go still through the training . It doesn't have to be the toxic material that they need to be using for the

training. I mean if this is, you know, the premise why we need to expose these kids to a pesticide, that oh, we have to do the training with the real material. What is the reasoning of the real material there? Use the same exposure techniques, go through your training but substitute some non-hazardous materials in place of that. I mean it seems like common sense and I would like to hear an argument against this.

MS. ASMUS: I suppose we could for a sense of time agree to disagree, and if you want to catch me later, we can continue this conversation.

MS. LIEBMAN: I do think we need better clarification from the Office of Pesticide Programs here about the population that these regulations are targeting. Because this discussion seems to have gone a bit far field from what we are looking at in terms of the worker protection standards and the certified pesticide applicator rule which deals with restricted use pesticides. I was involved with 4-H. I don't see any need for a restricted use pesticide to learn about agriculture when I'm 14 and 15.

So I really recommend that we take some time at some point during this meeting so you can explain the existing rule, particularly since you're going to issue something in the Register to roll it back. I mean it just, this is bizarre.

MR. KEIGWIN: So we do have some good materials on our website and we can get that link around to everybody, that provides sort of a basic overview of the two rules as they are currently in effect and would be in effect until and if changes were made through our formal notice and comment rule-making process. And so we'll get those materials around to people before the meeting ends.

Damon.

MR. REABE: One point of clarification I think on this particular rule is that there is a current exemption for family members to be able to get trained and handle restricted use pesticides at the age of 16. And so just to refresh everybody's memory, at the last meeting I pointed out that aerial application companies are typically small family-owned companies and we were interested in

having the provision of family members that applies to farms be applied to our small businesses because they operate much like farms. And so that's just a little perspective I think on the comments that I made at the previous meeting to kind of frame, provide some framework of what was one of the suggestions that was made.

MR. KEIGWIN: Andrew, at one point you had your hand up. I didn't know if it had fallen down or if you were --

MR. THOSTENSON: I just took it down because I thought we were going to move on. But I am a professional pesticide safety educator. I've been educating pesticide applicators formally for about 22 years. It seems to me that we're kind of talking across each other a little bit right now, but I can assure you that in a formal training setting where I have people in a classroom situation, I'm not using live pesticides whatsoever in those events. I mean it just doesn't make any sense.

On the other hand, there are times when we're doing some sort of continuing education or

some sort of learning-by-doing exercise with an FFA or 4-H project that may be outside of the venues of a traditional training that it would be useful to be able to actually use pesticides in those particular situations. And I do know that that sort of thing goes on. I don't have any qualms about that being done, but as I said in a formal training situation, we really wouldn't be using pesticides.

MR. KEIGWIN: Any last comments before we go to break? Let me check one time on the phone for Iris, Pat or Sharon.

MS. SELVAGGIO: Hi, this is Sharon. Can you hear me?

MR. KEIGWIN: Yes, Sharon. Go ahead, thank you.

MS. SELVAGGIO: Okay. Just a couple of things I guess I wanted to comment on. First, you know, in listening to the comments by Amy, you know, she emphasized the need to encourage and mentor young kids. And I have to agree with Amy Liebman and some of the others here, Leyla, that, you know, that's an important goal. Farming is a complex

business. There's a lot to it, and encouraging and mentoring teenagers to engage in farming can happen because there's a lot to teach. But it's not necessary to expose teenagers to live pesticides at that age when there is so many other ways and topics that need to be explored. So I just, I don't really buy that argument.

And I'm also recognizing that we do seem to be a bit afield since this doesn't seem to be covered, but it is a human safety issue that it seems like there should be some kind of protection for kids in a training situation, whether or not they were hired workers, that they're not inadvertently exposed to pesticides or other toxic chemicals by people who are training them.

Just a question on the technical data, going back to some of the stats that Steve covered. I was struck, like some others were, about the sort of performance metrics that Steve presented. Your performance metrics are looking really good, even though you have fewer workers working on this particular -- on PRIA stuff. And it raises a

question for me about whether mistakes are being made, you know, or if review is less stringent than it used to be. Have there been any changes in what's covered? So without being a registrant myself, I'm not 100 percent clear on the data that's being covered in these reviews and it would be helpful to get just a brief overview of that. Thank you.

MR. KEIGWIN: Thanks, Sharon. I think a lot of the efficiency has come from our use of electronic tools to review the label. If we were to -- Steve, in one of his slides, presented the percentage utility of some of our electronic label comparison tools. If you were to look at our percentage utilization of those tools from even a couple of years ago, you would see that those ranges that he presented were significantly lower. So we're upwards of 80-plus percent in some cases, you know, into the 90 percent utilization of the electronic label tools.

And from the people who are doing the final review and acceptance of the labels, in the past it

used to be a very manual process where you would literally put the previously accepted label on one side of you and the current or the pending label before you, and you would go line by line with rulers or fingers to figure it out. And now that piece of it, very manually intensive, is now essentially done by the computer. And then the reviewers are then looking at where there are differences to figure out if those differences are ones that warrant further technical consideration or ones that are acceptable to move forward. So that tool in and of itself accounts for a great deal.

In the science divisions, and I think you'll hear a little bit about this later today, a lot of work has been done to reduce reliance on animal testing and so we are starting to see either reduced data coming in or alternative testing beginning to come in that necessitates less science resources to effectuate the same type of assessment and so we're seeing some resource savings there as well.

We have hit 10:30, which was our target mark for our break. Thank you all for this discussion.

We will reconvene at 10:45. Thank you.

(Break in proceedings.)

MR. KEIGWIN: Okay. So our next two presentations that will take us, with questions, to our lunch break will be updates on two of our efficiency projects, one related to what we're currently calling the SmartLabel and then a second regarding making our confidential statements of formula available in electronic and digitized form.

So let me first turn to Patricia Parrott, who is acting as the senior advisor in our Field and External Affairs Division. She's also our Homeland Security advisor for the Office of Pesticide Programs. Patty.

MS. PARROTT: Okay, good morning. Thanks, Rick.

So I'm here to talk about SmartLabel. For some of you, this, some of it might be a little redundant and you've heard about it before, but I'm going to start and kind of give an overview.

So our SmartLabel is our electronic pesticide label and what we've done is we've

developed a way to bring it in as structured data rather than a flat Adobe Acrobat file. And it's part of our change and to utilize IT systems to help us gain efficiencies in moving information around and accessing the information.

So right now, our IT systems have developed over time, like a lot of big companies or bureaucracies, into these disparate systems that we cobble together to work with each other but it's not the most efficient process. So what we've done is through developing SmartLabel, we partnered with FDA and we built on their best practices that they developed in changing their pharmaceutical labels into an electronic, electronic label. And they've been doing it for years.

So we used their standard, the HL7 standard, which is an international standard that will allow us to share information with agencies and other health entities. This model is also expandable and the idea is we envision that we will eventually delve out and have a clean database that functions as a single unit for all of OPP's information.

We had to start somewhere. We started with the electronic pesticide label because that touched every aspect of the program and also the ECSF. Those are the beginning steps of getting our entire IT transformation.

So this will just show you visually how the information streams. The information will come in electronically through a submission entry point. At this time we're using the central data exchange portal. A lot of you are familiar with that. That's the agency standard. Then running validation on the information before it goes into our database that is modular in fashion and talks to each other, which is the honeycomb, and then it goes into a piece for electronic workflow. We're trying to move away from the paper, like Rick said, going down line by line.

We've made an interim step where we do document compare with Adobe Acrobat and we're envisioning moving to the fully electronic with internal validation that can go in and make sure that we have -- everything adds to 100, the

signatures are there, things like this, that are very routine so that we can use our human resources doing science review and things we really need to, using automation where possible.

So in the summer of 2014 we solicited pilot participants, partnerships to work with us and build out our model and to test it, and these are the companies that were selected.

We've had three phases through 2017, and this is to highlight some of the feedback that we got. So initially we came up with something and we got feedback that it was too complicated. It wasn't clear. It was just too cumbersome to work with. So we simplified the data model. And we have different parts, so we have a label content section and an index piece. We also updated our user guidance and in Phase 3 we started developing a builder, something to assist with actually building the label in the manner that we wanted. The idea is that we want the electronic data, the XML files submitted and that can be developed through our builder or not.

And think of the IRS. You can use Turbo Tax, you can use any number of tools, but they want that electronic file submitted. And so that's the model. As I said, not only with FDA but we're using other best practices within the federal government to develop our standards and our system.

So one of the major improvements that we had to work on, and it has taken time, is to get our arms around our terminology management, and so we standardized. We've built out vocabulary lists, we've borrowed lists. We've gone to experts, definitive sources. We're using the Entomological Society to help clarify our test list and we've established consistency with other federal agencies in our list.

We've taken our terms and we've registered them with the EPA system. It's currently Synaptica is the language or the system that we use for managing our terminology. This is to show some of the categories that we've used.

This next slide just shows that we have a description in here. It's a center pivot sprinkler

irrigation system. And then we've defined it and this is what it is. And what's not shown is we also have synonyms for this. So when someone comes in and they use a different term, like, okay, is this -- do we already have this in our list? And we can do an electronic check. We don't have to add any term. We also have rigor around if someone does, if there is something new that's invented or submitted, that we'll have a committee and a team and really look at it and say is this actually a new thing, do we have to add that? And this way we'll get away from what we have now, which over time, we have a drop-down list of 1100 items, which doesn't do anybody any good. It's virtually useless, so.

And this is to show how we managed to put some boundaries around what we have by getting basic categories and then fitting things into those, while still managing to cover all of the different systems that we have. It's pretty -- that's my layman's way of saying this. A lot of work went into this with a lot of developers and experts here in OPP.

So this is a screen shot, and this is our

test environment for the portal but this should look familiar to most of you. You can see that there is on the bottom right-hand corner, the SmartLabel submission. So if you went to the portal and you're registered to go in there and you want to submit a label, you would click on that icon.

And this is the next screen that you would get. So you can either upload a previous file. Like I said, if you have your own system, if you've already built a label and you just made a small change to it, you can just upload the XML or you can go, begin a new SmartLabel and you can use our builder that we've provided to go ahead and build your label.

This is the first screen that you would see and it's got the document information and it will pre-populate where it can, based on your name. And then you'll have a product label and the use index piece. The product label has more text and the use index has more data fields to it for specific information. The idea is that your marketing claims, places where you have latitude, that can all

be there, and then the underlying data that wouldn't change. Your application rate would be there, submitted as data that can automatically be pulled for risk assessment, risk mitigation purposes. And this way the registrant is submitting the information on the label. We do away with manual entry and any kind of errors that that could create, also any interpretation of the label. The registrant is telling us exactly what they intend on their label.

This is the ingredient statement, what it would look like. And as you can see, there is the guidance there on the right. And then at the bottom in blue there's a description of what the page is actually looking for for that additional guidance.

In addition to this, there is a user guide, all of the code, the instructions, everything is also posted online, like I said. So it's available if anyone wanted to build their own builder or a third-party vendor, either to customize for certain industries. That's available.

So what are the next steps? So right now

we're currently in the final phase. We've gotten our pilot participants back together. We've shown them what we have, and based on their input, they're testing it at the moment. On May 15th, we're going to get their feedback. We'll do some final revisions. At that time we'll be ready for our initial launch. We plan on doing a soft launch initially, just to get some additional testing done, and then we envision sometime later this year, it would be available for voluntary submissions.

While we're developing these electronic tools to get information in here quicker and to help the registrants and move things along, we need some tools internally so that we're not getting it in electronically and then turning it into paper and doing our Adobe Acrobat reviews and things. So while we're doing all of this, we are also working on developing tools for electronic review in management of our information within OPP.

So for implementation, we're reaching out. We're letting people know about this and we will, when it's launched, encourage some voluntary

participation and submission of your labels. It will be voluntary initially. Of course, there will be a learning curve. We plan on providing assistance in getting it in. Once the initial label is in and it gets reviewed, the advantages are going to be that it will be easy to track. It will be a quicker review time. It will be easy to make changes to your label for amendments and stuff, so there are benefits on both sides.

And then we're going to label, I'm sorry, leverage the label information to further develop our IT systems. Because the label contains, I would say, most or a lot of the essential information needed. It's got, you know, the registrant, the name, the active ingredients, tied with what you're going to hear from Diane about the ECSF as part of the package, and we're going to build on that to further develop our IT system.

One of the things we have to do is we have to find a new name. We realize that the Grocery Manufacturers' Association trademarked the name SmartLabel in December of 2016. So internally

we're, we're maybe going to have a contest to rename it. If anybody out there has a suggestion, feel free to raise it. And I'm not sure that you'll get the prize but -- which is lunch, but anyway. So we're calling it SmartLabel now but like I said, that will change, but hopefully it will be something obvious that you will know it's still there.

So here, like I said, we expect that there will be benefits on both sides when this is implemented. It's I think everyone -- labels are developed electronically, whether they're Word or any manner and stuff, so this is just an advance that's going to help everyone and it's just the way that we need to move and use the tools available to us to have efficiency.

And right now, I'll take questions or what?

MR. KEIGWIN: Why don't we have Diane do her presentation and then we can take questions on both.

So Diane Isbell is with our Antimicrobial Division.

MS. ISBELL: Okay. So I am going to talk about the eCSF. The electronic confidential

statement of formula is an electronic version of EPA's current CSF. This project began a number of years ago. Actually probably I believe it was 2008 we had a product chemistry workshop where we noticed that we had a lot of errors that seemed to be happening all the time and that we felt like we needed a way to help, you know, help everybody be more efficient. And we also knew that we wanted to move into a more electronic way of managing our work, so we started this project.

And now we are in the process of developing the electronic software so, and the software will provide an option for people to submit the structured product data in lieu of what people have been just submitting now, which is the paper version or electronic but not searchable. So in this case we'll actually be able to search for certain aspects of a formula because we often get inquiries about how much of a particular inert ingredient is in -- are in various products or a particular active ingredient, and it's a little bit cumbersome to do that now.

So similar to the SmartLabel, the eCSF will be submitted through EPA's pesticide submission portal. So this is, as Patty showed you, this is also the test area for the portal and the ECSF is located at the top right corner. And so similar to the SmartLabel, if you clicked on that, then you would be able to upload an existing file that you already had submitted before or a new one.

So this will allow applicants to submit the electronic information to EPA, and if you have submitted the electronic submission before, it will automatically populate your CSF the next time. So it will be a little bit cumbersome maybe at first, but eventually it will improve. But it will also prepopulate information from your portal logon, so it would be your company name, the company number and, you know, the address, all that information would be there.

The chemical name will link to the agency information sources, and we're using the substance registry system, and that's also consistent with the SmartLabel. And this also includes the product

properties as are currently assessed. And the manufacturer and formulating sites and addresses.

So this page shows the initial, the page just with the basic information about the company. So the name and the address and the company number, but there's a couple of new fields that are down at the bottom and they are for, asking if this is a food use or if it's a microbial. And those are new which I think will help the registrants of microbial products but also will help clarify certain uses, especially antimicrobials that are food uses where it may not always be evident.

Some of the benefits of using this electronic form are that we anticipate to have significant time and resource savings for both the agency and for applicants. We feel like most submissions of CSF are actually modifications of currently -- which are forms that are already in-house. And so if you had submitted it previously electronically, then you would just be able to update the fields that you wanted to change. We think that will help save resources as well.

And as I mentioned before, the structured data fields will allow for the data to be searched and you wouldn't need to reenter it. So we think that this will help everyone, especially reducing time to fill it out initially and also time and effort needed for error corrections.

So now this actually is the screen where you can see the -- where you add the components so, and on this screen you can actually, you can enter in the chemical name. If you would like to choose it, you can enter the chemical name or you could enter the cas number. So, and then once you fill in one of those, it should prepopulate with the other, other pieces of it. So we also ask the question is this nano material and also as part of this, it will calculate the upper and lower certified limits automatically because that seems to be one of the biggest error, errors that we get.

So some more on the benefits, just basically what I was mentioning about the microbial fields and the data validation, but also consistent with SmartLabel, we will be relying less on paper and the

paper-based processes because we are developing a database that will manage those, the SmartLabel and the eCSF data together, and this is just one module in our overall electronic management process.

So the eCSF team is continuing to work with all divisions on the eCSF elements and to include data fields, harmonized OPP-wide vocabularies and data validation rules, so that we're consistent with the SmartLabel.

And we have collaborated with the SmartLabel to overlap -- to harmonize overlapping vocabulary such as like the chemical names. And we have also been working with nine registrants on the testing and development. So we've had, I believe we've had two sessions working with the registrants and we will be having another one as we move along.

The rendered format for the eCSF will be very similar to the current format. However, there are some additional fields such as the microbial chemicals and the (inaudible) that I mentioned. So we're trying to fit those in the best that we can but we want it to remain as similar as possible.

And we're also working on establishing the workflow management for future eCSF data and we are, you know, looking toward the future in terms of how we could manage that workflow through our electronic processes. We anticipate releasing this the summer of '18 or some, maybe a little bit later. We're still kind of working that out, but at least sometime in 2018.

So the registrants, the nine registrants that we have participated with on the testing are listed here on this screen and we're very grateful for the input that we've had. It's been productive and we are hoping to have one more round as I mentioned.

So our next steps are to develop the electronic workflow internally and train OPP staff and encourage registrants to implement use of the ECSF. And we also plan to have more outreach and training with the registrants when we roll this out and we will provide assistance to the registrants as we do implement this . And well, it's going to continue with other modernization, OPP IT

modernization initiatives.

Do you have any questions or comments?

MR. KEIGWIN: Thanks, Patty and Diane. Questions?

All right. Damon, then Charlotte.

MR. REABE: My comment is for the first presenter. How about E-label?

MS. PARROTT: Sounds good to me.

MR. KEIGWIN: Charlotte.

MS. SANSON: First I would like to commend you guys, EPA for all the work you put into these tools. I know it's a lot of effort that's going into it and I think in the long run, it will be a big savings. I look back in the days years and years ago when I did this work and all manually. We've come a long way so that's, I appreciate that.

So a couple questions I have. I have a whole bunch. So if you want me to like stop, just tell me but I think most of these apply to both, the ECSF and the Smart or E-label.

One is if you could define a little bit more what you mean by soft launch that you're

anticipating on both of these tools. And will there be an opportunity for those registrants who have not participated in either workgroup to participate in providing some input and explore these tools before they're fully launched, if that's going to be part of the soft launch? So I can stop there if you would like to address that.

MS. PARROTT: Yes, I think that is part of the problem, not part of the problem but part of our thinking is to do a soft launch before we, you know, let everyone go and find all these problems is to somehow stagger it out in a fair manner. I mean we've been working with the pilot participants but how do we release it in a fashion where we can get feedback that's manageable to us, if any errors, or there are any problems that come up. We do intend to have webinars and training sessions to show everyone what's available and then, like I said, and then to have it available for voluntary use. We're still trying to work some of this out but yes, we do want feedback.

We also, at every step of the pilot

previously we've had, we've put all the materials up and they've been available for people to see and comment on into a mailbox. And that mailbox was available for additional comments but at this time since the next step is what we see as the soft launch, that's why -- I'm not sure about the timing of when we're going to be doing this. But yes, we do intend in doing some outreach. And for the ECSF, the same.

MS. SANSON: Okay. Thank you for that. And then the other question I have is is this tool intended for like from this point or when it's launched that point going forward or how will existing labels and eCSFs be uploaded and is there going to be any kind of a batch loading or one by one? How do you envision that going or is it just going -- in other words, is it going to be retroactive as well as going forward?

MS. PARROTT: Okay. The way the system is envisioned is that registrants would submit their own information. We're not going to like upload anything ourselves because we want you all, the

registrants to tell us --

(Simultaneous speech.)

MS. SANSON: -- or will they do that individually?

MS. PARROTT: To tell you, I'm not sure how that would go. You mean to upload many at once?

MS. SANSON: Right.

MS. PARROTT: That's an IT question I'm not sure that I'm -- that I can answer right now. It depends how the portal works but, yeah, we can look into that and get back to you, so.

MS. SANSON: Okay. So, but as far as, so it would be up to the registrants then to upload their own labels and go back to the existing ones is what you're saying.

MS. PARROTT: Correct.

MS. SANSON: There's an opportunity for that.

MS. PARROTT: Yes, yes.

MS. SANSON: Okay. And CSFas well, okay. That's all I have at the moment. I'll probably have more. I'll let somebody else.

MR. KEIGWIN: Okay. Andrew, then Jay.

MR. THOSTENSON: I saw with some interest the desire eventually to make this tool available to states and tribes, and I understand it's in the development phase right now, but what sorts of conversations and what are some of your visions for trying to make some of these tools available to other agencies that may be registering pesticides like states, as well as educators like myself, where I would want to do some sort of review about a particular label statement and how many labels might contain a certain PPE string and that sort of thing? Is that a five- or ten-years down the road sort of thing or is it maybe sooner than we think?

MS. PARROTT: Okay. For making the tools available, this will be available online to anyone who wants to use it. We are in conversations with Canada and California. We've also been speaking with NPIRS, so reaching a lot of the states. They're aware of this and we've gotten some input and we've presented them. So there is some harmonization and knowledge going on there.

As far as making it fully searchable to the public, what we'll publish is a structured rendered label in a consistent format for the master label and that will be available. Think of PPLS but it would be in a structured format.

As far as the searchability across, you know, different labels and things, that is a step that we're still going to have to think about and develop. Initially registrants didn't want to be potentially penalized if they were early adopters because someone could easily search and find like a gap and then come in with registration for that gap. So we're trying to think about what's fair to everyone and we'll get additional input with that.

You had another piece of your question and I'm not sure. Did I -- I can't remember. You got it?

MR. THOSTENSON: Yeah.

MS. PARROTT: Okay, all right. Thank you.

MR. KEIGWIN: Jay, then Eric.

MR. VROOM: Three quick questions. Slide 5 has a reference to 6A2 submissions as input. So how

and how often are 6A2 notifications impacting label changes and is 6A2, an electronic or an electronic option? The second question is could you tell us a little bit more about Synaptica. Are they a contractor that the agency has used elsewhere? Just give us a little more context to that.

And also you made reference to some learnings that were gathered from FDA, electronic submissions and ultimately that sort of comes back to the initiative at the administrator's level with the new chief operating officer and smart sectors, how much enhancement, synergy is going on across EPA to ensure that you're taking advantage of things that are on the shelf, that may be already adopted elsewhere in the agency? And also I'm reminded that the registration and registration evaluation offices have mentioned that their computing systems are on different platforms, so how does all that progress moving forward? Maybe Rick, for your kind of overarching perspective.

MS. PARROTT: Okay. For 6A2, we do have an incident data system where submissions come in, and

what we were showing on slide 5 was that eventually we see the harmonization of all of our electronic submissions. I mean as far as how often a 6A2 impacts a label, I don't have those data right now but that was the intention of the slide. That's a different question and we can get back to you if you need that.

For Synaptica, from what -- and I'm not the expert. It's what our Office of Environmental Information uses. I believe it's a platform for computer languages and stuff. I know it goes out. It's got (inaudible) codes and other things that go with it. Database people, programmers would probably know more about that, but it's an agency standard that we use.

As far as you said according to the chief operating officer, I think this started back in the last administration but what we've tried to do is to be consistent and harmonize and not redevelop to be consistent, use existing standards and best practices that exist so that we're not creating a one offer system that wouldn't be consistent with

any other thing. All of our IT development systems go through a review by our chief information officer. It's a SAKARA (phonetic) review and I have no idea what that acronym means, but there is, there is rigor around that, so we are aware of that and building to those standards.

MR. VROOM: I'm also curious to know for the registrants that have been participating in the pilot, I mean is there some metric that they can say, you know, we've gained something as a registrant by, you know, participating in this so that other registrants can see an incentive outcome as well?

MS. PARROTT: I will tell you that our pilot participants are enthusiastic about the tool. They have pulled -- the feedback we've gotten is that it's going to help them. They're building systems anyway. They want them to be consistent with ours because they need this tool themselves, something electronically to keep version control, to easily make changes, to react quickly.

We can, you know, have more of that as it

rolls out, maybe have the pilot participants seek, you know, additional advantages. We've said some of them. We think time, time savings is going to be a big, a big value to both sides of the equation.

Was there anything else?

MR. VROOM: Just about systems that can talk to each other between the offices, Rick?

MR. KEIGWIN: I think the agency has a longer term goal, to make sure that all of our systems across the agency are talking to each other, you know. We're starting here. There's also an effort -- some of this system, once fully operational, will also contain some of the tolerance information as well and so there will be an opportunity to share that information directly with our colleagues at FDA who do tolerance enforcement, for example. So we are building this in mind for that longer term vision.

MR. KEIGWIN: Eric, are you good?

MR. GJEVRE: I think you more than answered the questions I had. But I was just curious, how many total registrants after all this is built out

do you think you'll have that could use it?

MS. PARROTT: All of them. We've built it out to handle all types and we did a -- in selecting pilot participants, we want a representation from all of the major groups, small, large, antimicrobial, biopesticides. We've worked -- as well as conventionals. We've worked on all of the lists. So we're hoping that eventually because it will be fully, it will meet its full potential when it's fully loaded with all of the information and of course, we can't get it all at once but we're hoping that everyone will see value in using it.

MR. KEIGWIN: Liza.

MS. TROSSBACH: To follow up on Andrew's comment, I wanted to offer on behalf of states, tribes and territories, just the importance of the system. I think that state-lead agencies, tribes and territories ought to be on registration programs as well and so this is a tool, would be great for us. We use PPLS a lot to do label comparisons and that can be cumbersome and so anything to streamline that.

I would encourage EPA to have some kind of searchability function, in that at some point, particularly for us as your co-regulators, when we get a label in our particular offices, we want to make sure that it is in concert with the EPA accepted label and so having that searchability would greatly enhance our ability to do that.

And then the other thing with the webinars and the outreach that you're going to do, I would request that you have that, some of those sessions specifically for your states, tribes and territories so they can understand the applicability directly to those registration programs, in addition to those that you're going to do, you know, for the registrants and other interested users. Thank you.

MS. PARROTT: Okay, thank you. And we will, we will look into those.

And one of the things I wanted to say in addition to, we were talking about benefits of the system, is that right now web-distributed labeling, we haven't had any applications for web-distributed. Getting the labels, pesticide labels into this

electronic format we believe is going to facilitate also web-distributed labeling which will then also be a benefit to states and others. You can look for a particular section of a label, rather than going through all 30. So the searchability function and all of those attributes are things that we are working towards.

MS. TROSSBACH: Just one follow-up question for the web-distributed labeling. So this system, you know, when it gets to that point will be able to track the versions of the labels? Because that was really important with web-distributed labeling and what label was in effect at the time of application. So that would be built into this somehow as well?

MS. PARROTT: Yes, it is.

MS. TROSSBACH: Thank you.

MR. KEIGWIN: Let me check with PPDC members on the phone. Sharon, Iris or Pat, do you have any comments or questions?

Any more comments or questions from PPDC members in the room? Aaron.

MR. HOBBS: I'll be brief. You have a great

representative sample of the industry. I just want to encourage that more communication and outreach to a broader section of the community is going to be valuable as this moves forward and just, if you think you're communicating enough, maybe add another 10 percent. Thank you.

MS. PARROTT: Okay, thank you. We will.

MR. KEIGWIN: Okay. Any other questions, comments?

MR. THOSTENSON: You mentioned the term "web- distributed labeling" as something that we have had conversations over the last five or six years about and this would certainly facilitate that process. Can you give me some sort of indication or idea as to how many web-distributed labels have actually tried to go through the system as it exists now?

MS. PARROTT: None.

MR. THOSTENSON: None.

MS. PARROTT: Yeah.

MR. THOSTENSON: And presumably the impediment is the ability to generate some sort of

electronic labeling?

MS. PARROTT: Yes, we believe that is a limiting factor. I am not the expert on it but yes, we do feel that. And so the thought is that the SmartLabel, the electronic pesticide label will facilitate that. The information will be available in that format anyway, and so it will be ready to be delivered through the web-disputed labeling platform.

MR. KEIGWIN: Okay. So we are running 15 minutes ahead of schedule, which means you have a little bit more time for lunch which means you'll have a little bit more time to get through security to come back in. We are going to -- we've got a very packed afternoon, so we would like to start again promptly at 1:15, so you might want to try to get here for security no later than 1:00 or earlier, if you can. Have a good lunch. See you this afternoon.

(A lunch recess was taken.)

MR. KEIGWIN: All right, welcome back. So the first half of the afternoon we're going to

update you all on some of our efforts in employing some 21st Century toxicology techniques and transitioning to less animal testing. So we're going to start off with a session, Anna Lowit, who is the senior science advisor for the Office of Pesticide Programs and Garland Waleko, who is in our Pesticide Reevaluation Division, will kick things off.

MS. WALEKO: Hi, I'm Garland. I'm a chemical review manager in the Pesticide Re-Evaluation Division, as Rick said, and I help Anna co-coordinate the acute tox modernization efforts in OPP. This presentation, the background part, is similar to what I talked about last year, but we do have some updates further in on some of the specific tests, so bear with me if you've heard parts of it before.

So the 6-pack, easy pack 6-pack, those tests are required for all formulations as well as active ingredients. It's for precautionary labeling, re-entry intervals, clothing and PPE, things like that on the label. It's acute oral, dermal and

inhalation tests, as well as eye irritation, dermal irritation and dermal sensitization, so that's what I'll be talking about.

So some background, OPP has developed a strategic direction for new pesticide testing and assessment approaches, and this is to implement the 2007 National Academy of Science report called Toxicity Testing in the 21st Century. The strategic direction is on our website listed there and the anticipated outcomes of this move are many, but a few of them are listed below.

So they include more computer-aided methods rather than animal tests to identify hazard as well as exposure, as well as to focus testing, improved approaches with the traditional tests that we already have to minimize the number of animals we use while also getting more information, as well as an improved understanding of tox pathways so that we can develop other non-animal methods.

And this is all about adopting something called IATA which stands for Integrated Approaches to Testing and Assessment, and this is a more

weight-of-evidence based approach. It's hypothesis based, systematic and meant to integrate exposure and hazards in risk assessment.

So guiding principles for data needs for pesticides, this is for EPA staff, and the bottom line is that there is flexibility in our regulations to accept alternative approaches as well as grant waivers, so we do have that built into our regulations. But the guiding principle is to provide consistency in identifying data needs. They promote the use of existing knowledge and a focus on the critical data needed for the risk assessment, so what do we really need to know to make a decision? And it's more of an efficiency approach, not just a check the box.

So these are the acute test guidelines, and about the numbers, each test that we get per year. So 2012 through last year, as you can see about the numbers we're getting for each one and they're pretty consistent.

In 2016 our then director, Jack Housenger, wrote a letter to stakeholders sort of reiterating

our goal to reduce animal testing and also our commitment to that goal. So it kind of outlined our commitment to work with our partners, so NGO's, other federal agencies but also internationally across the government. So the activities outlined in that letter follow three main objectives which I'll go through examples of each of these things, critically evaluating which studies form the basis of our decisions, expanding acceptance of alternative methods and also reducing barriers to adopting alternative methods. And some of those barriers can be challenges of data sharing among our industry partners as well as international harmonization.

So we have an internal workgroup in OPP to work on these issues and we meet biweekly and sometimes monthly. There's representation across the divisions and we discuss updates and what's going on and who can work on what, that kind of thing. And then we also have a stakeholder group made of external stakeholders. We also meet regularly to discuss progress and opportunities to

work together. If you're interested in joining the stakeholder group, you can contact Shannon Jewell. Her information is there. I think the last meeting we had was at SAP in March of this year. We also have webinars pretty regularly on new developments on the different tests.

We also have a public docket where we post draft guidance for comments. We have draft guidance in there right now for skin sensitization which I'll talk about more later. And we also post our final guidance there which is also on our website.

So U.S. federal collaboration. EPA is part of the ICCVAM that was created in 2000 by Congress. It stands for the Interagency Coordinating Committee on the Validation of Alternative Methods. That's a mouthful. But it's 17 federal agencies that either require, use, generate or disseminate tox and safety testing information. The operationals and scientific support arm for ICCVAM is NICEATM at the National Institute of Health. They do most of the data collection and modelling and really are critical to our success in this area.

Okay. So an example of critically evaluating which things form the basis of OPP decisions. The acute tox -- the Acute Dermal and Pesticide Formulation Waiver was finalized in November of 2016. It had gone out for comment in March of that year. This is a collaboration between EPA and NICEATM to look at the relative contribution of data from both the acute oral and the dermal tox tests to what actually ends up on labels for hazard classification and labeling.

So data was collected on acute lethality, dermal and oral tox data from rat studies, just for pesticide formulation. So that guidance isn't finalized. We've been receiving and granting those waivers. We get about 200 or 300 dermal formulation tests annually, so you can see the potential for animal savings.

Expanding acceptance of alternative methods. So these are some of the OECD guidelines out there for these three tests, skin irritation, eye irritation and skin sensitization. And we're working towards accepting these existing guidelines.

They're kind of like our starting points.

So eye irritation, I have some updates on this one. So this is a collaboration that's currently ongoing. We have a policy in place right now to accept eye irritation assays for the antimicrobial products and we're looking to expand that to the conventionals as well. So NICEATM has collected over 200 pairs of in vitro-in vivo data provided voluntarily by industry and analyzed that. They've determined that we need some prospective testing to fill in some of the gaps in that database. So right now Phase 1 is underway to look at six formulations donated by industry and I think five different assays related to the eye. Once that's complete, anticipated about this June, we'll move into Phase 2 to look at 40 additional formulations donated by industry.

So this effort is co-chaired by PETA International Science Consortium as well as NICEATM, Physicians Committee for Responsible Medicine, EPA Canada, Europe and of course, our industry partners.

So skin sensitization, there's a lot going

on with this one right now. There was, last time I gave this talk, a project proposal had been approved, at an OECD meeting in December of 2016 and this was a follow-up to that. So in December 2017, they had a special meeting to talk about what happens next.

So there are multiple non-animal testing strategies out there that actually perform better than the mouse (inaudible) assay, which is the animal test we currently were using. There is an assessment framework that could serve as a replacement for that test and that performance criteria is laid out in that paper, the Casati paper cited up there.

So last time I talked to you about this, I said there would be an EPA draft policy forthcoming and we have just put that draft out last month, April 10th, that describes the science that supports moving towards this. The LLNA is a local lymph node assay in the mouse but the combination of different non-animal assays actually does better and is more reproducible than the mouse test. So the policy

that describes that science is out for comment now in the docket until June 9th, but this was a result of a collaboration between ICCVAM, NICEATM and then our European counterparts, as well as Canada.

So EPA will be accepting the alternative approaches for skin sensitization immediately under the conditions described in the policy. So only existing OECD guidelines for determining hazard, you can use the approach that's the best two of three described in the draft. Right now it's just active or inert ingredients, not formulations just yet. But the National Toxicology Program at NIH is working to see if we can't expand it to formulations and mixtures, and if that's the case, we can revise the policy later. But the docket is listed up there with the website. If anyone is interested in commenting, we're accepting those until June 9th.

Okay. The last example, we began a pilot program in December 2016 to look at the possibility of using the GHS equation for formulation for oral and dermal. We assembled a data set or we're trying to actually, we're still accepting data to look at

the oral and inhalation formulation testing that we currently require but also submitting currently with the GHS equation.

So the equation just adds to the components of the formulation. It adds up the LD50's to predict the hazard for the formulation. So this could potentially save a lot of animals by not having to do either of those tests anymore and just accept the equation.

But so far we've received submissions from Dow, BASF, EcoLab, Control Solutions and Procter & Gamble, and I think we have a few more anticipated, so we should be able to start that analysis in the next few months. But this is a good example of our efforts to harmonize. EFSA in Europe uses this already.

And then outside of acute tox 6-pack, we're looking at some potential with the dermal absorption triple pack, which is a human in vitro, a rat in vitro and a rat in vivo study that all use similar protocols, so like the same test material and doses. And this was used by OPP to refine the dermal

assessments, to adjust for differences between in vitro and in vivo absorption, as well as the species differences.

But NICEATM is in the process of looking at data from existing triple pack studies to see if we can't just rely on the human in vivo for risk assessment. So that's another thing that we're working on. And that is all.

MR. KEIGWIN: Thanks, Garland.

MS. WALEKO: Sure.

MR. KEIGWIN: Questions from the committee?

Let me check with PPDC members on the phone.

MS. BISHOP: Yeah, hi, it's Pat Bishop. Can you hear me?

MR. KEIGWIN: Hey, Pat. Go ahead.

MS. BISHOP: Hi. Yeah, thanks, Garland, for that update. I think this is really, I want to just say this is real great work that's going on and I think as Charlotte mentioned this morning, a lot of impetus for this came out of the tox 21 workgroup from PPDC as well as the Jack Housenger letter which was probably a first where some, where a major, you

know, regulatory authority director came out and committed to going forward with this work. And I know, Rick, you support it, ongoing work as well.

I just wanted to ask you one question. I was at a meeting last week at Croplife and Anna was talking about the HASPOC group that's also been -- you mentioned there's a lot of flexibility in Part 151 as far as granting waivers and so forth.

She mentioned that the HASPOC group has been reviewing a lot of submissions and has -- I mean the numbers she was talking about were astounding to me, something like 40,000 animals were saved over a certain time period. Can you comment on that at all?

MS. LOWIT: Hey, Pat, it's Anna. So yes, so as you know, I gave two presentations at the Croplife RISE conference last week, and they were largely two related presentations. The first one was in large part a similar presentation to what Garland just gave which was focused on our efforts around the 6-pack. So the acute oral, dermal, inhalation and then the three topical studies that

are used for labeling.

And then the second presentation was on our efforts on human health to reduce our animal usage for repeat dose testing. So for those of you in the room not familiar with the acronym, the HASPOC, OPP has an internal committee called the Hazard and Science Policy Council, hence the acronym HASPOC. It's kind of a little ugly, ugly acronym. But it's an extremely productive committee.

Since December of 2011, the group meets every other Thursday afternoon and looks at waiver opportunities for conventional actives with the health effects division but also antimicrobial products and biopesticides. And over the course since December of 2011, all the way up until April, we've granted 1,047 waivers and in fiscal year '17 alone, we granted enough waivers to save over 40,000 animals and save upwards of, I don't remember the number off my head, it's upwards of near $100 million dollars to the industry. That's just in a single fiscal year.

So we are fully committed to reducing our

animal footprint but also to use the resources of industry appropriately and the taxpayer dollars appropriately, as we're not asking for studies that don't make a real difference in our risk assessment, we're using our own staff time much better.

MS. BISHOP: Great. Thank you.

MR. KEIGWIN: Other comments or questions?

Okay, thank you.

So next up we have Kimberly Nesci who is deputy director of the Environmental Fate and Effects Division, and Melissa Panger, who is a senior scientist in EFED, who will share with you some of the work that we're beginning to do on reducing animal testing for ecological effects analysis.

MS. NESCI: Good afternoon, everybody. Thank you so much. So as Rick said, my name is Kimberly Nesci. I'm the deputy director of the Environmental Fate and Effects Division. So Melissa Panger, a senior science advisor, and Ed Odenkirchen, who unfortunately could not be here today, is also a senior science advisor and he sends

his regrets. I'm going to be talking a little bit about some of our reduced animal testing on the eco side, so sort of as a continuation of what Garland was just talking about, Garland and Anna.

This work is a priority for us and we're actually really excited about it. And as you will see from the presentation, we're open to ideas for collaboration and additional ideas that you all might have. So if you, as we're going through this, if you seem to have ideas and you want to come in and talk to us, please, please reach out.

And with that, I'll turn it over to Melissa.

MS. PANGER: All right, thanks. So yes, as Kimberly was saying, we're going to talk a little bit about OPP's efforts to reduce animal testing for ecological risk assessment, so focusing more away from the human health side, along the eco side and we'll just talk a little bit about new approach methodologies, methodologies and some retrospective analyses that we're currently working on.

So just as an overview of what we'll be talking about today, we're going to start a little

bit about, talking about some of the guiding principles that we're using as we move through some of this work. We're going to talk about two specific retrospective studies that we're doing, one with acute and subacute avian dietary studies and then one with fish acute studies. And then we're going to talk a little bit about a couple of groups that we're involved with with ICCVAM and then our participation in an upcoming toxicology forum, and then as Kimberly suggested, we're also looking for some feedback and ideas, so that would be the last slide.

So our guiding principles as we move through these projects and think about moving forward on these things, we want to make sure that as we're moving forward with new approach methodologies, so it's a new acronym NAM is what we're calling some of these approaches now. It's equivalent to the alternative test methods and strategies. So as we move towards some NAMs, we'll just shorten it to that, we're going to -- we want to make sure that the tasks that we're working on are fit for purpose,

meaning that they, the projects will be able to provide information that are usable for risk assessment, for eco risk assessments.

And we want to make sure that as we move forward, the approaches are scientifically relevant, reliable and confident. We have to have confidence in it, so we want to make sure as we move forward with the approaches that the answers we're getting from the data are as good as or if not better than what we're currently getting.

And then of course, we'll have to involve some staff training, education and collaborative work with this and we're trying to leverage as many partner resources as possible.

Now, also as we move forward with NAMs and the ecological risk assessment under FIFRA, we have a commitment of time and resources through the completion of some of these specific NAMs, and then as we move forward, obviously if we have, develop new approaches, they'll have to go through, we'll have to develop OPP guidance and policy that's publically transparent.

All right. And so for the NAMs, just to kind of remind folks or let folks know if you're not already aware that we've been using NAMs for years in our eco assessments, things such as ECOSAR, EPISuite, things that can model toxicity in fate parameters and in quantitative structural analysis and read-acrosses. So we've been using some of these approaches for years. What we've been primarily using them for are screening for degradates, effects toxicity, trying to prioritize degradates we need data for, using it to compare the degradate toxicity to the parent toxicity and then trying to address any potential data gaps we have with the parent.

So as we move forward, we'd like to expand the use of the NAMs and move more towards actually using it to replace whole animal testing where we can. And so as was said earlier, for this to happen, there will have to be fit for purpose. We'll have to be able to make sure that they are useful for risk assessment purposes and are scientifically relevant, reliable and we have

confidence in them.

Now, one of the retrospective projects that we're currently working on that I wanted to spend a couple minutes talking about is a retrospective of the acute avian studies we get and in comparison with the subacute avian studies. And just as a little background, when we get an outdoor conventional pesticide registration, we typically require two acute oral bird studies, usually those are with a bobwhite quail or mallard duck and a song bird species. And then two subacute dietary studies with birds, usually with the mallard and a bobwhite quail. And we use all of the data in our risk assessment process.

So what we typically do is we'll use the most sensitive acute oral endpoint and the most sensitive subacute oral endpoint, and whatever has the highest risk quotient when we compare it to our exposure values is what usually is the regulatory endpoint, the one that we use for our risk decisions.

And so -- and just, so we use, we use both

the acute oral and subacute dietary studies. And so what we're doing now is we're working with PETA, working on a collaborative project with PETA to do a retrospective analysis of those data and what we're trying to address is whether or not we really need both types of studies in all cases to make a robust regulatory decision.

So the question we're specifically answering or asking is can we confidently assess acute risk for birds using a reduced suite of effects studies focusing on the single oral dose protocol? And so what we're looking at is looking to see is how often are we actually using the subacute data to make a quantitative or qualitative -- use it for our risk decisions and ultimately our risk management decisions.

And so we're focusing for this retrospective not just on the toxicity endpoints but actually on the risk quotient, the risk assessment outcomes. Because for the birds, we test one species but we relate that, extrapolate to species of different sizes with different dietary categories, so exposure

values vary across the birds. So we're actually looking at that quotient of the exposure versus the effects which is our risk quotient or RQ. So we're comparing the RQ's across the acute oral and the subacute.

And the data set that we're using is we're focusing on chemicals that have been registered from 1998 to 2016, with the idea that we're using the most recently registered chemicals, thinking that that would be the best examples of the types of chemicals that we'll be getting in the future.

So PETA is doing a lot of legwork and they're reviewing most recent publically available risk assessments for these chemicals and because they don't have CBI, they're using the publically available assessments and they're also looking at determining the mode of action for each pesticide, and we'll see what the value of that is in just a minute.

But from each risk assessment document, we're pulling out and extracting and comparing the single oral dose in dietary-based risk quotient to

see how they're deriving the risk conclusions and ultimately the risk management decisions and then summarizing any of the risk characterization that is qualitatively addressing the subacute dietary studies.

So the analysis, what we've done is there's been 181 pesticides new to the agency of conventional pesticides based on the annual reports from 1998 to 2016, and of these, 119 of the chemicals have publically available eco risk assessment documents. Of these 119, 79 of the chemicals did not have an RQ value calculated. Most of those, 70 of them it's because they were limit tests. There were no effects noted at the highest doses tested for the acute oral or subacute dietary.

In nine of the cases, there weren't RQ's calculated because it was an odd kind of a substance, indoor use, greenhouse use, that type of thing. And in 40 of the chemicals from those 119, there actually were RQ's that could be compared. In 37 of those cases, the acute oral dominated the dietary and drove the risk assessment, meaning that

the acute oral RQ was higher than the subacute dietary RQ's. And in two cases the RQ's, we had RQ's for dietary studies and no RQ's for acute oral because the acute oral studies were based on limit tests, where no effects were noted at the highest concentration. But in those two cases, there were no risks identified to birds, so acute oral data would not have likely changed that risk conclusion if we had RQ's for those.

And then in one case, we did have dietary RQ's that were higher than the acute oral RQ's and it was for an anticoagulant rodenticide, where you kind of could expect that that might happen because of the cumulative effects of those types of pesticides.

So the bottom line of the analysis was that in over 99 percent of the cases, 118 out of 119, the subacute dietary approach did not change the risk conclusion that was already reached using the oral dose-based RQ's.

Now, there were 62 cases that were not evaluated out of the 181 chemicals that have been

registered since 1998. So what we did was looked at the mode of action for those, for those chemicals to see if those, those chemicals that were not in the analysis matched the chemical classes, any of the chemical classes for chemicals that were in the analysis, so kind of using them as an analog. And we found that of those 62 cases, most of them had a chemical class that was involved in the analysis. There were only eight chemicals that were not included at the chemical class level in the analysis and they had unique modes of action, so they were kind of unique.

So the bottom line in that is that the majority of the unevaluated cases, those 62 cases, the subacute dietary approach was represented by a chemical analog or a member -- a chemical in the same chemical class. Now, it did indicate that for unique modes of action, we may need to do some additional analysis in the future.

So the next step with this is that we are currently developing a manuscript and hopefully for publication in a peer-reviewed scientific journal.

PETA is the lead author on that and then agency staff will be co-authors on that.

And EPA will be developing a policy guidance document that basically, outlining the kind of project that I just discussed here. And then we'll be recommending that for new chemicals with mechanisms of action that were covered in the analysis that we rely really, we rely heavily on the acute oral avian studies and hold the subacute dietary studies in reserve.

And that we do recommend that for a certain set of chemicals, those with unique modes of action, cases where the data on the mode of action suggests a mechanism of cumulative damage such as what we saw in the anticoagulant rodenticide, those chemicals that have a high potential for bioaccumulation or facilitated transport mechanism for absorption, that any kind of chemical that we think that the route of exposure via the dietary route might be more sensitive than the oral route, then we will need additional information or may have to call in those data.

And then as we move forward, we'll continue outreach to our international and other partners and then obviously any policy, before it goes final, will have to go out for public comment.

Now another retrospective study we're currently working on is dealing with our fish acute lethal endpoint studies. And just a little background there is that for most conventional outdoor-use chemicals, we require three acute fish studies, two freshwater fish, one warm water, one cold water, and then also an estuarine marine fish study. And so in these we usually, in the assessments we'll use usually the most sensitive, the freshwater endpoint as our regulatory endpoint and then the estuarine marine fish for estuarine marine fish as regulatory endpoint.

And so just the point here, that the exposure estimates for each fish RQ calculation are identical across the fish, whether it's freshwater or estuarine marine. And so here, as you will see, we won't have to compare RQ's in this retrospective analysis. We can actually compare LC50 values.

So the question we're asking here is can we confidently assess acute risk for fish using a reduced suite of effects studies focusing on a consistently most sensitive fish? Basically is there a consistently most sensitive fish across all compounds is one question we're going to ask. Another one, if not, are there patterns of most sensitive fish based on chemical properties, chemical classes or modes of action? And can we reduce the data sets to two or even one fish study?

For this project, we're collaborating with NICEATM as our federal partner. And as I said earlier, exposure is not a confounding factor here, so we're actually going to be comparing the effects endpoints in this retrospective and so we're actually going back to the data evaluation records or DER's for the studies that have been submitted for the chemicals. And I'll just state, I think I might have skipped this, we're going to be focusing on the same chemicals that we're using in the avian retrospective so those chemicals registered from 1998 to 2016.

So the data points will actually be extracted from the data evaluation records. They're going to be submitted to a shared drive. NICEATM will then review the quality of the information, see if there -- and cross walk with available structure and mechanism of data.

So so far to date, we have shared about 250 individual fish toxicity records with NICEATM and there's a little over 700 studies, fish studies associated with these chemicals, so this is a subset of the total. And what they're doing now, NICEATM is looking through them to see if they're going to be adequate, the information in there will be adequate to do the type of -- answer the types of questions we're asking. So they have the 250 studies now and they're going through them and so we expect to hear within a few weeks back from them in terms of getting feedback on whether we think we should move forward with the additional studies or how we should move forward.

So those are the two, the two retrospective studies I wanted to talk about. Then there's also a

couple of groups that we're involved with. One, ICCVAM had an organizing committee on predictive modelling of rat oral acute systemic toxicity. There was an organizing committee that was held, it was a workshop in April, and we had participation, as he said in -- on that committee. The objective of the committee is to integrate the collective expertise of the international modelling community to develop predictive models for acute oral toxicity based on regulatory needs put forward by ICCVAM.

And the role that we played there in EFED is to basically make sure the EPA, the ecological risk assessment perspective was considered in the prioritization. Because a lot of this is driven obviously by human health and toxicity, so we wanted to make sure that as we move forward that the eco part is considered as we move forward.

And we focused on methods most suitable for application in a quantitative manner. As we said previously, it needs to be fit for purpose and we wanted to make sure there's transparency and consideration to the mechanism of action, a high

degree of documentation for the method and any method would have to have an accuracy in predicting the LD50. And then EPA selection criteria led to a proposed methods selection that was highly consistent with other agency priority selections.

And then another group that ICCVAM has started, it's a new ecotoxicity working group and EPA will be represented on the group and also will be a co-chair, so Ed Odenkirchen will be a co-chair of that workgroup. A draft charter has been developed and the charges for the group are basically to identify agency needs across the United States for different agencies, what the ecotox data requirements and needs are, and also move into the international data needs also but in a catalog existing approaches to toxicology testing for emerging technologies to see where they might fit with the data requirements and needs for the different agencies.

And then the plan is to establish a stakeholder group comprised of both government and non-government scientists to coordinate efforts

towards developing and implementing alternative approaches for ecotoxicology testing.

And then a final kind of group I wanted to talk about today is that there is -- we'll be participating in a toxicology forum which is -- will be a meeting this summer in July in Annapolis and the objective of the toxicology forum, if folks aren't familiar with it, it's an international nonprofit organization and it's really devoted to creating an open dialogue among various groups in the society, primarily for experts of U.S. and international government regulatory and health agencies to get perspective on issues of mutual interest. And so some of the topics that will be, session topics at the meeting that we'll be involved with is, one is building on the science, possible opportunities to reduce toxicology testing and better allocate resources for evaluating ecological risk and, and Tom Steeger in EFED will be chairing that session, I believe.

And then there's integration of toxicokinetics and kinetically derived maximum dose

into toxicity testing and risk assessment. And then U.S. FDA's predictive toxicology road map.

And just in closing, I just wanted to reiterate a couple things. One is that EPA is committed to reduced animal testing burden but we want to do that without compromising the quality of the risk assessment process and that's the fit for purpose that we've talked about throughout this session or this talk today.

We are, as Kimberly mentioned, interested in considering ideas for additional projects, so we would like to hear feedback on that from folks. We're operating under of a set of principles to achieve streamlined testing, alternative method endpoints for, as we said, fit for quantitative ecological risk assessment.

And we are considering different mechanisms for policy and guidance, and one of those is things like waiver guidance. And then we intend to partner with government and private stakeholders, and so we're looking for feedback and thoughts on who, you know, if you guys have ideas and thoughts and

suggestions on who we can include in these discussions. And then we're open to other ideas and opportunities for collaborative work in the future, in future retrospective studies. So if folks have ideas for those, we're open to that, too.

MR. KEIGWIN: Thanks, Melissa. Questions?

Amy.

MS. LIEBMAN: Thanks, everyone, for the update on this. I have a couple of questions. First of all, I think -- I don't think there's any argument it's great that you're trying to reduce the animal testing, but particularly in light that the EPA is about to propose rules that will gut protections for people exposed to pesticides, I'm just curious as to where you are in terms of some of your population and exposure data that's part of the whole 21st Century toxicology approach.

And also, you know, we talked a long time ago about some biomark hearing, and EPA does have the regulatory authority to request that in terms of the registration process. What's happening in that area?

MS. LOWIT: So I can talk a long time on where we are on tox A-1 and not everyone wants to hear me jibber-jabber for that long. I know you don't. So we're advancing the science with respect to modernizing our risk assessment approaches on many fronts. I think one of the ones that really highlights what you're asking about is advances we're making in physiologically based pharmacokinetic modelling or what people called PBPK modelling. If you're not familiar with that acronym, essentially a PBPK model is a set of differential equations of known human physiology so you can make very accurate predictions of how someone is exposed from the outside and what happens, where that compound goes in their body and the frequency and the speed at which they eliminate that.

And it's a very powerful tool that allows us to look at specific life stage effects, gender effects. You can make very scenario-specific evaluations of a child playing on the lawn versus a worker working in the field and make very explicit

refined assessments of those to ensure that we're doing accurate and predictive assessments. And those models also have the power of doing full-on population based evaluations using Monte Carlo and different kinds of techniques.

And we are active in this area. We have multiple projects looking towards advancing PBPK for both individual chemicals but as a science in general. We have a lot of projects in that area that I think is what you're talking about.

MS. LIEBMAN: Thank you. My next question is I'm just curious in terms of some of the work that you're doing in this area and there's another proposed rule out right now about sensing transparency in regulatory science and I'm wondering how, how it is currently proposed, how that will impact the work that you're doing?

MR. KEIGWIN: We're reading the proposed rule as well and evaluating that ourself and we would encourage anyone who has perspectives on that proposed rule to submit comments to the docket for that proposed rule.

MS. LIEBMAN: Our initial reading of that is that it's pretty dramatic for some of the work that you're attempting to do.

MR. KEIGWIN: We're in the process of evaluating how it would impact the program. We encourage you to submit comments.

MS. LIEBMAN: And I guess I want to just keep encouraging everyone to remember people in the process and that when we regulate pesticides and we use them, people are exposed and they're human beings. I just want to say that for the record. Thank you.

MR. KEIGWIN: Thanks, Amy. Any other comments? Lori Ann.

MS. BURD: I commend this office for its efforts to reduce animal suffering in the lab and also remind you all that animals are suffering in the field where these pesticides are used across hundreds of millions of acres and most generously, but this office is making incredibly slow progress on Endangered Species Act consultations. So as we factor in people and lab animals, we should also be

factoring in the suffering experienced by all these species that are not having any analysis done on the impact of these pesticides on them.

MR. KEIGWIN: Dan.

MR. KUNKEL: Thanks, Rick, and I just wanted to shout out also, it's great work. It's really good to see all the progress that's been made over the years. From I guess our perspective with minor uses, it kind of resonates back to using crop groups to extrapolating to really address some of the minor use issues. So we really appreciate the work with crop groups and some of the other chem sac decisions to set standing policies for extrapolations to some of the other ultra minor crops. I think we would just like to continue to encourage you to look at other areas where you can extend data or reduce data requirements, where we can use extrapolation and good science and models to deal with that.

And my last comment would be, again, just to make sure we're in tune with the other international regulatory agencies, that we're not doing something that's going to -- well, we're going to reduce data

requirements here in the U.S. and not address some of the requirements in other areas of the world. So thanks.

MR. KEIGWIN: Jay.

MR. VROOM: I have a couple comments about tox 21 but just to respond to a previous comment, I believe it's a matter of extensive public record that there is an incredible amount of ecological risk assessment testing, including on wildlife species in all places in the United States the EPA collects, receives and analyzes in ecological risk assessment and so I just couldn't leave that comment left unanswered.

With respect to tox 21, topics both the acute and the environmental risk assessment, two questions. One is where else can this go beyond the two areas that you've just addressed in the two presentations? And secondly, what do you see is advancing in traditional toxicological testing?

(Teleconference interruption.)

MR. KEIGWIN: Let's regroup, so we are going to kick off the last session of the afternoon before

the public comment period with regulatory updates. What we'll do in this session is we'll have the three speakers do their presentations and then we'll open it up for questions. So Yu-Ting Guilaran, who is the director of the Pesticide Re-Evaluation Division, has an update for us on progress in registration review.

Mike Mendelsohn, who is the branch chief in the Biopesticides and Pollution Prevention Division, has a presentation for us on some novel mosquito products and then Bob McNally, who is the director of the Biopesticides and Pollution Prevention Division, has an update for us on the new types of biopesticides in general that we're seeing in the registration queue. So let me first turn things over to Yu-Ting.

MS. GUILARAN: Good afternoon, everybody. I hope you're -- I'm going to try to bring you back on schedule now. No, I never listen to him. That's what he says. I'm listening now. I will keep up with the pace.

So like Rick said, I'm Yu-Ting Guilaran,

director of the Pesticide Re-Evaluation Division. I just wanted to start from kind of the beginning, I know there are a few new faces here, is that registration review of a pesticide is a statutory mandate as part of FIFRA, section 3G. That means the agency needs to review each registered pesticide every 15 years. So overall across the program, I'm overseeing the conventional pesticides, while Bob sees, the biopesticides, Anita Pease, who is the acting antimicrobial division director. All combined we have about 725 cases that's going through the registration review program.

And that means it's about, a little bit over a thousand active ingredients that we're looking at. And we have to finalize this round of review by October 1, 2022. So time is coming up pretty fast. It's about four and a half years left.

So for the registration review program in general across OPP, I think you guys have a sheet that's in your packet. Basically as you can see overall speaking, we're about 50 percent complete with our draft risk assessment. Folks probably know

we start with a docket opening of work plans, talking about data gaps that we have, the risk assessment that we plan to do. That's the work planning. And then we issue data call-in to get all the studies in, and now we're kind of in the process of developing draft risk assessments. So we have about 50 remaining to do, 50 percent rather.

And then for the next step which is the proposed interim decision, that will take the risk and the benefit of the chemical into consideration in determining whether or not any risk mitigation needs to be done. We're about 50 percent remaining to do, and similarly with our interim decisions. So that's kind of overall for the program.

Kind of diving in a little bit into the conventional program, which is my division, we are doing pretty well. We have 40 percent of our risk assessments left to do and then we have about 50 percent proposed interim decisions and interim decisions. So that's kind of the overall big picture of what's happening with the registration review program for the conventional chemicals.

So I think in your one-pager, we also have a few things that we are intending to do for FY18. I think generally we're trying to complete about 55 cases of both the risk assessment and also proposed and interim decisions.

So I am going to go into some of the higher profile chemicals that's going to happen for the remaining of 2018 and perhaps slightly going into the early of 2019. Number one is our Neonics. So we have the four Neonics that's going through registration review right now. The status update is in your sheet, which is we already issued all the draft risk assessments, including both the pollinator and also the non-pollinator risk assessment and the comment period is for, they kind of came up at different times throughout 2016 and 2017 and the last batch of the draft risk assessment, the comment period just closed the end of April.

We're currently considering all the public comments. Well, first the docket step, we have to load, all the public comments in, but so far we have

a million comments that we have received. (Inaudible). We have a million comments we received. So we're going to have to go through those comments and work with EFED Marietta's shop to figure out if we need to make any revision to any of the draft risk assessments and then basically start to look at the benefit assessment associated with these pesticides.

We have also at the same time as the latest batch of draft risk assessment, issued the draft benefit assessment for cotton and citrus. So we will be looking through those comments as well. And that is prepared by our division BEAD, the biological and economic analysis division. So considering both the risk and the benefit, we're planning to hopefully try our best to propose interim decisions by later this year and then trying to come out with our interim decision by 2019. So that's for the Neonics.

For Glyphosate, we issued our draft risk assessment also back in 2017. The comment period for that, we had a 60-day extension I believe, also

just closed as of Monday. So so far, we have about 7,000 comments received. We set up a separate email box just as well and we have about 75,000 emails to go through and try to gather information and consolidate that with the comments. So we'll be spending a lot of our time in the remaining of 2018 going through the public comments that were submitted and working with HED, Dana Vogel's division, to figure out if we need to revise the risk assessment based on either new data or comment that we receive. And then we're also hoping to propose the interim decision by this year, and in 2019 hope to issue the interim decision.

So another group of chemicals I think folks are interested in is Pyrethroids. For that we issued the ecological risk assessment a little bit earlier and we tried to streamline that and there's about 20 chemicals right here, 20 active ingredients in this group. And we have also completed a draft risk assessment for the human health piece of this. So some of the human health risk assessments go out for comment so in the meantime, we're starting to

look at ecological risk assessment comments, which is about, a little bit over a thousand, 1400 comments that we have received and trying to start to look at the benefit associated with this group of chemical and trying to figure out if we should take a look at the ecological risk-mitigation first.

And so that is currently still on schedule in terms of what we're planning to do is hopefully come out with some proposed interim decision by the end of this fiscal year as well. So as you can tell, it's going to be fairly busy for my division.

And Rick knows that, right? Yes. He's nodding, so.

And then the last group and not the least is the fumigants, so structural commodity fumigants which is already information on your one-pager. So we have been working with the registrants and also NPMA on addressing the OIG report that came out last year. At the same time, we are going through the data that have come in, trying to get our risk assessment together by 2019, so this group is a little bit behind the schedule compared to the

previous three that I spoke about. So we're planning to do proposed interim decision and interim decision 2020 and '21. So that's an update on the conventional registration review program.

MR. KEIGWIN: So I think, Mike, you were going to go next.

MR. McNALLY: I'm going to go next.

MR. KEIGWIN: Oh, you're going to go next. Okay, great, thanks, Bob.

MR. McNALLY: Try it again. Hello. So thanks, Rick. I just want to talk little bit about the biological pesticide program we have within the office. As you see here, this is kind of the mission statement for all of OCSPP, and I want to try to differentiate a little bit about what we do in the biopesticide program.

So in essence we're a stand-alone division. So Yu-Ting just talked about the registration review program. That's something that's done within our matrix within OPP, so we have the Health Effects Division, the EFED folks and others working together to handle conventional pesticide registration

review. In our case, all the science resources or all the regulatory resources, all the policy resources are within the division.

Now, there's three categories of biopesticides in general. The first category would be biochemical pesticides. So something like kaolin clay would be a natural substance that would be classified as a biochemical. These are things that are naturally occurring. They have a non-toxic mode of action and there's a history of minimal toxicity. So those are biochemicals.

The next category is microbial pesticides and my colleague, Mike Mendelson, will be speaking to you a little bit about Wolbachia mosquitos. That would be a microbial pesticide. Now those are not genetically engineered type of pesticides or GMOs or biotech. They're completely different.

The third category that we work on in my division are biotech pesticides. So those of you who are familiar with Bt corn, for example, or Mike will speak a little bit genetically engineered mosquitos, those types of biotech products are also

handled within BPPD.

So what I want to cover today is sort of some of the nuts and bolts of our results and how we do our work, but I also want to also cover a little bit about some of our key policy issues to give you a flavor of the types of issues we confront in our program.

So this is just a snapshot of what we did in 2017. We registered nine new active ingredients, so again, we're doing both registration and registration review. That's some of the work we did in registration review last year.

One thing I do want to point out is the electronic label submissions, how important that is. We had over 500 last year. That is an upward trend and we want to try to keep those numbers going. We think it's efficient for the regulating community. It's also efficient for us to utilize that technology.

The next slide here is sort of a graph of our renegotiation rate since 2010. And as you see, in 2010 it was roughly 60 percent and today it's

roughly 14 percent. Now, you might wonder why that is. And I think there are two major reasons as to why we've seen the decrease.

First, we've really put an emphasis, not just in my division but all divisions, on the initial screen. So when a package comes in, we want to make sure it's ready for prime time and can get through the entire process. So we emphasized that initial screen in the last several years to try to move packages out that aren't ready to go through the rest of the process.

I think the second reason is better communication between the regulated community and the staff in BPPD, to kind of clarify expectations. We have what's called a presubmission meeting. So a registrant will come in and we'll talk about kind of what they have in mind. To some extent there's some coaching going on there and some problem formulation to make sure when we embark on this, we kind of know where we might be going. And that doesn't mean we might get something rejected at some point down the road.

The best example or analogy I can use about the screening process is how many people here took an airplane to the meeting and came through Reagan Airport? Anybody? So the airport that you left from, there's a screening process we go through to get on the airplane. And those of you who are seasoned travelers, you know what to do. You know to take out your laptop, your iPhone, your keys, you put them on the thing and you move right through. You know, we all know people who travel once every ten years and they're the ones up there emptying their pockets while you stand in line waiting to get through to get on your airplane.

So I think what we're trying to do with the technical screen is the same thing. We want the registrant to meet, to make their destination, which is a PRIA registration on time, and if that means taking people out of line who aren't quite ready yet, we think that's an effective tool.

So when I started in BPPD about five years ago, I think it was Nina Wilson or someone else in EPA pulled me aside and said, look, there's going to

be this growth spurt in biopesticides, so get ready. Now, if this were Apple stock, I wish I had invested in 2015. You see there's been a precipitous increase in these types of products to the point where in 2018 and 2019 combined, we could make as many as 60 registration decisions for new AI's. Mostly the new AI's in OPP come through biopesticides, I would say roughly two-thirds are in my division and the other third might be in the antimicrobial and the conventional world. So clearly there's an interest in this technology.

The next slide gives you a flavor for the types of decisions we have pending, what's been accomplished thus far and the type of pesticides that we're looking at. So as you see, we've registered I think about eight or nine. We have another two or three that will be done this month. There's some that are pending and some that have been withdrawn and some that have been rejected.

Now that rejected number is a bit of an outlier. Normally we have about 20 to 25 percent of the applications to get rejected or withdrawn. This

year it's much higher so far. I think there was one application that had four or five similar new AI's that were all rejected for the same reason.

So as you see on the right there, that's the list of the ones we registered thus far. Mike will be speaking more about Wolbachia in a few minutes. My sense is the rest of the year we'll finish with about 15 or 16 registrations for the biopesticides program through the fiscal year.

A little bit of history on the program. Since its inception, we've registered over 400 biopesticides. And the next bullet gives you some sense of some of the most popular ones, you might say, in terms of use. We had numbers of over 8 million pounds applied in 2015 is our best guess. And the last bullet is several crops really seem to be using a lot of biopesticides. You see the distribution there.

Now I don't want to steal Mike's thunder here, but we'll be talking a little bit about Wolbachia and the mosquito registration we did last year. This current section 3 registration is in 27

states. There are several experimental use permits they're still working on for this particular registration to expand that use. Basically the way it works is there's some incompatibility between the male mosquitos that are the Wolbachia mosquitos are released into the wild to breed with the wild female mosquitos, which have a different type of Wolbachia that results in unsuccessful reproduction.

One thing I want to highlight, even though we're a standing division, a stand-alone division, is we use the same committee structure that the conventional pesticide program uses. So we go through these committees as appropriate. I think for the most part, the one I would focus on for BPPD is the first one, the HASPOC. Generally we've been taking all our biochemicals through this particular committee. It's an effort to make consistent decisions across the office. We don't use the other committees as much.

One thing in our program, we tend to have from the registrant more often than conventional waiver requests, rationale in lieu of data. And I

think the reason for that is in certain instances, there might not be exposure potential. So for some of the non-target studies, we don't necessarily need those, let's say for aquatic species, and so more often than not, we're going to have more of the waiver requests and we want to go through HASPOC to make sure we're making decisions in a consistent fashion.

I just wanted to highlight this. So this is not just for our division but all the programs in OPP, that the acute dermal toxicity tests, we're not encouraging these, and if you meet the criteria that are listed there, you don't need to submit those. Again, we have a lot of waiver requests to begin with and again, the goal at the bottom is to try to reduce the amount of animal testing to save resources for everybody, including time for us to review those studies.

As I mentioned, every year we deal with some policy issues. I want to highlight just two this afternoon. The first one deals with tolerances. I think the main message in tolerances is that for the

most part in biopesticides, 99 percent of the registrations we have have complete tolerance exemptions for all crops. So no tolerances.

The reason for that is there's no hazard endpoint. Now, there can be a rare case where there may be a toxic endpoint that suggests a tolerance might be appropriate and in that case, there may or may not be a need for a tolerance. There could be some conservative assumptions about exposure. There could be a weight of the evidence argument presented by the registrant, but even in those cases, there might not be a need for a tolerance.

To illustrate kind of how we do our work in the division, is every year we try to have at least one policy issue we try to work with the industry. So I see Keith Jones here, we worked with BPIA in February and had a workshop dealing with tolerances. The goal of these sessions is to try to figure out a way that we can deal with an important issue to industry or a stakeholder to kind of work through it and provide some clarity in terms of what the registrant needs to do or doesn't need to do. So

this year we dealt with tolerances and tolerance exemptions.

I just want to highlight the last point there on the slide. Again, these presubmission meetings are critical. We really encourage the members to come in and talk with us about what they have in mind, and if there are hazard endpoints, which happens rarely, let's kind of talk about what that involves. Does it involve some kind of rationale that would suggest you don't need a tolerance or do you need to do residue data?

I suspect Rick and Arnold and Ed probably have talked about this already, but PRIA 4 in the budget, the key thing I want to highlight here is the third bullet under PRIA 4, which is there could be changes that deal specifically with microbial and biochemical pesticides. So for example, just like the rest of OPP, we would go to the two-day label review. There might be some new codes for plant incorporated protectants. There might be a slightly longer timeframe for new AI's and there could be a fee for a pesticide determination. So those are the

changes, the key changes that would affect the biological biopesticide program.

Another key policy area, I mentioned tolerances, is the whole biostimulant area. Is there anybody here today who is in the biostimulant industry field at all? Anybody? Okay, I see a few hands.

So why is this important to OPP? Well, those of you who know FIFRA, we have a provision dealing with plant growth regulators. And you see the definition there, anything that meets those criteria has to come in and be registered, just like any other pesticide.

So one thing we're doing this year is putting out guidance to help the regulated community to get a sense of when they have to come in and see us because they're a plant growth regulator, even though they may call themselves a plant biostimulant and when they do not have to come in. So if it triggers that requirement, then they need to get registered. And we think this is an important clarity for industry because I think sometimes

there's confusion whether or not you have to be registered by EPA or you don't.

Now biostimulants, as I understand it, are increasing in importance in the agricultural industry. These are products that help farmers. It's not just a growth in this country but also in Europe, and so this is a developing field. I think the goal here is to provide clarity in the guidance on what label claims would trigger FIFRA and what label claims would not trigger FIFRA.

A good way to look at this, you know, there's fertilizers, which I think we all know what those are. There's pesticides and then there's biostimulants. So those are sort of three categories. There's a lot of confusion, I see some state folks here at the state level, as to what falls into which category. So one of the goals of the guidance is to provide more clarity, not just to industry stakeholders but also to states to understand, you know, what the definitions are.

There's also been a lot of work in Europe in this whole area of biostimulants. So an example of

a biostimulant would be something that might enhance water uptake in a plant, whereas an example of a pesticide that's a plant growth regulator might be something that accentuates or accelerates the ripening of the fruit. So there's a little bit of a delineation in terms of the categories if you're not exactly clear.

Now in FIFRA, there's certain things that are specifically excluded, and you see those on this slide here. Those four are mentioned by name. They do not have to be regulated under FIFRA. And the guidance will also expand a bit on those topic as well.

Again, for those of you who have been looking for the guidance, I apologize. It's taken longer than we thought. We have to go through an agency clearance process. Our goal is to get it out this year, so if you bear with us, we hope to have that out for comment in the latter half of 2018.

So I've covered a lot of the pesticides. I also want to cover something that's also in our division, integrated pest management. As I look

around the room, I see some folks here who were involved in the PPDC over the years dealing with structural IPM, so that's been part of our program. I just wanted to give an overview of how this works.

That's kind of the pyramid of IPM. The first one is set action thresholds. Just a take-home point here is if you see one insect, don't panic. You know, that's only one insect so maybe you're okay.

Monitor and identify, the second one, is maybe there are a lot of insects but upon further identification, they're beneficial insects. So maybe you don't need to do anything in terms of taking any action at that point.

The third category is prevention and it's sort of in the ag realm. That might be crop rotation, a way to address an insect problem. It also might be putting screens on windows, for example, in a structural sense. So that's an idea of prevention.

And the last item is control at the base there, which is you would treat with pesticides as

appropriate if you do, in fact, have a pest problem and you haven't been able to address it otherwise. This is just an overview of how we would deal with IPM in the agricultural sector.

You know, those of you who have been around a while, we had a SAI, the Strategic Ag Initiative. A number of years back we worked very closely with growers. Part of that was IPM. You know, more recently we've had a series of webinars. I don't know if any of you participated in webinars we've had on structural IPM, we have them monthly, or on mosquito vector-borne type issues, and those are run monthly out of our Dallas Center of Expertise. And generally we get 200 or 300 people attending those webinars. A lot of them are state and local government officials who want to understand more about IPM and we view those as a real successful outcome.

So let me wrap up, the outlook for the future. As predicted, there's been a surge in these applications. The vast majority of these are not in the biotech realm. They're in the microbial and

biochemical realm. The 60 applications there, I would say 55 are biochemical and microbial and the remaining ones are sort of the biotech area. Obviously if PRIA 4 passes, we'll implement with those provisions I highlighted that are specific biopesticides.

I don't want to steal Mike's thunder but to sort of tee up some of his issues, he's the emerging technologies branch chief. We see a lot of innovations coming down the road, gene mosquito, gene editing, RNAi interference. The one commitment I make to this group, and we've done this before, is if you all would like to hear more about any of these technologies, let us know and we'll be happy in future PPDC's to give you an overview and some examples that might be useful for you to consider.

And last but not least, we hope to get the biostimulant guidance out to help stakeholders understand when they do or don't have to come in to see us. So you can ponder this on your way home tonight. And with that, let me turn it over to Mike Mendelsohn. He'll talk some more specifically about

the mosquito technology. Thank you.

MR. MENDELSOHN: Great. Thanks, Bob.

Good afternoon. As Bob mentioned, I'm Mike Mendelsohn, chief of the Emerging Technologies Branch, and I'll share with you some information about some of the novel mosquito products we're looking at right now, some very exciting things we have. And I'll be talking about Wolbachia. As Bob said, we consider that a microbial pesticide because it's a microorganism, Wolbachia, a microorganism that's causing the effect and then also some GE mosquito product that we're looking at.

So this slide here, the two species that are currently being targeted are the Aedes albopictus and Aedes aegypti. And just want to talk a little bit about them, of course, the Aedes albopictus is also known as the Asian tiger mosquito. It prefers forested areas, is active during the day. It can carry Zika and other diseases and it's invasive to the U.S. That map there shows its estimated range in the U.S.

Aedes aegypti, or the yellow fever mosquito,

is anthropophilic or it prefers humans, is active during the night. It's a major carrier of Zika and it's also invasive, and that blue shows its estimated range in the U.S.

Now current methods for mosquito control include adulticides, both fogging and spraying, larvacides, and the use of IPM. And I'll talk a little later here, we did register Wolbachia in November so that's also a tool.

I'm first going to talk a little bit about Wolbachia mosquitos. And as we mentioned earlier, EPA regulates the Wolbachia as a microbial pesticide. Wolbachia is a bacterium that is estimated to occur naturally in over one million insect species, including mosquitos. It's been around for a while and it's been out there. The bacterium resides within mosquitos throughout their lifespan and the mosquito bacterium combinations are often fixed, so specific species with specific Wolbachia.

And what they figured out is if you take a different Wolbachia and put it into the mosquito, it

ends up providing sort of a sterile insect release effect. So the Wolbachia is a ZAP strain, we're talking about, occurs in the common house mosquito which is Culex, while the two other strains are present in Aedes albopictus. And essentially what the technology does is it switches the strains in the mosquitos and that provides control when you release the male mosquitos.

The presence of Wolbachia can cause reproductive failure in mosquitos when mating partners carry different strains of the bacterium. When Aedes albopictus males carrying the ZAP strain, that's the current product we have registered MosquitoMate, mates with females that carry the natural strains, the offspring's development is arrested and they will not reach adulthood. So it's a cytoplasmic incompatibility they call it that prevents the offspring from surviving. So that's the method. That's kind of the mode of action for the Wolbachia mosquitos.

Now, Oxitec has submitted applications to the agency for using another technology that

achieves roughly the same thing as far as the sterile release. Regarding that, FDA was previously overseeing this, and in 2017 they finalized guidance that moved that jurisdiction to EPA. This was following through with what we had -- what was put forward in the biotechnology strategy that went out in 2016.

The mechanism of action for the Oxitec or the GE mosquitos is they carry two additional genes, tTAV and DsRed, which they pass on to the next generation when they mate with wild type mosquitos. Essentially what happens is the mosquitos produce a lot of the tTAV protein which interferes with regular cellular functions and the mosquitos die before reaching adulthood. The DsRed is used as a marker so they can tell which mosquitos are GE. So essentially the Oxitec genetically engineered mosquitos and the Wolbachia both act by preventing the offspring from surviving. And the technology that's using by releasing male mosquitos, you prevent the population from increasing.

This is another diagram here explaining the

Wolbachia, MosquitoMate's Wolbachia mosquito. And let's see here. I don't want to get anybody in the eye there. If you look at the picture, the little blue dot, that's supposed to represent one type, one strain of Wolbachia that's in the mosquito. And as you can see in the first diagram, the male and the female have the same type of Wolbachia, the offspring have the same type of Wolbachia and they survive into adulthood.

The second diagram here shows two different colors, one is yellow and one is blue, just to show different strains of Wolbachia in the mosquito and when they mate, the offspring are not viable. They don't survive.

Again for the -- let's see here. Let me go forward here. Okay. This shows the situation with the Oxitec or the GE mosquito. As you can see here, on the left part of the slide, the little gray circles represent the tTAV protein. And when they're growing this in the lab, they're growing up all these mosquitos, they have tetracycline which interferes with the tTAV. When they go into the

wild, the tTAV is not suppressed, and as you can see, there's a whole lot of this gray circle. Those gray circles represent tTAV being produced and when that's produced, it interferes with the cellular machinery and again, the result is is that the progeny or the offspring don't survive to adulthood.

Okay. I want to point out a couple of things here, here we go, about the slide, about the technology here. So here is some commonalities between MosquitoMate and the Oxitec products. You can see on the left there, this is from Oxitec and then below is MosquitoMate. They're releasing the male mosquitos into the environment. So basically how this works is that the mosquito control authorities and the folks that are doing this have to release lots of these male mosquitos.

Another technology that has and we have an EUP, is some trucks that blow them out, but they're essentially releasing thousands of these male mosquitos. So the release of live adult male mosquitos in the environment. The offspring of these males cannot develop into adulthood, much like

many of the sterile release programs that have successfully been done by USDA. There's a species specific effect, so really, you're only affecting the species that you're releasing the male mosquitos. Right now the Wolbachia product that we have out there is for the Asian tiger mosquito. That's the only mosquito species that is being controlled by that release. Similarly for the Aedes aegypti, if you're releasing those mosquitos, those would be the mosquitos that would be controlled.

And then again, it reduces the mosquito population by hindering the successful reproduction. I want to point out that the two pictures at the bottom there kind of show some of the benefit as far as the release. All those little red dots in the kind of grayish, that's kind of an aerial photo of a neighborhood, and those would be where all the larvacide would have to be placed in the neighborhood, whereas these green circles on the right show the areas of release for the Wolbachia or for the Oxitec or Wolbachia.

What that means is that the mosquitos can

fly around and they can fly into areas that are hard to get to. You don't have to apply the larvacide. You're not having to apply in the same degree that you are with the larvacide.

And then another thing to point out here is that only the female mosquitos bite, so we're releasing -- the male mosquitos are being released but it's the females that bite.

A couple other points to make here, special considerations for both products. That first square there shows the release point as opposed to where the mosquitos disseminate. The dissemination is mosquito-dependent. The release point is not equal to treatment area. You release the mosquitos and they fly away. It's a broader area than where they're actually released.

Efficacy testing and claims are unique among mosquito control products for these. And again, the other thing is that these can get where other products can't because the mosquitos are flying away from where they're released.

The second block there, health of released

mosquitos, is a consideration. We have to consider the age of the mosquitos at the time of release. They need to be viable and able to release and mate. Handling conditions during shipping is a consideration, and fitness cost of the new trait. So again, these are some of the considerations that EPA evaluates in looking at these products.

The next issue below there, that block is the density of the existing wild mosquito population. You have to kind of fine tune how many mosquitos you're going to release based upon how many mosquitos are in the treatment area. You adjust the release numbers according to population density.

The last thing I want to mention here about special considerations for these types of products is accidental female release. So we need to make sure that the females are not being released, ID the mosquito species, species specific to make sure that female mosquitos are not being released and there's a monitoring program in place. Also there's human health risk considerations. One of the things we

look at is to make sure that the mosquitos that are being released are not carrying disease and that they're not, they're not females.

I want to mention a couple of things about the current status right now. EPA, as Bob mentioned, issued a registration in November for the Wolbachia ZAP strain in the Asian tiger mosquito or the albopictus for five years in several states. We also issued experimental use permits and experimental use permit amendment extensions that allow experimental field testing and release of both the Aedes aegypti and the albopictus in several states, Florida, Texas, California for the aegypti; and Florida, Hawaii, Texas and Virginia for the albopictus. And for both of these, field efficacy data is needed to support label claims for registration. And the current states that were approved for the ZAP strain had existing efficacy data that was sufficient to support those uses.

I want to also mention that Oxitec, that's the developer of the genetically engineered mosquito, has submitted both an experimental use

permit and a registration application to EPA. Both are currently under review. And for the experimental use permit for Oxitec, the Federal Register notice of receipt comment period, we're reopening that for another time, for another month to allow more time for public comment.

That's it. Thanks. If you have any questions, let me know.

MR. KEIGWIN: Thanks, Mike.

Questions, comments for Yu-Ting, Bob or Mike.

Eric.

MR. GJEVRE: Where is your presentation available?

MR. KEIGWIN: So the presentation should be on the PPDC website.

MR. KEIGWIN: Stan, then Jim, then Michelle.

MR. COPE: Thanks for the presentation, Mike. And Rick I want to publically go on record from the AMCA of thanking EPA for giving the mosquito control people some more tools in our toolbox. Because you know better than anybody that

we've been asking for them.

Three points. These two mosquitos are not only driving some of this innovation but they're also driving a huge uptick in private industry mosquito control, because of the fact that they do occur in people's backyards, primarily in artificial containers. And so the conventional mosquito control methods that have been in use for 60, 70 years really don't impact them very much. The typical truck driving through a residential area in the evening putting out an ultra low volume does almost nothing to control these two mosquito species which tend to hang around in people's yards and sometimes even inside their houses. So we're very excited to have something like this.

But they're both active during the daytime and this is -- they also feed at night but they're particularly active and biting during the daytime. And this has been really kind of a public information nightmare for organizations such as ours and NPMA trying to get people to understand that they're being now bitten during the day and it's not

just when they're sitting out in the evening being bitten by mosquitos and they need to protect themselves during the daytime. And that's a point that we still need help on, anytime you're talking to people about these mosquitos.

Secondly, the maps that he showed, those have caused a lot of consternation for mosquito control people. They were first rolled out at the White House Zika Summit almost two years ago now, which was held in Atlanta, Georgia. I was really excited when I saw White House Zika Summit on the invitation but it was at CDC.

Those are not distribution maps for those two species. And it got into the media that, oh, my gosh, all these Zika vectors are occurring in Connecticut and New Hampshire and places where we've never had them. So be very careful when you see those maps. They are not distribution maps. They are estimated potential ranges based on the optimum conditions for those two species.

The distribution of Aedes aegypti in this country is actually pretty much restricted to the

Southeast and the Gulf Coast, although there's one population that reoccurs every year in a place called Washington, DC, and nobody has ever been able to find it, of the yellow fever mosquito. They don't know exactly where it's coming from. So be careful when you look at maps. Be sure you know what they're trying to say.

And just thirdly, let's don't let our guard down. These two methods and a couple others that are coming along are fairly slow acting. They're just another tool in our mosquito control toolbox. They in no way are a substitute for the pesticides that we need to be able to apply by ground and aerially when we're in the middle of a mosquito-borne disease outbreak, because we're going to continue to have them. So we need to keep those other tools in our toolbox as well. And that's all I have to say about all that.

MR. KEIGWIN: Jim, then Nichelle, then Nina.

MR. FREDERICKS: Thanks, I want to thank you for your presentation. We really appreciate all the hard work that's getting done.

Actually a comment and a question. One is actually, I didn't realize, we didn't plan it but I am going to echo some of Stan's comments about, you know, this is a great additional -- with regard to these mosquitos, it's a great additional tool to be added to the integrated pest management toolbox. And when we saw the pyramid up on the screen that Bob showed us, you know, you take into consideration as many different tools as you can and then use those tools in the best possible fashion. But it shouldn't be lost that we still are in need of the pesticide tools that we use. So that's the comment I really wanted to echo, that we can't lose sight of that we have these innovations, but those innovations are not enough. We need every tool possible.

And third, the question was with regard to Yu-Ting's presentation. We appreciate actually the opportunity to continue to work on things like structural fumigants and we hope that we can be helpful as a resource there. But my question is with regard to the Neonics, a million comments. How

does, how does OPP deal with a million comments?

I mean if you spend five minutes each, and I'm no mathematician, but if you spend five minutes on each comment, you know, you're talking about 83,000 staff hours, 40 years of work. How does that even work? I imagine some are duplicates but it's still a lot of comments.

MS. GUILARAN: Right. So obviously some are substantive comments. So the first, number one is to, for us to receive all the comments I don't think it's quite done yet so. And then first is to figure out the, sort of the mass letter writing campaign versus substantive things that we can consider and use to reconsider what we had done in the risk assessment and also the benefit, for example. So that will probably take the bulk of the time.

The other tool that we're trying to put in place is actually some kind of contractual support to help, so to free up our staff to respond to substantive comments and then for contractors to help us kind of sort them and thin them so that we can more easily identify the ones that we need to

address earlier. I mean Rick was the previous PRD director and had the staff pretty well set up for responding to a mass amount of comments. So I think we'll basically still shoot for the target for the Neonics for some time later this year to try to propose any necessary mitigation.

Yes, I agree. Thank you. Yes, 100 percent agree.

MR. KEIGWIN: Nichelle, then Nina, then Charlotte.

MS. HARRIOTT: So thank you for your really informative presentation. My first question/comment is for the mosquito staff, Mike. In your presentation you mentioned that there is some efficacy testing and claims that the mosquito product, I guess the registrant has. Do you have that efficacy data? Do you know how efficacious these Wolbachia mosquitos are or could be?

MR. MENDELSOHN: Yeah, the current claims are for suppression and we have, the label claims are backed up by data that's been submitted. And that's why the original registration was limited to

the states that it was because those were the states that were supported by data that we had in hand.

MR. HARRIOTT: So do you, can you share some of that data with us in terms of the numbers of efficacy that we're working with?

MR. MENDELSOHN: Not right now, but we can get that information for you.

MR. HARRIOTT: Okay, I'm just, I'm just really curious because I, I am cautiously optimistic about this new tool so I am just curious about efficacy.

My other question and maybe this is more a question for Stan actually. I'm just curious how would, if I was a mosquito control district and I'm interested in using this Wolbachia mosquitos, how would the timing work with actual spraying? Because it would be a shame to release them and then spray, release them in the morning and spray in the afternoon, so how would that work.

MR. COPE: Do I have to put this up first? I want to do the right thing.

Actually what you brought up is a little bit

of a misunderstanding. There are lots -- of the 950-some mosquito abatement districts that we have in this country, many of them, the majority of them do not spray. They do source reduction and larval surveillance and they only spray if there's an indication of disease in the mosquitos. So the idea that they go out three nights a week or four nights a week in every district and spray doesn't happen.

Also with the sophistication of how they do the sprays using GIS and everything like that nowadays and other tools, one of the larger districts could easily be releasing these genetically modified organisms in one part of their district where they might be spraying in another part of it. So it would go hand in hand. They certainly wouldn't want to -- this is not cheap. I mean you can tell from how it's done, it's pretty expensive. So they'd really be shooting themselves in the foot were they to release all these mosquitos and then drive the truck that night and kill them all. But as I said, most of them are not going to be out during the evening anyway, so the sprays

wouldn't harm them too much.

And also if you don't know, the flight range of these mosquitos is very limited to maybe the length of a football field or a little more from where they breed in the water, so they're not going to be really great distances. Thank you for that, Mr. NPMA.

MS. HARRIOTT: Thank you. My second set of questions for Yu-Ting. So you have here like your high profile risk assessments, and thank you for all the work that you guys have done in that, I really appreciate it and I look forward to EPA finalizing these decisions. And I do not envy you going through one million comments but I guess there is a lot of public interest in these things.

So my first is about, so you have your neonics, glyphosate, pyrethroids and the fumigants but you didn't mention anything about chlorpyrifos. And the last time we were here, EPA said to us that they need more data or more understanding about how chlorpyrifos impacts children's brains. So I'm just wondering where the agency is on that? Are there

going to be data call-ins? Like what more does the agency need? How can we help provide you with information so that you can quickly come to a resolution on chlorpyrifos?

My second question is about mosquito spray again. There are several pesticides or classes of pesticides that are registered for mosquito spray and I know you have the pyrethroids that I'm expecting a decision on, a decision on maybe in the New Year. But I'm thinking of some of the OP's that are still registered for mosquito spraying and particularly Naled (phonetic), which was in the news a couple years ago, and since mosquito season is almost upon us, I'm just wondering what is the registration review status of some of the other mosquito spray pesticides?

MR. KEIGWIN: Nichelle, thanks. I'm going to start with the chlorpyrifos question, and Yu-Ting can respond to the mosquito products question.

So we have been in a dialogue with Columbia University to get some additional information that underlies the analyses that they've done in the

epidemiological area. There have been, and I think we've got a number of these exchanges posted on our website currently and we've recently reengaged with Columbia to try to obtain some additional information that would help to inform moving forward with our analyses.

So let me turn to Yu-Ting about the mosquit part.

MS. GUILARAN: So for the Naled DDVP, we're still working on the risk assessment and we're working on some additional studies that will have to be incorporated into the draft risk assessment and right now, I think we're expecting the studies to be completed by the end of this year and hopefully we will have a draft risk assessment out shortly after that.

MR. KEIGWIN: Okay. Nina, and then Charlotte.

MS. WILSON: Thanks for that information, Bob and Mike. You said tolerance exemptions, biostimulants, IPM and PRIA, and those are all words that I feel like I say everyday 100 times a day.

But as you know, we're very interested in tolerance exemptions and making sure that the tolerance exemption requirements and how to get there are commensurate with the risk. And that is a very, sometimes a confusing process because I think people don't realize that it's something like 6 to 8 percent acetic acid which is vinegar, if we call it a pesticide has to go through all the requirements and we have to demonstrate to you. And we try to do that in such a way that it doesn't require a lot of animal testing and use the weight of evidence as much as possible.

But, and as for biostimulants as well. It somewhere lays in between an IGR, insect growth regulator which is a FIFRA product or a fertilizer which is more state-regulated and so trying to find a home and definition of that was very important to us as well.

And these products all work in integrated test management which your group also looks at, not just for schools which you have looked at but also we work in -- with conventional products. We work

with genetically modified and the whole idea is to get a total reduced risk program. And I know anybody and all these different sectors that we have are interested generally in that kind of reduced risk IPM, resistant management programs.

And as far as PRIA, I think just a reminder to everybody that if you -- that not having PRIA and not giving you the tools, the resources to be able to review all these products in the same diligent way that we tend to think of some of the other products, does keep these lower-risk pesticides from being reviewed and registered in a timely manner as well. So I appreciate your comments and your support and all the work that you guys do there.

MR. KEIGWIN: Okay, thanks, Nina. Charlotte and then Dan.

MS. SANSON: All right, thanks. I have a request for Yu-Ting. Yu-Ting, as you were talking about the comments, I think, I think it might have been relative to Glyphosate, I just wanted to clarify that I heard correctly. You mentioned about 7,000 comments have come in and then you mentioned

an email box. So I was just curious as to what the difference is between comments that you're receiving via email versus -- as opposed to the docket. Are you talking about the same thing or are they different processes?

MS. GUILARAN: So for some of these chemicals where we know the case will receive a lot of inquiries, so we have set up both emails to receive those inquiries and also a phone line. So there are some comments that were submitted through the email system, so that's part of what we need to do is go through the emails as well, and then the ones that are actually comments and to incorporate that with the comments that we receive through the docket.

MS. SANSON: Okay. So the comments that are uploaded to the docket I think are visible to the public. What about the comments you're receiving in the mail --

MS. GUILARAN: We'll be adding them to the visibility of the docket. So first we need to go through all of them, extract all the comments that

are relevant, load it onto the docket.

MS. SANSON: Okay, yeah. And the million that you've received have also come through --

MS. GUILARAN: The million, we did not have a specialized email for the Neonics, so I guess that's why there were a million.

MR. KEIGWIN: Okay, Dan and then Eric.

MR. KUNKEL: Thanks, Rick, and I think my comment and it's not really a question, is for Bob McNally. And one of the outcomes, we had a global minor use summit last October. One of the outcome action items was to develop a list of products that are exempt or very low toxicity so they can be recognized. So we're working on this through Codex and OECD, but I wanted to make you aware of that. But again, we're just trying to create an international list that's internationally recognized so if we could draw from some of your experiences that you had in your workshop last year and so on, we would appreciate that. Thank you.

MR. KEIGWIN: Okay. Eric.

MR. GJEVRE: I saw, early I saw a bullet

point for CRISPR. Can we get a CRISPR update or can you put it on? I'm just curious, does EPA ride herd on that regulatorily?

MR. McNALLY: So the question is about CRISPR. So as I mentioned earlier, we can do, maybe at the next PPDC, just an overview briefing of what the technology is and specifically how it might apply to the pesticide realm because we have not received any applications for any CRISPR products but we do know the technology is out there and at some point it might be a possibility.

One of the things we did as part of the coordinated framework update and the national strategy sort of for ag-biotech is we kind of highlighted some approaches that the government is looking at on things like gene editing, and so that's certainly something we want to establish some policy on in the next year or so, and we're working with our colleagues at FDA and USDA to have hopefully a concerted approach across the government, maybe not entirely consistent, given the different statutory mandates but at least the left

and the right hand know what each is doing.

MR. KEIGWIN: Stan, did you --

MR. COPE: I can tell by looking at everybody's faces that you're all wondering how you can learn more about these invasive mosquitos, and there's some really good news on that. If you are interested or you need to learn or any of your staff want to learn more about these, about a year and a half ago the CDC came to AMCA and awarded us a sizable contract to develop best management practices for these species. So if you go to -- we have a very cleaver website address, it's WWW dot mosquito dot org, and the very top button says CDC Training and Certification.

The best management practices manual is there. It's about 78 or 80 pages, and it covers all, all aspects that you would need to know about biology, surveillance and control for these things. And then there are four E-modules that you can sit down and take at your own pace. They're not -- it's not easy. You have to get 85 percent to pass. That's 15 percent above what we were required in the

military to pass, by the way, so that tells you how important mosquito control really is.

You don't have to be a member of AMCA to take them. They're a great place for people to start that might be get thrown into a job or a responsibility where they know nothing about these things. And at the end you get a nice little certificate that says that you have been trained on the CDC/AMCA best management practices, which is a pretty good thing to have in your dossier.

So it's available, everything is available now in English and Spanish as of last week and we're very proud of that. So take advantage of it but study hard for the test.

MR. KEIGWIN: Damon.

MR. REABE: This is a comment with regards to the biopesticides. I would like to encourage the EPA to -- and maybe this is already being done, but we're starting to see more use of biopesticides in our business and one thing I'm noticing that's lacking is real clear instructions. I'll use an example. There's a particular biopesticide that we

handle that requires refrigeration. So there is the, the company that formulates the product is well aware of it. The sales staff might be well aware of it. It gets distributed, it gets watered down. It gets to dealerships, that information gets watered down. And when it finally gets to the applicator, they may not know that. And so, you know, clear packaging, labeling that would, you know, provide that type of direction.

Also for aerial applicators, from what I can tell, it's quite obvious to me that because these products are so specific at how they control a pest, the timing of application is extremely critical. So aerial application will play a very significant role on that. So clear instructions for us, droplet size is important for us to know what works best. How long these products can be in the diluted form in our hoppers. As time goes on and these products become more widely used, pesticide dealers go into bulk mixing. Certain products that are conventional products when they're at a particular pH may have really short half-lives. Some of these

biopesticides may no longer be viable after so many hours, and this is all information that we, that we need in order to use them properly and have them work.

MR. KEIGWIN: Lori Ann.

MS. BURD: Thanks. I have a few questions. First I know it's the practice to do final final interim risk decisions. Do the decisions ever become final final and not final interim? And can you explain why that is the practice? And then I'll ask my two other questions after.

MS. GUILARAN: I know. So yes, that's my goal to have final decisions. So part of the reason I have the interim is we are, I think Marietta is going to cover it tomorrow, the ESA piece of it. So that piece we're still working with Fish and Wildlife and also USDA and NMFS on trying to figure out the ESA piece of it. So the biological evaluation for EPA, the biological opinion for the services, so that's a part that is not -- when we have that figured out, that's one of the pieces that we need to have for the final decision. So that's

why it's interim right now. Does that answer your question?

MS. BURD: Yeah, great. Thank you.

My next question is can you give us an update on Malathion re-registration?

MS. GUILARAN: So for Malathion, the draft risk assessment was already released and is currently going through -- the second part of it is the ESA. So I think, are you going to cover some of the -- or are you asking about the ESA piece of it or just --

MS. BURD: No, I just wanted to know what was happening.

MS. GUILARAN: Yes, the risk assessment has been released and also the comment period closed, yeah, but that's part.

MS. BURD: So that's what we're waiting for. You don't anticipate doing the final interim on Malathion, you'll hopefully have a final final?

MS. GUILARAN: It depends on how the timing all works out. Sometimes it depends on if we can effectuate some of the risk mitigation earlier on,

we'll do a piece of that and have that implemented first. It really depends on the timing of everything, how it's going to work out.

MS. BURD: Okay, great, thanks.

And my final question is on Neonics. As we all know, the EU finalized its ban on outdoor use of three Neonics on Friday.

MS. GUILARAN: Right.

MS. BURD: And I'm wondering how you all will be incorporating the information they utilized in your decision-making processes and also the information coming out of Canada as well.

MS. GUILARAN: Right. So as I said before, with all the comments that we have received, obviously part of our consideration for EPA is different from EU. So we need to first of all take a look at the comments that we have received on a risk assessment and then along with the benefit assessment that we have put all together. So FIFRA requires us to balance both pieces and then basically make a determination after we have sufficient time to look into that and to see whether

or not we need to revise any of our risk assessment as well, so.

MS. BURD: So you will be looking at the information that they looked at?

MS. GUILARAN: Yeah, I don't -- I don't know specifically what information.

MS. BURD: The EFSA report.

MS. GUILARAN: Yeah, we have looked at that.

MS. BURD: Okay, great.

MS. GUILARAN: Yes.

MR. KEIGWIN: Let me check with Sharon and Pat to see if they have any questions.

MS. SELVAGGIO: This is Sharon. Can you hear me?

MR. KEIGWIN: Yes. Go ahead, Sharon.

MS. SELVAGGIO: Okay. So I'm sorry, I was taking some notes and I'm trying to find my question, okay.

So my question was to Bob McNally about the biopesticides. Recently at the IPM symposium that happens every couple of years, the one that just happened in Baltimore this spring, there was a

discussion on nano technology by Jason White, the state chemist for Connecticut, and the takeaway from his presentation was basically that traditional risk assessment methods are inadequate for nano pesticides because nano pesticides interact in unique ways with biochemical, genetic and cellular processes. And according to him, there's no nano specific safety assessments that are required right now by either the EPA or the Food and Drug Administration, although the EU is a little bit further along.

So in thinking about Bob's presentation and also this morning's discussion about EPA's efforts to streamline testing and risk assessment methods, I'm curious about what discussions, guidance and policies are underway to achieve the mission of safety for OPP that Bob pointed out at the very beginning of his presentation and basically to ensure adequate assessment of human and ecological risks for both biopesticides and nano pesticides.

I am also just kind of curious, given the sort of division of responsibility that Bob talked

about with conventional and how you guys are classifying different kinds of pesticides, where do nano pesticides fit into that structure?

MR. McNALLY: Yeah, this is Bob. Thank you for the comment. I guess what I would like to do is get -- we had people at that IPM conference in Baltimore and they were basically our IPM folks, as the name would suggest. If you can give us more information about the presentation, I think the first thing would be to take a look at it and see how it relates to our program, either in the biopesticide program, the conventional world, the antimicrobial world.

I think the first thing we look at is the delineation between a biochemical, you know, the three criteria I listed, to see whether it fits in our bin or somebody else's bin. I think we would probably need to know more about the specific delineation that the presenter in Baltimore made about nano pesticides. So I think that's the key criteria for us that I listed, and I think maybe the best bet is for us to look at that paper and then

see what impact, if any, that has on the program in my group, in Yu-Ting's group or in the antimicrobial group.

Can you tell me again the name of the presenter?

MS. SELVAGGIO: Yes, Jason White. He's the state chemist for the state of Connecticut.

MR. McNALLY: All right, thank you.

MS. SELVAGGIO: You're welcome.

MR. KEIGWIN: Any other questions for Bob, Mike or Yu-Ting? Amy.

MS. LIEBMAN: I have a question on this overall session, so is it okay to ask that now? I'm just kind of curious, like particularly given sort of how the agenda went today and the time that's on a regulatory update session within the PPDC, why some major regulatory updates were not included on the agenda when they were requested by many participants. So I'm specifically asking like it just seems like when you're about to start gutting the WPS, and when we have the judge, federal judge saying that the certified pesticide applicator rule

is actually now in effect, why you wouldn't sort of bring us up-to-date on that in this setting.

MR. KEIGWIN: So we are now in the rule-making process and that's really the next step in the process. Our websites are up-to-date on the status of those two regulations and so we felt that the information was out there. We -- there was an opportunity to ask questions earlier in the session. Those questions were asked. I think the agency answered them.

I know there were a couple questions, Amy, that you asked earlier this morning that we're in the process of getting answers for and we hope to have the answers to those tomorrow. And very much consistent with past PPDC meetings, we have tended to provide regulatory updates on other aspects of the program, be it registration review and the biopesticide program, and so this part of the agenda is consistent with that.

MS. LIEBMAN: Okay, I guess I just see some large gaps in the overall agenda. It was brought up but it wasn't really on the agenda today. So I

think in the future I think it's important when, when it's current, when it's a current event, even if it's on your web -- everything else is on your website, too. So I'd appreciate it being addressed.

MR. KEIGWIN: Other questions? Okay.

No one here in the room signed up for public comments. I just want to check quickly to see if anyone participating on the phone would like to make public comments.

Okay. Well, then, I want to thank everyone for their participation today. We will give you back the gift of an hour of your time.

Thank you all for today's discussion. We will begin tomorrow at 9:00 a.m. Have a good evening.

(The meeting was adjourned.)

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