UNITED STATES

ENVIRONMENTAL PROTECTION AGENCY

PESTICIDE PROGRAM DIALOGUE COMMITTEE MEETING

DAY ONE - MAY 3, 2017

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: Welcome, everybody. Good morning. Thanks for coming. We've got a very busy day ahead of us, so we look forward to the discussions.

I first want to introduce to everybody Wendy Cleland-Hamnett. She's the Acting Assistant Administrator for the Office of Chemical Safety and Pollution Prevention. She has a couple of welcoming remarks.

MS. CLELAND-HAMNETT: Thanks, Rick, and good morning, everyone. I'm really happy to be here to welcome you all to this PPDC meeting. As Rick said, my name is Wendy Cleland-Hamnett. My position of record in the Office of Chemical Safety and Pollution Prevention is Principal Deputy Assistant Administrator, which is a career position.

I'm the Acting Assistant Administrator now, presumably until we get a presidential appointee in the Assistant Administrator position. So, I've been doing this since January 20th, or 21st, right after Jim Jones left. I just started as the Principal DAA back last October 1st. But I've worked in the Office of Chemical Safety and Pollution Prevention since 2004

this round. I had worked in the office way back when at the beginning of my EPA career.

Before I became the DAA last October, I was the Office Director for the chemical side of the office. So, I worked on TSCA reform and implementing the older version of TSCA prior to that. So, I am familiar with the pesticides program, although I am learning a lot. Have been learning a lot since last October about some of the specific issues and projects that people in the OPP have been working on.

It's really been a great experience meeting the great people who work here, the management team, learning the issues, meeting many of you and your colleagues in the stakeholder community. So, I've really enjoyed this, and I look forward to continuing to work in this area as acting and then, hopefully before too long, back as the Deputy Assistant Administrator. So, again, welcome.

I actually have attended a few PPDC meetings before when I was Office Director in the toxics program. I came to a few to see how you all work together, because we have thought about creating a similar kind of group for the chemicals program, once we get our framework together to start implementing the reforms to TSCA. I think a couple of times since

then I've been to the PPDC, but the first time in this particular role.

I just think that you play a very critical part in what the pesticides program does. Transparency is very important, hearing from all of the stakeholders who have an interest in the pesticides program on behalf of your sort of constituencies that you represent, formally or informally, and also just on behalf of the American public in terms of protecting human health and the environment, protecting the food supply, public health, all of the things that -- the products that we work on here in the pesticides program are meant to provide to the American public, as well as protecting human health and the environment.

I know that it's a huge time commitment to be on a committee like this, to prepare, to come to the meetings, to follow up from the meetings, to be on the working groups, and so forth. So, I can't tell you how much I appreciate that and Rick and the people in the program appreciate that.

So, one of my goals during this period that I'm the Acting Administrator is to make sure that we keep doing what we need to do, that we keep focused on the mission here in pesticides on the chemical side,

that we keep, you know, the registration process moving along, the registration review process moving along, the work on the science moving along, while we are helping the new leadership in the Agency to transition in and figure out what they need to focus on, want to focus on, and so forth.

So, I am here to help with that. Unfortunately, I won't be able to stay with you through the day today, but if you don't know where to find me, Rick can tell you where to find me. So, you know, I'm open to e-mails, phone calls, meeting requests, and so forth. If any of you would like to follow up on particular issues, I am happy to do that, as I know the folks over here in the pesticides program are as well.

So, if that does it, thank you so much. I look forward to hearing what you're all talking about. I'll try to pop back over here today or tomorrow to catch up on what's going on, but I'll also get filled in by folks here. So, thanks very much. Hope you have a good day and get to enjoy the outdoors at lunch time. Nice weather for DC itself. Two weeks a year we get this kind of weather. Thanks very much.

MR. KEIGWIN: Thanks, Wendy.

So, again, welcome to everybody. We do very

much appreciate all the work that you all put in outside as part of the work groups. Having you all give us advice on important matters facing the program I think really helps us to advance our work working with you to, as Wendy said, protect public health and the environment.

Before we go around, I want to give folks a few updates on what has been happening in the office since our last meeting. But I first want to recognize some of the people on the committee who this will be most definitely their last meeting, because some of you are term limited as part of the FACA requirements.

So, among those are Cheryl Cleveland, Beth Law, who wasn't able to participate today, Ray McAllister, Jake Vukich, Virginia Ruiz, Valentin Sanchez, Captain Calvert, who is not here today, Mike Kashtock, who is not here today, Robyn Gilden, Marc Lame, Wayne Buhler, Tom Delaney, Doug Hanks, who I believe is going to participate over the phone, and Gabrielle Ludwig. So, thank you all again.

Those people have been on the committee now I think for almost six years, so we really appreciate all the efforts and all of your contributions to the work here. I know, even though you won't be on the committee for the foreseeable future, we'll still be

hearing from you and contributing in other ways.

Membership did close for the next cycle of the PPDC on April 21st. We had a very high interest in participating on the committee moving forward. So, thanks to the current members who were eligible to reapply for reapplying. We're going through the process now of, you know, reviewing the applications. We'll make our recommendation to Wendy. Then Wendy will take the OCSPP recommendation forward within the Agency. Hopefully, in time for our fall meeting, we'll have the new PPDC up and running. So, that's the update there.

I want to quickly go through the agenda. This one is obviously a little bit different than other PPDC meetings because we're trying to squeeze a lot of things into day one, so that we can use our session tomorrow to focus on the regulatory reform efforts as part of implementing President Trump's executive order on the regulatory agenda. So, we're going to move pretty fast today.

So, we'll first soon go around for introductions of all the PPDC members. Then we have a session on pollinator protection. We have a session on biotechnology. We'll break for lunch. Then, in the afternoon, we'll provide an update on some of our

efforts to implement some 21st century toxicology techniques.

We have a short Q&A session on some topics that we had heard from you all that you wanted to hear some updates from us. Then we'll have a report back after the break from the incidents workgroup. Then we'll wrap things up with a presentation from Arnold and his team on vector management and Zika. Then there will be an opportunity for public comment at the end.

As I mentioned, tomorrow we will do our regulatory reform meeting. There will be a different configuration for tomorrow's meeting. We're not going to sit around a hollow square. It will be more of a theater style because we wanted to be able to allow as many people to participate as possible. But for PPDC members, we'll have some space reserved for you all up front.

So, the first half of tomorrow's meeting will be you all, and then the second half will be from the public. I think we have upwards of 15 or 20 people from the public who will be participating with public comments either in person or over the phone.

We are starting a little bit early tomorrow. We're starting at 8:30. I know how challenging it is

to get through security in this building, and with even more people being here. I think we have several hundred people who are registered to participate in person or observe in person. We'll remind you at the end of the day, but please plan accordingly for tomorrow so that we can get through all the public comments.

So, in terms of what's been going on in the Office of Pesticide Programs since our last meeting -- I think the first thing I should probably point out is the departure of Jack Housenger, who is a huge loss to OPP. I think Arnold and I knew how much he did, or thought we knew how much he did. Now that he's gone, we appreciate everything that he did even more because now we're trying to divide it up amongst the two of us. So, Jack carried a very heavy load for this program, and he is sorely missed.

Before he left, however, he left us in a good place. We selected three new permanent division directors for the Office of Pesticide Programs. I just wanted to introduce those people to you all. Marietta Echeverria is now the Director of the Environmental Fate and Effects Division. Wynne Miller is now the Director of the Biological and Economic Analysis Division. Mike

Goodis is now the Director of the Registration Division. So, thanks. It's great to have the three of them in their new positions.

We've also been going through -- and I won't go through all of these, but as part of trying to rebuild the management team and to provide some opportunities for career growth and advancement, we've been rotating a number of people around the program into the Deputy and the Associate Division Director slots.

So, if you look at the org chart in your packet, you'll see a lot of names that you're probably familiar with, but you're like why is that person there? I'm not used to them being there. Part of it is to rebuild our capacity and get people experiences in different parts of the program. I think that's been a good effort here for them and for us.

On the registration front, since our last meeting, we have registered nine new active ingredients. That's about half of where we expect to be by the end of the year, three in the Registration Division, five in the Biopesticides and Pollution Prevention Division, and one in the Antimicrobials Division. We're on track to complete the other 10 or so decisions by the end of this year.

On the registration review side, by our next meeting, we likely will have hit a very significant milestone in the re-evaluation program where we will have by then opened all of the dockets for all of the active ingredients going through registration review. We're making very good progress on the scientific evaluation side.

At this point, and I'll focus on conventional chemicals, we've issued about half of the draft risk assessments for public comment that we would expect to issue as part of registration review. We've issued about 40 percent of the proposed decisions that need to come forward as part of completing the re-evaluation program by 2022.

So, there's been a lot of effort across the program to get those things done, and a lot of great input from you all as we have public comment periods on the draft risk assessments and the proposed decisions.

Some other highlights to note, we're working with our colleagues in OPPT, as well as FDA and USDA. Recently received some advice from the National Academy of Sciences relative to biotechnology and how to prepare ourselves for some of the new tools and some of the new technologies coming forward.

This was an important piece of an effort launched in the last administration, and we suspect we'll continue as we move forward and as these technologies continue to be developed as part of the updates to the coordinated framework and our long term strategy for biotechnology.

Probably, for our next meeting, we'll be in a position to provide you all with an update on the SmartLabel effort. I think we've talked about that initiative here in the past, and we really think this is an important effort for us to modernize pesticide labeling, not only for us but for the users of these products so that they have accurate information in a more digestible format so that these products are used in a way that they're intended.

We'll get an update today on the pollinator efforts and the work that the workgroup has been doing on informing metrics for measuring the success of the managed pollinator protection plans.

And then, finally, I should note the work that we've been doing with the Services on the pilot set of chemicals for Endangered Species Act biological evaluations and biological opinions. A lot of great work that's been going on with the Services and with input from USDA to help advance the science in that

area.

Let me stop there. Maybe we can go around to introduce who is here, and then we'll go to the phone for the PPDC members. I'll start to my left.

MR. LAYNE: Hi, good morning, everyone, Arnold Layne, Deputy Office Director, Pesticide Programs.

MR. STELL: Hi, good morning, Fred Stell from the Armed Forces Pest Management Board.

MR. TAYLOR: Good morning, Donnie Taylor with the Ag Retailers Association here in Washington, D.C.

MS. FLEESON TROSSBACH: I'm Liza Fleeson Trossbach, and I'm representing the Association of American Pesticide Control Officials, or AAPCO.

MR. FREDERICKS: Jim Fredericks with the National Pest Management Association.

MS. CLEVELAND: Cheryl Cleveland, BASF, RTP.

MS. PALMER: Cynthia Palmer, American Bird Conservancy.

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

MS. JAIN: Good morning, Komal Jain, American Chemistry Council, the Biocides Panel.

MR. BUHLER: Wayne Buhler, and I'm serving on this board as the overly enthusiastic entomologist from the East Region to counter my western colleague. I'm with the Pesticide Safety Education Specialists at NC State University and representing the American Association of Pesticide Safety Educators.

MS. WILSON: Hi, I'm Nina Wilson with Gowan Company representing the biological products industry.

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

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

MR. VUKICH: Good morning, Jake Vukich with DuPont Crop Protection in Wilmington, Delaware.

MR. DELANEY: Tom Delaney, Georgia Urban Ag Council, representing the landscape industry.

MS. GILDEN: Robyn Gilden with the University of Maryland School of Nursing and also the Alliance of Nurses for Healthy Environments.

MS. HOYLE: I'm Sarah Hoyle with the Xerces Society.

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

MR. COY: Steven Coy, American Honey

Producers Association.

MS. LIEBMAN: Good morning, Amy Liebman from Migrant Clinicians Network.

MS. HARRIOTT: Nichelle Harriott, Beyond Pesticides.

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

MR. SANCHEZ: Valentin Sanchez with the Oregon Law Center.

MR. MCLAURIN: Good morning, my name is Allen McLaurin. I'm actually a cotton producer from North Carolina, but I represent the National Cotton Council.

MR. MCALLISTER: Ray McAllister with Crop Life America.

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

MR. LAME: Marc Lame with Indiana University representing the National Environmental Health Association.

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

MS. GOUGE: Good morning, Dawn Gouge, overly enthusiastic entomologist from the western side of the continental U.S. I work on public health pests.

MR. KUNKEL: Hi, I'm Dan Kunkel with the IR4 minor use program. We're located at Rutgers University.

MS. RUIZ: Virginia Ruiz, Farmworker Justice.

MR. ALARCON: Walter Alarcon representing CDC, the SENSOR pesticide program.

MS. SHULTZ: Gina Shultz, U.S. Fish and Wildlife Service.

MS. KUNICKIS: I'm Sheryl Kunickis. I'm the director in the Office of Pest Management Policy at the US Department of Agriculture.

MR. KEIGWIN: I think we have a few members of the PPDC who are participating via the phone. So, why don't we go to them. Are there PPDC members participating via phone? Could you introduce yourself?

MR. BENNETT: Steve Bennett, Consumer Specialty Products, on behalf of Beth Law.

MR. HANKS: Doug Hanks, National Potato Council.

MS. LIANG: Charlotte Liang, U.S. Food and Drug Administration.

MS. COLOPY: Michele Colopy, Pollinator Stewardship Council.

MR. KEIGWIN: We're only asking for introductions from PPDC members. So, I think the other person that we thought might be participating is Louis Jackai. Are you on the phone?

(No verbal response.)

MR. KEIGWIN: Okay, perhaps he'll join us a little bit later.

A few housekeeping issues before -- registration desk. If you haven't done that yet, please do so at the break. We need to have that for purposes of the FACA requirements for the meeting.

This is the same mic system that we've had now for the past couple of meetings. So, just a reminder, the little red button, if you see it red, that means it's on. When you're done speaking, please turn it off. I think I have the ability to turn them all off, but I'd rather not have to do that.

Turn your tent cards up when you want to speak, and we'll try to get to as many of those cards as we can. The teleconference line is open, so hopefully folks on the phone are hearing this well. Another reason why when you are speaking to use the mic, so that the people on the phone can hear you. We do have it set up on a global mute and we'll be controlling the muting and the unmuting. For people

that do want to speak who are PPDC members, we can unmute your line so that you can speak when we go around for the discussion within the PPDC.

For members of the public that have joined us today, there is a 15-minute public comment session at the conclusion of today's meeting. Today's comment period is to focus on the topics on today's agenda. Anything related to the regulatory reform pieces is for tomorrow's discussion. If there's a member of the public that wants to make a comment today, please sign up at the registration desk out in the lobby here.

Then, one last thing for fire code purposes, in the event of an emergency, please note that there is an emergency door at the front of the room here. And then there are four exits out into the lobby from this room as well.

Any questions?

(No verbal response.)

MR. KEIGWIN: So, why don't I ask Mike to come forward and lead our first session on pollinators.

MR. GOODIS: Good morning, my name is Mike Goodis. I'm the Director of the Registration Division, Office of Pesticide Programs. And sitting next to me is?

MS. GUILARAN: Hi, I'm Yu-Ting Guilaran, Director of the Pesticide Re-evaluation Division.

MR. GOODIS: So, this segment, I think it's slated for an hour to talk about pollinators. I think we're going to start off with just really an update or report out on some recent activities from EPA on pollinator-related actions, specifically the acute mitigation policy, the risk assessment for neonics. I'll talk a little bit about pollinator protection plans, too.

We want to reserve most of the time for the managed pollinator protection plan workgroup to report back on the status and the approach that they're taking in providing recommendations to the Agency, looking again at metrics for evaluating managed pollinator protection plans.

The group had started back in October. We've been meeting monthly now. I can say I think the workgroup is working very well together. I think, again, they have a proposed approach, and I think we're looking forward to getting feedback from the committee and the workgroup on the approach and whether it's the right direction or if there are other factors that should be considered. So, there will be a presentation on that topic, you know, on the second

half of our segment here.

So, I'll start things off. So, the main topics, again we'll just talk about some of the activities, our commitments from the National Pollinator Health Strategy, we'll talk about managed pollinator protection plans, the acute mitigation policy, and then we'll finish up with the status of the neonic re-evaluation reviews.

So, as many of you probably already know, it's been about two years now that the federal agencies have put together a strategy. As part of that, the EPA had various commitments as far as that strategy in promoting pollinator health, namely looking at ways to better assess the effects of pesticides on pollinators. Also looking at expediting reviews on new products to help protect pollinators also. Also, pollinator habitat protection and development. But also in there there were commitments of looking at reducing potential exposures to pollinators from pesticide applications and also engaging states and tribes in developing pollinator protection plans.

Some of the recent activities that are ongoing, just notably, we're continuing to ask for pollinator data through data call-ins for our re-

evaluation program. Recently, I think it was earlier this year, the EPA hosted a workshop here in this building with stakeholders and looking at pollinator effects on non-Apis or non-honeybees.

As part of the ongoing efforts, we're still using the -- and this is an evolving science too, that we're using the pollinator risk assessment framework and looking at potential effects to pollinators from use of pesticides under our re-evaluation, and also our registration regulatory programs.

One area we're also taking a closer look at is the variability of the toxicity for residues on foliage study. This is the RT25 data. We'll be talking a little bit more about that later in the acute mitigation policy. But we're looking at finding ways to better utilize that data and to make it more specific for its intended uses.

So, managed pollinator protection plans, or MP3s, again, this is something the Agency had committed to in the very beginning. This was something that again was identified from some states that had taken this initiative earlier on in working with stakeholders in their states to develop pollinator protection plans. We thought it was a great idea and committed to working with states and

tribes to help other states and other areas, tribal areas, to also develop pollinator protection plans.

We hosted a symposium about a year ago here in Washington, D.C. for various stakeholders, states, tribal representatives, but also others to share experiences and lessons learned and provide information and tools for developing pollinator protection plans.

As you know, later last year, a workgroup was formed under the PPDC for providing recommendations to the Agency on how we can better evaluate or measure the effectiveness of these state plans more at a national scale, as opposed to just looking at each plan individually.

This was an area that I think -- again, we weren't sure what the best tools were for doing that, and we're really looking forward to the input for this workgroup and for the committee to give us some recommendations.

So, the acute mitigation policy, as many of you probably know, this is something I worked on. Again, it was a commitment coming out of the strategy that was released a couple years ago. The policy itself was finalized and released in January this year. We had a proposed policy, in which we received

a large number of comments that were considered. We made adjustments based on the comments. We thought the information we received was very informative.

In the changes that we made in the policy, it was more towards making the restrictions on the use of pesticides more quantitative, more risk based. So, based on the application rate and the toxicity of the compound, if a certain use pattern exceeded the level of concern, then we would impose restrictions on labels for products under certain conditions. That's in fields where pollinators are being brought in for commercial pollination services and the crop is in bloom. Those products will be restricted for use during those periods.

We also identified, based on the feedback we got from the comments, that there needed to be some flexibility about that overall restriction. So, we did look at areas where -- and we received quite a few comments on the reliance of, again, lower residual toxicity data out in the field, what we call RT25 data. We thought that that was, you know, again, helpful information for growers, and it was being pretty widely utilized, from the feedback we received. So, we thought that was an opportunity to allow some flexibility for growers to use products when they

really needed it.

Also looking at some crops that are indeterminate bloom or long-term blooming periods, allowing for some flexibility use in products based on the potential impacts of just an overall restriction for any use of pesticide products.

Here is the basic language that we are looking to put on the labels that's included in the final policy document. I won't read the whole thing, but as indicated, for crops that require pollination services where bees are being brought in for pollination services and the crop is under bloom for a foliar application, we're looking at restricting the use of toxic compounds, toxic products that are listed within the policy document.

Under those conditions where -- again, the main words are here, foliar application of this product is prohibited to a crop from onset of flowering until flowering is complete when bees are under contract for pollination services. Again, we do allow some flexibility, and I'll talk about that here in a moment.

Again, depending on the application rate of those products and if they actually exceed the level of concern, again those products would be prohibited.

If they don't exceed our level of concern, again, based on the combination of toxicity and the application rate, those products will be allowed to be used under these conditions.

Again, as I mentioned earlier, there were a couple areas that we thought was appropriate to allow some flexibility around that overall prohibition. One, again, was reliance on lower residual toxicity compounds. So, if a product was identified what we're calling an RT25 of six hours or less, meaning that the toxicity of the compound basically reduces to a level that's acceptable within that six-hour period, these products can be used from two hours before sunset and up to eight hours before sunrise. So, basically, it's a nighttime application to allow for the toxicity to reduce to a lower acceptable level and allow for the pesticide products to dry before bees may be visiting the blooming field.

The other area, as I mentioned, was for longer term blooming crops or indeterminate blooming crops. Again, we received a lot of information on some of those crops that not allowing certain products would have a significant economic impact on the harvesting of those crops. So, we thought it was appropriate for those particular crops to allow

products under a nighttime application. Or, if the temperature is below 50 degrees, we recognize that bees generally aren't visiting the field during that time.

One other change that we made was regarding the environmental hazard statement. This was comments received from the state lead agencies. Some of the language that was included on some products in the environmental hazard section, which is more an advisory section, was too broad and was being too descriptive. It was creating potential confusion in the field and also difficulties in enforcement in the field as well.

Based on the feedback and recognizing that if states are having difficulty enforcing the language, it's probably not the best language to be having on the label. So, we did make some adjustments to the label, but keep in mind we are putting the language that I just mentioned earlier to be in the directions of use.

So, this language basically is again more advisory to letting the growers know that these compounds are potentially toxic and that they really need to follow the labeling and the directions for use to make sure to minimize exposure of the pesticide use

to pollinators.

So, with that, I'll turn it over to Yu-Ting, and she can talk about the latest on the neonics.

MS. GUILARAN: Good morning. How is everybody doing? Good? Excellent.

So, I just wanted to give you an update on where things are with the neonic re-evaluation. So, we're really talking about the four neonics, imidacloprid, clothianidin, thiamethoxam, and dinotefuran. So, as folks know, the pollinator only analysis was released January 2016. We received a lot of comments. I have been going through them. Just kind of going forward a little bit, we also released aquatic risk assessments associated with imidacloprid earlier this year, along with the two other neonics, clothianidin and thiamethoxam.

I know folks have been wondering where is that Federal Register notice. So, we're still working on that with our Office of Policy. As folks know, through transition, there are times that the new administration wants to take a look at what we have put out there. So, that is still in that process.

Yesterday, we had a really good discussion with Office of Policy. Hopefully, people will see the Federal Register notices soon. In the meantime, you

get a preview of what the draft risk assessment is all about and can start taking a look at our assessment and prepare your comments. So, we anticipate a 60-day comment period once we have the Federal Register notices out there.

Dinotefuran is the same position, which is along with all the other three neonics. A tier 1 pollinator risk assessment has been posted and will be released for comment through the Federal Register notices as well.

So, what are we seeing from these preliminary risk assessments? We see some potential on-field risk for some use patterns. Some are low, really depending on how attractive the crops are and the different practices. The seed treatment uses tend to be low risk. Some potential on-field risk for some use pattern is still uncertain.

So, we're anticipating some more data coming in this year. Have some residue data coming in and also feeding studies. So, both are critical information for us to better understand through these tier 2 studies that is there really risk associated with these categories, the use pattern that's an uncertain category.

There are some on-field risks that we have

already seen with some use patterns. A couple of the ones that jump out, cotton and citrus, so I'll talk on the next slide a little bit about where we are with that.

Basically, our overall strategy on risk mitigation is really to engage the stakeholder as much as possible to really better inform us of not only the risk, give us feedback on the risk, but also the benefit of the chemical. So, as folks know, FIFRA is a risk benefit balancing statute, so we definitely need a lot of the information on the benefits to really kind of holistically look at that and also the risks associated with these pesticides.

So, there are a few things that are happening right now that we're reaching out to, specifically the citrus and cotton industries. So, we are talking to both Florida Fruits and Vegetables Association and also -- so, that's in May. And then we also have a crop tour that's coming up for California, which we will also talk to the citrus growers there. We also have something set up with the Cotton Council.

So, all of these are an effort to really understand some of the uses that are happening out there. So, we want to make sure that we understand the implementation and how things are being used, and

also the benefit of the different chemicals.

So, in general, this is kind of a summary of where things are and where we see that things will go. So, for the rest of 2017, first we'll have human health risk assessment for imidacloprid. And then, for the rest of the three, we'll have the preliminary pollinator assessments out there. Then we'll have the human health associated with those three as well. And then the other taxa other than the pollinators.

In 2018, our focus is really based on data that we receive in 2017 to update and revise as necessary and hopefully finalize these risk assessments. And with an eye towards 2018/2019, to have the different risk mitigation preliminary decisions, proposed decisions, out.

So, part of what we're contemplating too is usually our benefit assessment goes along with a proposed interim decision. For the neonics, it's probably a good idea -- and we've been working with our Biological and Economic Analysis Division -- to work on the benefit assessment for the different neonics. So, we will aim to also have that information available so people can provide us feedback so that we can take that into consideration as we're contemplating about the mitigation strategy.

MR. GOODIS: So, I think we're on track here right now. I think we have a few minutes to maybe take some questions on mine and Yu-Ting's talk before we ask the metrics workgroup to report out.

MR. KEIGWIN: So, let's start with Lori, and then Marc, and then I think that's Nichelle's card up.

MS. BURD: Thanks. So, you had proposed acute risk mitigation regulations, but instead issued a policy, which of course does not carry weight of law, and growers are free to ignore. Can you explain why you backed away from the regulations?

MR. GOODIS: Well, we didn't actually propose a regulation. I mean, it was a policy that was proposed initially. Again, this was a finalization of the policy.

We are intending on moving forward with letters to registrants for the products that were listed in the policy to start implementing, you know, the label language changes that I just described. You know, that's being finalized here within the program, and it still needs to go through senior management review before that can be released. I don't have exact timing on that.

I recognize there was some confusion about whether it was referred to as a regulation or not, but

it was strictly a policy, is what was proposed.

MS. BURD: Okay, just to be clear, the Federal Register described it as a regulation.

MR. KEIGWIN: So, I realize there was some confusion in the Federal Register. It got published in the regulation section, but it was clearly discussed in the notice announcing the availability of the draft policy, that it was a draft policy, and not a rule-making.

Okay, Marc, Nichelle, and then Wayne.

MR. LAME: Quick comment and then a question for clarification. My comment is very short. I really appreciate the rigorous work that the Agency scientists have put into this. So, good work.

So, it says on the last page on preliminary pollinator risk assessments that the Agency intends to engage stakeholders to inform itself. So, could you give me -- and I'd like to follow up with this, if possible -- name the stakeholders that you're talking about?

MS. GUILARAN: So, currently, we are looking at a preliminary risk assessment where certain uses are showing risk. So, I named two different grower groups. One is citrus, one is cotton. So, those are the ones that we have planned. But as always, we will

work with also our partner in USDA and also different -- we have different groups that come in and want to talk to us about neonics in general.

So, we are specifically right now going on these crop tours that were originally already planned or adding the citrus part to it so we can better understand how things are going in California and Florida in the citrus. Then we added recently a cotton tour as well. Does that answer your question?

MR. LAME: It does. I just want to make sure that actually, you know, beekeepers and consumers as well are represented in that list of stakeholders, or is that just kind of a if they show up kind of thing?

MS. GUILARAN: We have always had ongoing coordination with beekeepers. So, as always, if there are things that the beekeepers think that we should also make a side visit, we definitely will. We have in the past already done so, and we will continue to do that as well.

MR. LAME: Excellent. Consumers obviously are the end product of any risk here, you know, considering their food source. So, I hope that’s at least part of it, although I know it is difficult.

MS. GUILARAN: Right. So, just to be clear,

we continue to have a transparent process that's associated with pesticide re-evaluation. So, anything that we determine or the benefit assessment on the different neonics and also the proposed interim decision, they're all for public comment. So, people obviously should take that opportunity as well.

We have to address every single comment as we're making our decision. So, that's another way for folks to provide input on how we're doing with our risk assessment, how we're doing with our proposed interim decision, and are we capturing the benefit correctly.

MR. KEIGWIN: Okay, Nichelle, then Wayne, then Cynthia.

MS. HARRIOTT: Hi. I have two questions. The first is your work on non-Apis bee exposures. You mentioned that EPA hosted a workshop recently. From that workshop, does EPA have a strategy for evaluating exposures to non-Apis bees?

Then, secondly, my other question is you got in your acute risk mitigation policy. On one of your slides, you're recommending the use of products with short residual toxicity times. I'm just wondering whether all the chemicals that you considered under this policy have RT25 data. If so, where can I find

that information?

MS. ECHEVERRIA: Good morning. My name is Marietta Echeverria. I'm the director of the Environmental Fate and Effects Division. So, Nichelle, I'd like to respond to your question regarding strategy for non-Apis bees.

Yes, it's correct. We held a workshop in January where we had academic scientists, government scientists, industry scientists, international scientists come together and work through the differences between exposure routes for honeybees relative to other non-Apis species.

So, the next steps from that workshop are to do a comparison of exposure routes that our current process for honeybees may be missing and make an evaluation on whether or not the current process is sufficiently conservative to apply to those other non-Apis species. So, that's the first step going forward.

On the effects side of things, we are continuing to work with OECD and other international partners on the development of toxicity testing for non-Apis bee species, including bumblebees. So, that's where we are with respect to the non-Apis issue.

With respect to RT25 information, we do not

have RT25 information for all pesticide products. So, with the implementation of the policy, the RT25 exception would only be applied to products that do contain those data that we've evaluated and we've found acceptable.

We do have a web site that lists the information that we currently have. We're working on a process to update that information annually.

MR. KEIGWIN: Okay, Wayne, then Cynthia, then Steven.

MR. BUHLER: I, too, want to echo Mark, and thank you for your work on this. I know decisions regarding pollinators are always tricky, challenging.

One aspect that I just have a quick question regarding, the acute risk mitigation policy affecting a crop under contract. Has there been consideration to like neighboring crops, knowing that bees forage two to five miles from the hive? How will that be addressed on the label?

MR. GOODIS: That's a good point. I mean, bees just don't stay in one particular area, obviously. But again, we're looking at those crops where they're under contract for service for pollination and those restrictions would apply. But that's the area where they're most likely to be and

the most likely to have exposure.

Any other applications beyond that scenario, we're relying on managed pollinator protection plans for beekeepers, and applicators, and land owners to have some sort of mechanism to communicate or coordinate the applications and minimizing national exposure of bees.

So, that was the general strategy, you know, that we had set up before. So, that's where we hope or expect that that type of interaction between the pesticides and the products would be addressed.

MR. BUHLER: Thank you.

MR. KEIGWIN: Okay, Cynthia, then Steven, then Sharon.

MS. PALMER: Hi. So, I have two questions. First, with the MP3s, to what extent will EPA guidance require that they include birds, butterflies, native bees, and other pollinators beyond managed bees?

Second, with regard to the pollinator risk assessments, I think it's great that you're focusing on the benefits, and you did some good work on soybeans before. I'm just wondering, for the seed treatment benefits, for which commodities we can expect a similar type of analysis?

MR. GOODIS: Well, I'll start on the first

question. Again, the managed pollinator protection plans are not mandatory; they're strictly voluntary. So, we are encouraging the development of these plans. Again, we're partnering with SFIREG and AAPCO and other organizations on the development. So, the whole concept is to allow the region, the state, or the tribe to identify what the particular issue is within their state or tribal area or region.

Based on the stakeholders that they are able to gather in that interaction, what are the real concerns in that particular area. What's the best way to address them and to make potential exposures? So, the states and tribes have the flexibility to expand beyond managed pollinators. I've seen where through revisions of plans, they've broadened the scope in some states to include habitat protection as well.

As far as other pollinators, again that's an option if they want to consider it. But again, this isn't something that's mandatory. So, it's really up to local stakeholders to identify what the priorities are.

MS. GUILARAN: Thank you, Cynthia. So, as I was mentioning before with FIFRA being a risk and benefit balance, I think we're going to start with the benefit of citrus and also cotton to accompany the risks that we have seen in some of the assessments.

MR. KEIGWIN: Okay, so, after these three, I think we're going to move on to the next part of the pollinator session. Then there will be some opportunity for additional questions at that point.

So, Steven, Sharon, and then we'll wrap up with Cheryl.

MR. COY: I took some notes here. You're looking at better ways to use RT25 data, so I applaud you with that. I think that will be very helpful.

The comment about, let's see, the bee analysis -- I get so nervous doing this. I don't know why.

So, I just would like to remind you that you need to incorporate the impact of moving colonies and the effects that the pesticides have on colonies in two months, six months down the road as opposed to just immediate impacts of a kill when the bee analysis is done to mitigate the risk.

And then, Mike, you mentioned that in the acute mitigation policy, acute risk mitigation policy, that -- initially, you said that the two hours before sunset -- the sun rises and nighttime application. I know several guys are cringing when I say nighttime application. Two hours before sunset is definitely

not nighttime. Then you mentioned the 50 degree temperature thing was maybe not accurate.

So, do you all have any plans on adjusting those times or temperatures on the label to reflect what your intent is?

MR. GOODIS: Right. Well, just to clarify, I mean, I wasn't perfectly clear when I was saying the two hours before sunset was mostly a nighttime application. I get it. You have a couple hours to allow for perhaps aerial application to take place, you know, before sunset. So, that was intended. So, you know, the timing that was proposed was what we intended.

Regarding the 50 degrees, we actually adjusted it from the proposed policy from 55 degrees. Based on information we received, the 55 degrees was too high. So, we actually lowered it. So, again, those are the intended restrictions for the policy.

MR. COY: Okay, thanks.

MR. KEIGWIN: Sharon and then Cheryl.

MS. SELVAGGIO: Hi. There's been some recent data that shows extremely high levels of residues of neonics in ornamental plants, both trees, shrubs, and flowers. I'm curious about the risk assessment process when you have a crop that

essentially moves off field but remains intact. In other words, you know, this is not a manual crop that the residues get incorporated into the soil.

Where does this fall in the risk assessment when you're considering that these residues remain in plant tissue and there's a potential for exposure off field?

MS. GUILARAN: So, we consider potential residues on field, and we would also do a consideration of any residues that we might expect off field. In terms of actual measured residue data, what we actually find, generally speaking, is that there's a refinement to our risk assessment process.

So, at the lower tiers, we're making very conservative assumptions about how much potentially could get into bee attractive matrices. Actually, when we have actual real world data that tends to actually refine our assumptions, it makes the risk assessment less conservative.

So, we will be considering monitoring data and other residue data that are available, both being generated by pesticide manufacturers and also those available in literature.

MR. KEIGWIN: Cheryl.

MS. CLEVELAND: That's a perfect lead in to

my question, which was citrus is a permanent crop, so it's right there. And cotton, as a row crop, is still highly regional. So, has there been any use of some geospacial incident reporting to help confirm or ameliorate the risk assessment? Likewise, has there been any use of any regional use laws for the pesticides that help? You said citrus and cotton are the things that have popped up.

So, has there been incident data from those regions or use logs of those chemicals to help ameliorate the risk assessments?

MS. ECHEVERRIA: So, in terms of utilizing incident data to confirm, we have characterized available incident data with respect to the risk characterization. In terms of actually having enough sufficient robust geospacial location information associated with those data, I don't believe those data are robust enough to make that kind of analysis. If we did have that data, we would be happy to incorporate that into the risk assessment.

With respect to refined usage information, we would consider that in the risk assessment. However, really, what chemical companies have agreed to do in response to our uncertainties around the pollinator risk is to develop a lot of residue data

following actual applications under field conditions. So, those data are very useful for refining the risk assessment. That is part of the strategy.

When Yu-Ting was talking about that sort of middle tier crops where we have uncertainty, those data are designed to address those uncertainties.

MR. KEIGWIN: Okay, thanks, everyone. So, I think we're going to move into the second half of this discussion.

MR. GOODIS: So, we have Don Parker from the National Cotton Council as part of the metrics workgroup that graciously volunteered, right, Don?

MR. PARKER: Graciously volunteered is not what I would call it. I came to DC expecting to have our metrics workgroup meeting and not knowing that I was going to do this. But my distinguished colleague, Tom Van Arsdall, had an emergency fishing trip that came up. It's in D.C., we're all in D.C., so his secret is safe, I'm sure.

Anyway, the metrics group has made some pretty good headway, we think, on a very complex issue and a very challenging issue. It took us quite a while, though, to get our heads around what's actually the question that we're being asked. At first we caught ourselves asking questions about, okay, what

should be in an MP3, a pollinator protection plan.

Now, I want to say up front that whenever I talk about these today, I'm going to talk about an individual plan. You can call it a state plan, a tribe plan. Just for ease, I'm going to say individual plan a lot, but you know what I'm talking about now.

When we got ourselves caught into what are the questions that we need to ask, what's the components we need in this plan, then we realized that's not really what we were asked as a workgroup. That was not really the question that was put to us.

So, I want you to keep that in mind as we start moving forward because I want to very carefully lay out first to you -- because there are some nervous areas around what we're presenting. But I want you to very carefully look at what we're presenting as the entirety.

Whenever you think about the objectives that we brought forward, it's how to look at the state plans and come up with something that is a metric, is something that we can measure. It wasn't how to create a state plan. It wasn't what are the necessary components of a state plan. It was given these, how do you put some type of metric to it.

What we're asking the PPDC today is to look at what we're proposing and think about this as we get through this. Is this response from the workgroup meeting what you've asked us to do? If it is, do we continue in the development of this? That's the big focus for you to think through today in our proposal.

What we're proposing at this point is a point system. I know a point system makes a lot of people nervous, especially in individual states. But I want you to think about the entirety of this proposal. It's not a grading system; it is points, okay. There is no approval or disapproval. That's not what EPA said. It's not what they asked for.

They said is there something here that would help us give some kind of measurement, understanding, as to are these state plans making an impact, are they making a difference. And you're given the state plans already. And they are very diverse.

So, how do you look at that diversity, that complexity of cross different areas, and understand what is going on? The point system then gives credit where credit is due because it will add points for different areas, but it doesn't compare between states. It provides an individual plan measurement that can be monitored over time.

They start out with a certain number of points. They make some improvements. They have better points next year. It gives you a measurement over time. Then you can summarize those across the states to come up with a national metric that helps you realize on a national scale are we making an improvement.

With this type of system, it provides flexibility still for the local groups to focus in on what are the needs of their area. Whenever I show you some examples of what we're getting into here and you think about --

One of the big areas that we have here is participants. I think we all agree that the whole concept around these plans is can you get the right local stakeholders to the table. If they sit down at the table and they start talking to each other about this, they resolve a whole lot of it right there in that room.

So, one of the points would be the various stakeholder groups that you have engaged. Well, in California, that may be huge because you may have many different stakeholder groups. Whereas, in another state, there may be fewer crops grown there, fewer different stakeholder groups to have. So, there's

going to be variability. They're not comparable across states. They're comparable across time for that state.

It's also a mechanism that -- Katie gets nervous when I put this in there, but it's cheap, it's measurable, it's reportable, and it does not imply that EPA has approved or disapproved anything. So, keeping that in mind, and I will touch back on that again, but I want you to keep those in mind, especially it's not a grading system, it's not comparing between states.

Now, we looked at the complexity of everything we were given. We went through state plans. Believe me, if you get on the committee with Katie, volunteer to be the chairman. Do not let her be the chairman. She will load you down with work.

We looked at most everyone of the plans to try to see what are the commonalities, what's here, how do we start pulling this together. Then we identified some common categories that were in those. Then, that's when we started into this concept of this point system that looking at this national metrics and how would you implement some national metric, that we came up with some basic guides.

It's key to keep in mind that you were given

these diverse plans from the get go. So, whenever we started getting those common themes put together and putting them into different areas, we realized that each common category had multiple areas under that. You could kind of line those out for a point system measurement.

There are some other aspects that we've talked about. If we move forward, there's this thing called a rubric that once a point system could lead to how do you group some of this in a rubric. But right now we want you to focus on the point system.

As an example of one of those point system areas, we identified the participants. Like I said, if you think about who are the participants, there is still a lot of questions and all that you have to focus in on around that. Of course, we want all the producer groups there.

So, you get a point for each different producer group that's in this. You get a point for each different beekeeper group that's in this. You get a point for the state lead agency, the extension service, all of these different areas. The nice thing about it is are there some that we didn't think of? Fine. Add them to it. Give credit where credit is due. It provides the flexibility to show what that

state is really putting forth the effort to do.

Then, whenever you list all of this type of stuff out and you give these points, there are some areas that we were a little bit more sensitive about. What about federal agencies? We said give them a point one. No disrespect, Rick. The reason for that is very important. The local people have to own it. So, you can't give a lot of points to outside influence. The value is the local people have to own it.

So, this is one of the categories that we looked at. Then we identified communication where you could list out what are all the avenues of communication that are involved in this plan. Give points for all of those different avenues.

Education, what is your evidence that you have actually given this educational material into the hands of the participants around the country, around your state. That's a whole list of things you can have points for there.

BMPs, how many different BMPs do you have in your plan? You get point systems for all the different BMPs that may be added into your plan.

Progress measurements, so have you got some evidence that has shown that you have changed what has

happened in your state. Some states already have some questionnaires that they have developed. Those questionnaires have asked their participants are you more aware than you were the previous year? That's an evidence of change. Do you bring your stakeholders back to the table on an annual basis to improve your plan? That's an evidence of progress because you're keeping everybody engaged and involved.

So, that's back to the repeat of the slide I started you with, trying to keep this as tight and concise as I could to let you know where we are with this, this point system, but to make sure to emphasize it's not a grading system. It's a self-evaluation that you would provide to that individual planned leadership to tell them, okay, here are the things we need. Do you have the evidence of these areas? You would report a point back to EPA.

We would say that if we need to move forward with this, there would be a guidance document developed around this to explain what's the evidence, what's the different things, how do you lay all of this out.

We want to point out, too, to the group that this system, because of those lined items, it gives a guidance document of its own. Even though you're not

comparing between states, you all know how we all are. If we get numbers, we're worried about it, we've got a grade and who is beating us.

So, it gives some encouragement for others to look and say what did they get points for. Oh, here's something we hadn't thought about. We can add this to ours. So, it helps because it continues to expand and it's flexible. It helps guide continuous engagement and improvement.

So, that brings us just back to the closing of this plan being something that we would offer for the initial proposal to the group. We believe that EPA implementation of it, if recommended by the PPDC, would probably also maybe have a guiding committee over this aspect, the metrics, maybe in conjunction with USDA that would have a board to review what do we add, how do we change this as needed over time.

So, with that, I will turn it back to you.

MR. GOODIS: Thanks, Don. Stay here. So, I think we'll open up for questions. Now, there are actually other members of the workgroup that are on the panel here. If there's anything else that they would like to introduce or contribute to that discussion first?

(No verbal response.)

MR. GOODIS: Okay, we'll open up for questions.

MR. KEIGWIN: Okay, I see Tom, Marc, Liza. We'll start there. Tom?

MR. DELANEY: One suggestion in those different categories, that you might put a maximum number next to some of those so it doesn't get so out of balance. That might be a good thing to do.

MR. PARKER: I think we've still got quite a bit of work around where do you put the points? I think that there is also value in how many points do you give for participants versus did you develop some brochure. Participants are probably more important. So, I think there's still some discussion that we have, but I appreciate that point.

MR. KEIGWIN: Marc, then Liza, then Dawn.

MR. LAME: You know, I find what you've proposed very interesting. First of all, I want to say, you know, continue in that direction regardless of my comments.

I will, of course, also say this is about metrics. And we all know that if you can't measure it, you can't manage it. So, the idea is that we do want to manage it. On the other hand, if you don't have a management plan in place, then measurements are just numbers. So, we want to make sure that there's a

good situation there.

First of all, I am always leery of self assessment. The idea of states doing points the way that you currently have it is an additive situation where you can just add on points, which I'm not entirely against. I think each group you get, add on points, for instance, which I like that.

On the other hand, I think that there probably should be a subtractive element to this. So, if there are states where there are more incidents in a proportional sense, that maybe should be a minus point, just as a matter of metrics. You can have all the points you want, but it can still looked like hell when the thing is over with. So, I certainly would go with that.

Now, I know that's not the new American way. Everyone doesn't get a trophy that way, but I think it's probably a good management scheme.

I would always encourage the use of citizen scientists. There's lots of new research saying how productive citizen scientists are when it comes to this. They can be trained correctly and objectively. They would allow for a different dimension in measurement. So, that would be my suggestion. But good job.

MR. KEIGWIN: Liza, then Dawn, then Nina.

MS. FLEESON TROSSBACH: Thank you. I do understand that trying to determine from a national perspective if state plans are successful is challenging. I do have great concerns about this particular point system. This is a situation where the metrics were determined after states have developed their plans. The vast majority of plans are final or close to final. States were provided guidance, but it's a voluntary plan based on the local state.

So, we have our own measures that are specific to our states. To try to take those to a national level is problematic. The assumption that states are going to change their plan or continue to develop in a certain way to help inform this national success is problematic. It also puts into place, from what I understand, what's going to be required reporting for a voluntary plan that states did not have to do, and people do not have to participate in. So, I have concerns.

I also have concerns because we are human, and we do compare. No matter what anybody says, it will be a comparison between Virginia, who of course is going to have the most points, and somebody else

who is not. But that doesn't mean my plan is any better. So, I have really big concerns about this approach. Any type of -- while you say it's not a grading system, as soon as you put a number onto something, it's a grading system.

I do understand the concerns about self assessment. You know, if this was going to go forward, I'd rather have the EPA come in and assess the plan as opposed to putting that burden on the states. We've already done our work. We did the voluntary work. I believe states have a good plan based on their, you know, situation. They have metrics that I think they are happy to report.

But I do have concerns trying to put plans that were already developed into this system. This should have come first, the metrics, what the national success is and what state plans develop to be able to report the same type of information.

You have states that did not engage any stakeholders at the onset. They drafted a plan, sent it out. They have a plan that was acceptable to their state. You have other states who brought people in. So, you have so many different ways to do that. Grading based on that does not talk about how effective the plan is, and I don't believe that it

necessarily equates to the success of the plan for that state for the purposes.

You have states that are ag and non-ag. You have states that have crop-specific plans and those that have one. So, this system I don't believe lends itself to be able to truly access the success of these plans on a national level.

I mean, I think there's a way to do it, but at least preliminarily and based on what we've seen, I would say I can speak for state lead agencies that we would have grave concerns about this type of a system going into place. Thank you.

MR. KEIGWIN: Okay, Dawn, then Nina, then Steven.

MS. GOUGE: Thank you. My question is just for the whole group. As you reviewed the plans, were there any specific recommendations that you sent back to the people who submitted those MP3s? That's my first question.

I was very encouraged at the mention of mosquito abatement, particularly because we have some areas where day biting mosquitoes are going to be critically important vectors. If there's any additional information you can give us on that, I'd be keen to hear that. Thank you.

MR. PARKER: So, no, we did not send any recommendations back to the plans for the exact reason that she was mentioning there. It's hard to not slip back into the thought of are we trying to come up with a plan. No, we were not.

As we understand it, the question to the committee was, given these plans, how do we, without trying to change them, without involvement of them, they're not approved, they're not disapproved, we're not shaping the plans, given the plans, how can you put some type of metric together to get some idea of what they're accomplishing? So, with that, that's why we went that way.

The mosquito abatement or victor control type things are another group that had been identified by some states, not all, but some states had that in their plan. So, our whole approach on this was you don't have to check off each box, but give credit where credit is due. If this state went this direction, acknowledge that. If this state went a different direction, acknowledge that. It probably fit their local needs. But it gives you a way to see how they're progressing over time.

MR. KEIGWIN: Thanks.

Nina, then Steven, then Sharon.

MS. WILSON: Hi. So, I'm unclear when you talk about the metrics. Are the metrics bubbling up and you're looking for common metrics across the states that came from the plans that would be nationally accepted metrics and then have a corresponding point for a specific metric? I'm not sure I understand exactly how the point system works, beyond just the participation.

MR. PARKER: Okay. So, in this scenario, if you went through and gave a point for these various areas for that particular state plan or that plan, and then you sum that up, then you have a measurement for that state that year. The next year you do the same thing with their plan.

MS. WILSON: It's not common metrics; it's by state. They have their own stated metrics by state, okay. So, I understand the concern about the quantitative measurement not being exactly representative maybe of what's going on, but that doesn't discount that you could have a qualitative portion of that -- it doesn't have to be just all quantitative as well.

MR. KEIGWIN: Steven, then Sharon, then Richard.

MR. COY: Don, I know you're waiting on this

question. The purpose of the MP3 plans are to protect managed pollinators. The charges the EPA gave the workgroup is real close to impossible. I'm on the committee, but I just listened to a few of the conference calls. I mean, I think what you all have done is really good. It's beyond what I could have conceived it to come up with.

But the purpose of the plans are to protect the pollinators. There's no measurement of how pollinators are being protected in this point system. It's actually just measuring the plan. It's not measuring the objective of the plan, which is what I see as the point of this whole exercise.

So, any thoughts on how to measure the effectiveness of protection of the managed pollinators?

MR. PARKER: Sure. How much money do you want to put up? And that's what we wrestle with quite a bit. You know, we had a lot of discussions about different things, but with the recognition of they're all costly. The committee was trying to do its best not to try to put any unfunded burden back on the states.

Now, obviously, yes, there's a little bit of answering some points that may be put back on the

state, or it's possible EPA could do it themselves. But they'd have to ask states to submit the evidence and all. To say that it's not measuring anything, you would essentially be saying that you do not believe the goals of the state plans have anything to do with pollinator protection. I believe that the goals of the state plans do have a lot to do with pollinator protection.

I believe whenever you get those stakeholders to the table and they sit down across from each other and start working out commonalities, that that is a very strong change in pollinator protection right there. Does it measure pesticide residue? No. Does it measure the level of varroa mite? No. But it measures a cooperative group that is working together to try to mitigate risk.

MR. KEIGWIN: Sharon, then Richard, then, in the interest of time, we'll just see if there are any PPDC members on the phone who want to speak. Then we'll conclude this session. So, Sharon?

MS. SELVAGGIO: I think this is a really intriguing framework that you've come up with. I have a few different thoughts and questions. First of all, there are people that kind of specialize in evaluation. I'm wondering if you had anybody like

that on your committee, because evaluation is sort of its own science.

So, just to kind of build off Steve's comments about implementation monitoring -- in other words, have you basically monitored the plan versus monitored the outcome? I think that that's an important point and something that if you ran this framework by people who are skilled in evaluation, you might be able to get some good feedback. So, that's one comment.

When you talk about locally driven, I think there's a lot of strength in that. I would suggest that maybe there might be baseline measures that should be assigned points separately from add-ons that might be suggested by local stakeholders. So, if a set of baseline measures that is considered important enough that you would want every state to try to achieve full points on that, just because of the point tendency that we would have to sort of assign points for whatever and have this grading system, it could become meaningless. So, I think that there's a need for certain baseline measures independent of whatever local stakeholders would add on.

I guess my last point is that we didn't really see enough on the detail from what you

presented, especially on the progress measurements. That's the most critical piece because, again to go back to Steve's point, if you are giving people information, knowledge is power, but people may not implement best management practices no matter how many times they hear them. This is a voluntary effort. It relies not only the information but on people's willingness to implement and actual implementation of those measures.

So, I would suggest that you have within your progress piece of this an ability to measure people who have received the information, have they actually implemented it. I think you need monitoring on behalf of the pesticide applicators or the farmers. Have they implemented these practices, these best management practices, to really understand if in addition to whatever objective measures you might collect on bee health and so on and so forth, to have some idea of whether people are actually taking this information and putting it to use.

MR. PARKER: We had that discussion as well. We did have some evaluation experts to come in and talk. We talked about the complications around these measurements. A lot of times it still goes back to what is the question.

The question we were asked was, without interfering with these voluntary plans, how would you create a metric. That's very hard whenever you're wanting to talk about okay, let's mandate a monitoring on this. Well, it's a voluntary plan. You can't mandate a monitoring on it.

So, given what is here, can you put some type of indices here that gives us an idea over time that it's doing something. I mean, the committee has gone from starting to think about what exactly needs to be in the state plan to what's the questions that we need to ask of a state plan.

Then it all kind of turned around and said we're looking from the bottom up. We're not supposed to be starting at the state plan building process. We need to be looking from the top down saying given this set of cards, how do you make sense of what's going on.

This was our proposal that we've come up with at this point for the committee. Yes, there's still a lot of work to do on details. We do have a list. The committee decided that maybe under each of those categories, that long list was a little bit too much on a slide for everybody to digest in this time, because our question mainly to you as a committee is,

do we move forward with this? Is this the direction that meets what you're asking the workgroup to do? Do we move forward with this to develop that other and to develop the guidance around what those areas are, or do we need to find a different avenue?

MR. KEIGWIN: Richard?

MR. GRAGG: Okay, I'm a little confused on this whole objective here. You said that you were asked to come up with your approach without interfering with the plan, right? So, then, to me -- and if you're looking top down, then, then you, in my opinion -- one approach is to measure or assess whether or not the plans are being implemented or operationalized. That's a yes or a no. Then there's a degree of implementation.

Then, the other, from a top down, in my opinion, is whether or not the plan is achieving what they said they were going to achieve. If you're not going to interfere, you're not going to go into the weeds, then, to me, I think your numbers or your metrics or your rubrics should be around those two things.

Then one way in terms of a national approach is to assess the plans and group them in terms of maybe some similarities. Then you may have different

pools. Then you could group those together in some type of assessment outcome or indication.

But I do think as well that you should work with the states to get them to collaborate with each other in terms of improving the plans based on EPA's analysis or assessment or review. I do think it's very important on the evaluator.

I think looking back, in an ideal situation, you would have an evaluator help the states put together the plan. The whole thing the evaluator is putting into the plan is helping them set it up to accomplish their objectives. So now going back, maybe an evaluator could help them improve that, get those things in there. That would be a benefit to the state. It's not a burden. You would be lending some level of assistance, so I think it would be received well.

MR. KEIGWIN: Let me just check and see if there are any PPDC members who wanted to speak on this topic who are participating over the phone.

MR. HANKS: Rick, this is Doug Hanks.

MR. KEIGWIN: Go ahead, Doug.

MR. HANKS: In the past four years, this pollinator issue has been on the table. It seems like it's been in my estimation pretty well discussed and

gone through. The original four metrics that we talked about, if you look at the plan, the fifth metric that I'd only suggest, is the awareness now from 100 percent to 1,000 percent. That ought to be included in these metrics of these plans as we've discussed today. That's all I wanted to mention.

MR. KEIGWIN: Thanks.

Any other PPDC members on the phone who wanted to speak?

MARK: This is Mark with Apiary Inspectors of America. I just wanted to throw out there --

MR. KEIGWIN: I'm sorry, you can participate or make a comment on this during the public comment session at the end. Right now, this is only for the members of the PPDC.

I think Dawn had one more comment to make, and then we'll conclude this session.

MS. GOUGE: Thank you. I just wanted to back up the comments -- but I would ignore that. I really think that this is a lost opportunity for anybody to go through all of these plans and review them and then not give feedback to those people. I'm even okay with the self-assessment part because I feel that the teams that are looking for opportunities for improvement will take any feedback that you give and

work on it.

They're voluntary, so nobody is mandated to do anything. I think you're in a position of great strength. Feedback that would be given would be at the discretion of the groups involved to put those practices. But to go through that process --

I also wanted to ask if that's an evaluation or review that's going to happen annually, or even if the team comes together annually. Getting some feedback now would be something that they may choose to implement over five year plans or however long. Thank you.

MR. KEIGWIN: Mike, anything to wrap up?

MR. PARKER: No, I don't think so. Is the consensus of the committee that the workgroup should move forward based on that the feedback received in general? Is the approach and the scope of the efforts meeting its initial goal? Again, the goal is to provide a final recommendation to the committee in November. I think the group will be on track to do that if this is the right direction. So, violent objections?

MS. FLEESON TROSSBACH: I do have grave concerns about the point system. I understand what EPA is trying to do. I understand the purpose. I've

been involved with this since the very first time it was mentioned about pollinator protection plans. All state lead agencies have, AAPCO has, SFIREG has, and we've expressed our concerns.

I do believe that there is a way to measure the success on a national basis. I think it needs to be based on the state plan. The way they developed the plans, we were given latitude to develop them as we saw fit, measure them how we saw fit for our state, for our industries, for anywhere there's crops, for our apiary industry. I think a point-based system just is not going to really give you that particular measure.

I think that I would personally like to see the workgroup go back to the table and not necessarily get rid of the idea behind the point system, but I agree with my colleague here from Florida A&M that the plans are already in place.

Virginia has worked on our plan for 18 months, and it's now final. We've done a lot of work on our plan because we were given that latitude to make it our own. We're open to comments, et cetera, but we were given the ability to develop our plan based on our program. We have our own metrics. If you want to look at our metrics and somehow maybe

group categorize, communication was a big focus on this, do that.

So, I think it can be done. But, once again, I have concerns about the point system, and those particular items that were pulled out, and how that data is going to be used. Our plans have never been evaluated by anybody else except our own stakeholders and our agencies.

The EPA indicated straight up that they're not going to approve them, they're not going to review them. But yet, we're going to be measured based on our plans and our components for our plans, when all we were given was guidance and latitude.

So, once again, I just have grave concerns about that approach. I do believe there's a way to measure it, but I think additional work and other considerations need to be taken into play or into consideration.

MR. KEIGWIN: So, what I'm hearing, noting Liza's remarks, is that the workgroup should continue doing work mindful of the point that Liza and Richard were also making, that these plans are in place. So, sort of a retroactive development of metrics could be challenging, but the workgroup should continue working and let's see where you all are come November. Does

that work?

MR. PARKER: All right.

MR. KEIGWIN: All right, so that was a great discussion. The downside is we're 15 minutes behind already after the first topic. But I think we can make up some time. So, why don't we come back here at 11:00. That clock is only a few minutes fast, so keep that in mind.

(Whereupon, a brief recess was taken.)

MR. KEIGWIN: So, our next session is Preparing for Future Products of Biotechnology. So, let me turn things over to Bob McNally, and he's got a crew that's going to work us through this session.

MR. MCNALLY: Yes, thanks, Rick. I just wanted to say that when we discussed ag biotech with you all last fall, we covered two areas, if you might recall, from that session. There was a White House memo issued in 2015, and it sort of outlined three things that the federal government needed to do. The first was the coordinated framework update. That was to clarify the current roles for EPA, FDA, and USDA. As we talked about in the fall, that was issued in September 2016. That's just updating the roles, or clarifying the roles, in the coordinated framework.

We had a presentation by Mike Mendelsohn on that.

The second piece of that memo was to outline a long term strategy for ag biotech. That also was issued in September 2015. My sense from that meeting, you all had a lot of interest in this area, so we're sort of back here for a sequel.

We did not cover the third item then because it had not yet been issued, and that's the item you see here. It's the NAS report on ag biotech. That was issued in January. That's available online if you'd like to get a copy of that.

What we want to do today, though, is provide an overview of that report's key information as it relates to your mission here with PPDC. There's other information there you might find interesting about how the federal government should improve its training, should improve its risk assessment processes.

But we want to focus in on what you were interested in last fall, which is what are these technologies, and how might they have pesticidal applications that are of interest to you, and when might they arrive here at EPA, and, more importantly, what do they mean to you in terms of who you represent here at the table.

So, the feedback, we have questions in the back of the presentation that we need from you. It includes these novel technologies, might they address some of the issues that are important to you. If so, how? The second question is, do you have concerns with these technologies. If so, what are those concerns? And then, what other stakeholders need to be involved in this discussion?

Now, as I said last fall, in a few years, rather than the topics you see on today's agenda, we might have new ones that are very, very specific to these technologies. So, sort of in the movie nomenclature, Chris Wozniak's presentation this morning is kind of like the coming attractions that you see when you go to the movie theater. However, we think in the very near future, some of these technologies and their registrations may become sort of the feature presentation.

So, today we want to give you an overview of some of those and get feedback. So, with that, let me introduce our sort of leading man to go over this morning's coming attractions. Chris has been following sort of the horizon scanning with these technologies for a number of years and has a lot of expertise in these areas.

So, with that, let me turn it over to Chris for this morning's presentation.

MR. WOZNIAK: Thanks, Bob. I've never been introduced as a sequel or a coming attraction or a leading man, but I think that's a positive thing. Get your popcorn, and we'll get started.

So, as Bob mentioned, this is like the third prong of this effort where we had the CF update, long-term strategy, and then the NAS, or National Academy of Science, engineering medicine report came out a few months ago.

By the way, I apologize. I meant to put the URL on here. I can send it today. I can send it around to you. There's a PDF of this available online for free, so you can download all 200 pages of it. It's a thick, meaty document. So, my emphasis when I say brief summary is on "brief". We're going to focus on one particular area.

So, this slide here, the first one, is one that I borrowed from Richard Murray, the panel chair of that committee. Again, this commission of an external independent analysis of the future landscape, basically an attempt to be as clairvoyant as possible and looking 5 to 10 years out.

Again, a rather meaty report, so there are

several areas here, all very interesting. My focus is going to be really on number 4, on understanding risk related to future biotech products. Quite frankly, what are some of those biotech products.

For some of them, the future is already here knocking on the door. Other ones, again we have to extrapolate and speculate a little bit. But yet, given the way the technologies are moving forward so rapidly, it's certainly within the realm of possibilities without any hyperbole needed.

So, statement of task, the panel had several areas that they were to address. Some of my colleagues would say there were some things that they weren't supposed to address, but they still did. So, I think we definitely got our money's worth in that respect.

Again, I'd like to focus here on the potential for these future products and whether they pose different risks. Are they somehow different than the regulatory system as we know it today and our risk assessment processes won't be able to handle it? That's the simplest way to put it.

So, we're going to look into some of those specific products and talk a little bit about the potential challenges that they will give to the

agencies. I also want to point out that regulation is not static. We're constantly horizon scanning, but also improving our techniques for risk assessment or just trying to further our understanding of possible exposures in the environment to all kinds of biotech products from microbials of all different kinds to plants and even mosquitoes.

So, here's a partial list of some of these novel products. On the right side I put a time frame. This is, in some cases, I think, pretty accurate, in some cases it's my guesstimate or my speculation. I'll point where that is the case.

So, these male-sterile genetically engineered Aedes aegypti, or yellow fever mosquitoes, for population suppression, they're obviously a reality. You've certainly seen them in the news lately. They're in review at FDA currently, and I'll talk a little bit more about that in detail a few slides later.

The Wolbachia-based mosquito population suppression mechanisms, those are already in house and being reviewed. Again, I'll go into more detail in a minute.

Gene drives, that's a really interesting area, I think. This is for both plants and animals.

This could be for something agricultural like pest control, pest management. It could also be for conservation. There's a group that's working, for example, on rat and mouse control on Pacific islands. I'll go into a little more detail later as to how this might work.

There's currently a moratorium on use of these gene drives, so again, we're looking probably at 5, maybe even 10 years out, before they're a reality in the environment. However, in laboratories and in discussions and meetings, these are already here and being discussed thoroughly.

I'll talk a little bit about the American chestnut and the efforts to engineer that for blight resistance, one of my favorite projects. That is also, shall we say, knocking on the door.

The microbial consortia is something that the panel paid some attention to. Some of these may be more TSCA oriented. They may be more for soil remediation. They might be for geomining. But some of them could have pesticidal properties.

The reason that this is significant is that it's quite likely these microbial consortia will have novel genetics. They may have synthetic sequences, even synthetic non-natural nucleotides. They could

certainly have kill switches, most likely will to prevent their spread and persistence in the environment. So, there's a whole area there.

Again, I applaud the panel for focusing in on that, because, as I said, I was impressed when I saw the presentations on geomining and people using bacteria to concentrate metals and things. This is exciting stuff.

Synthetic double stranded RNA for RNA interference, inhibiting gene expression, again, already here. There will be nuances, changes to it, certainly. Some products we haven't seen that we know are out there by talking to academic and industry researchers. Some are already, like I said, in house in review.

These genetically recoded organisms, this is again a case where you're literally changing the genetic code so that organisms that you release may not be able to talk to each other. In other words, they can't exchange DNA because they're using two different sets of score cards to express genes. So, these are all things again, maybe a few years down the road, but certainly within the realm of possibility soon.

And gene edited plants, microbes, animals,

we've seen a lot of that in the news, certainly. These could be small tweaks to the DNA sequence that can have major ramifications. In some cases, they're knocking out a gene. In some cases, they're turning on a gene. In some cases, they're modifying the protein that's produced by that gene, et cetera.

So, there's a whole gamut there. We have not seen these come through the door yet. Other regulatory agencies have, however. I have no doubt that it's just a matter of time before one is submitted to EPA.

So, I'll talk a little bit initially about the two mosquito products that I mentioned. Again, the emphasis here is on population suppression. The first, the Wolbachia pipientis, this is a bacterium that lives symbiotically within the cells of certain insects, really about a million species. Some people estimate about 60 percent of all arthropods have Wolbachia of one type or another in them, also in some crustaceans, some nematodes as well.

The beauty of this system is that you end up, if you have mischaracterized strains -- in other words, the male and female have different strains or one is missing a bacterium completely -- you end up with non-viable eggs. Therefore, the population goes

down over time.

The second is the genetically-engineered or oxy type mosquito that I mentioned in the previous slide. Again, this is already in field testing in other countries and on the verge here. It's being reviewed currently at FDA.

Both of the technologies work through a release of just male mosquitoes. I want to emphasize that. So, these mosquitoes aren't the kind that can bite people. Secondly, they're incapable of reproducing. They're short lived, so they don't persist in the environment.

So, first we'll talk about the OX513A mosquito from Oxitec. This is one that I think is really a nifty system where in the laboratory you have the larvae in your little pan of water. You keep tetracycline in there and that keeps them happy and they're able to reproduce. Once you remove the tetracycline, they'll die. So, that's a bit of an oversimplification, glossing over some molecular biology, but for the sake of brevity, they require the tetracycline to complete their life cycle.

There's also a red fluorescent marker protein in there that can be used to track these in the environment. So, when you release the males and

they're carrying this DS red protein, they mate with the native females, and you can see it in the offspring. The interesting thing about this one is the larvae go through their first few molts and actually compete with other larvae in their little puddle of water. It's significant from a competition standpoint. Then they die before they would pupate and go on to become adults.

Again here, population is the stated goal. It's not about saying this will eliminate Zika or change the disease incidents. That certainly could happen. But the claim is for population suppression, and that's one of the reasons that EPA has pending oversight over these mosquitoes.

As I mentioned, outside of the country there is credible efficacy data in several instances and ongoing studies in several countries. Both of these products require repeated release. The amount and how often you do it will depend on the situation. Early in the season when the populations are high, you're going to be releasing more mosquitoes because you want about six or seven times as many males as there are native males that are going to compete for the females. So, you do your baseline measurements, your range finding before and then you do your releases.

These only last a couple days in the environment.

So, you release them twice a week, maybe in some cases even three times a week. You're constantly monitoring to see what's happened to the population. And over the course of a few months, you would see that population go down in some cases, the published studies, 92, 94, 96 percent. So, that's pretty significant.

So, I mentioned FDA having current oversight. To kind of put it in a nutshell, currently there is a guidance document that was published online for comment. The comments were received. We're waiting for that document to be signed off on over at FDA and the Center for Veterinary Medicine.

Following that, those mosquitoes that are indicated for population suppression will come to EPA for oversight. Those that are making claims of say reducing viral titers in the mosquitoes or reducing the number of virus particles or the incidence of a disease, that's an animal drug. So, that would remain with the Center for Veterinary Medicine as an investigative new animal drug.

So, on the Wolbachia, I mentioned it's a bacterium. However, it's one bacterium that you just can't culture in a petri dish the way you can with so

many others. That has frustrated a little bit of the research, although it made some great headway in understanding the mechanism quite recently.

As I said, about 60 percent of all insect species, depending on who you ask, are presumed to have this. There are some mosquitoes, for example Aedes aegypti, that typically don't. There's one report of one incident of having a natural Wolbachia, but, in general, they don't.

That's significant because again, as I mentioned, if you release the males with a Wolbachia strain and the native population of females don't have a Wolbachia, then you end up with these non-viable eggs. The eggs are laid. You've occupied the female's time for mating, but it's a dead end.

So, again, you're looking at population suppression over time with releases, again, occurring depending on the density of the area, the number of houses in the area. You might be trying to (inaudible) this mosquito in, the population of the mosquitoes themselves, et cetera.

So, again, the releases, take them with a grain of salt, once, twice a week, maybe even three times a week. Again, monitoring with ova traps for eggs and adult traps to see where the population is

going as you progress through the season with multiple releases.

You know, with both of these technologies, I mean, they are only limited by how many production facilities you want to build, basically, and produce. You can produce millions of mosquitoes a week in a relatively small facility. Again, depending on the density of area where you're trying to treat, you can treat whole neighborhoods, even small cities.

Some of this has gone essentially commercial in Brazil, for example, with the Oxitec mosquito. If you're interested, again there's a great little film on line about five minutes and it shows you how they do it. It's rather impressive.

So, the regulatory status, if I didn't mention it earlier, this is a microbial biopesticide because we're dealing with a bacterium. There have been some field trials in California, in Kentucky, upstate New York. There are a couple pending here, some that actually have just started releasing in Florida and also in certain parts of California. There's also a pending registration for Aedes albopictus, the Asian tiger mosquito, that will likely be completed this year as well.

So, I mention these products because they're

on the cusp. I mean, they're right here ready to go. There's already been some field testing. So, we will see how that turns out, how the data looks.

In terms of gene drives, again, this one is a little bit further in the future, as I mentioned, simply because I think, appropriately, the scientific community has said this is a very powerful tool. We really need to think about what we're doing, and we need to get input not just from the scientific community but from a broader cross section of society.

The way this works is simply to skew the inheritance of a specific gene. So, for example, we typically have paired chromosomes. We have 23 pairs in our body. You've got roughly a 50/50 chance of getting the genes from one or the other into the sperm cell or an egg cell. With the gene drive phenomenon, you can get essentially 100 percent.

So, if you want to drive that gene into the population, every single offspring is going to contain your gene. So, that's extremely powerful. You can see, if you put in a gene that deleterious to an organism, you could, in theory, drive that organism to extinction. So, that's a different scenario than what we're used to dealing with.

Functions in sexually reproducing organisms,

if your organism clonally propagates like some plants do, it's not going to work. It's not going to work in bacteria or viruses. Won't work in long-lived elephants, humans, other things, whales. It's not going to function there. But for a lot of other things, you can see some annual weeds perhaps could be the target of a gene drive, mosquitoes, rats, and mice, as I mentioned on Pacific islands.

So, again, the National Academies has done a great job with the report. There's the URL for those of you who are interested. Again, a thick document, good bedtime reading. But it's very interesting stuff, and there are meetings going on, I can tell you, all the time around the world, people focusing on what can we do with these gene drives and what should we be really considering ahead of time before we get to that point of environmental release.

Island conservation dot org has a good website. Again, I urge you, if you're interested in more detail, they have some published peer review articles, as well as press releases on there. I don't think I need to tell you just how devastating some of these rodents have been on certain islands, I mean, just wiping out bird species as well as changing the flora as well. They really ruined some areas.

Dropping broad spectrum toxic pesticides has helped to some degree, but it also obviously has its consequences and costs. So, this would be a really powerful technique.

I should also mention some of these, and one of the ones that they're considering, is a naturally occurring gene drive. They still have to do some genetic engineering, but it's not like the CRISPR/Cas9s you may have heard of; it's a naturally occurring gene drive in this mouse where only males are produced. With a world full of male mice, what can I say. But anyway, it's a dead end for the population.

The great thing is, starting this off on an island kind of makes sense because whether it's a mosquito or a mouse, if there's some level of containment simply by the geographic isolation of the island, I think some people would be a little bit more interested in it.

Another example, avian malaria carried by mosquitoes, wiping out honey creeper species on Pacific islands. That's another area where folks, both government and academic and private, are looking at potential for attacking that mosquito on these islands, driving it to extinction at least locally,

and hopefully saving the honey creeper species from extinction.

RNA interference with pest control already here, but there are some nuances that we haven't seen yet but we likely will see. So, these can be expressed in plants. We have that already under review. It's actually been registered for a seed increase for corn root worm control.

But here's an example where this is a group at Beltsville that's highlighted in the URL at the bottom, the UMD EDU news. They're looking at brown marmorated stinkbugs and gypsy moths and targeting again specific genes that you can silence. So, you pick a gene that's specific to that organism. You get the sequence just right, and you make sure that that gene is important enough that the organism either dies immediately or can't reproduce or whatever, but just simply leads to population suppression.

Now, some of these can be even as a spray. I mentioned it can be expressed in plants. You could express them in bacteria. You could put out live bacteria with these or you could heat kill the bacterium and use them just as a carrier and a production model for your double strand RNA. You could put your double strand RNA into a bait, whether

it's for ants, fire ants or something like that, or whatever, and have it target them. It doesn't work in all species the same. Certain lepidopteran (phonetic), for whatever reason we don't fully understand, it doesn't seem to be as functional, but it certainly has great potential.

So, I should just mention these can also be used to reverse herbicide resistance and weeds. So, you can target the gene that's giving the resistance and potentially, at least theoretically, tank mix it with the herbicide and undo the resistance and kill it at the same time.

Gene editing for plant disease resistance, we have not seen this come in, as I mentioned earlier. Other agencies like APHIS have seen these types of products come through their door. We will soon. I have absolutely no doubt.

So, I'll just give you one example of the power of this technique. This doesn't have to but often uses CRISPR/Cas9 for gene editing. TALENs are another method or another product that can be used to edit the gene sequence at a fine level.

So, this one is bread wheat. Bread wheat isn't simple the way I mentioned, where we all have paired chromosomes. Well, they have three sets of

pairs. So, when you try to breed this conventionally, it's like the whack-a-mole. You do something here and something else pops up. It's very difficult, if not impossible, just to breed in this resistance for this fungus that causes a powdery mildew.

With this system, these folks were able to change all copies. There's really three sets times two, so it's six alleles, or six genes, and edited in one fell swoop. Basically, what they did, I mentioned, there's 530 DNA base pairs changed. It sounds like a lot, but if you consider the size of the genome and the billions of (inaudible), it's minuscule.

These are gene knockouts, so there's no new protein produced. No potential for allergenicity alterations, other than what wheat already has. If you look at the picture on the lower right, you can see on the far right that leaf surface is clean. The others all have the little white spots, the mildew on them. There's a big reduction, obviously.

In fungicide use, if you don't have the fungus, you don't have to spray. This can be a very devastating disease in terms of yield loss. But, in addition, it's a timing thing and you have to play games and predict. Well, I think it's going to be a

bad year; I'm going to go ahead and spray. So, your fungicides may or may not hit the target, may or may not be needed, but you sometimes can't wait to put them on. So, the reduction here is significant.

There's an interesting article there on PBS dot org that I mentioned below, if you're curious again. It's called Editing Out Pesticides. So, these can be really powerful tools for reducing all kinds of pesticides, not just fungicides.

American Chestnut Research and Restoration Project, as I mentioned, is one of my favorite topics. I think it requires big thinking and a brave heart, so to speak. This is totally out of the normal paradigm of OPP in the sense that at least with biotech, we tend to look at highly managed row crops and things, cotton, corn, potatoes, et cetera, some public health pest control.

This is about engineering a tree and putting it out into the environment all over the place. This map is the historic range map of the American chestnut. You can see from Maine to Mississippi, quite extensive, obviously a dominant tree in the eastern forest at one point. Thanks to this fungus, there are just stumps with sprouts for the most part left. There are a few isolated populations of trees

in Wisconsin and up in the northeast.

But basically, without genetic engineering, the breeding efforts with the Chinese and European chestnuts, it helped some, but you don't necessarily get an American chestnut habit. The form is not the same, and you don't get the degree of resistance that the Chinese trees already have.

So, coupling that breeding scheme with this genetic engineering I think will be a successful route. Bill Powell, who is at the State University of New York in Syracuse, is headlining this effort but by no means works alone. There are state chapters all over the eastern seaboard that deal with the American Chestnut Foundation and academic institutions that are trying to move this forward.

The nice thing about it is it's a fairly simple system. They took an oxalate oxidase gene from wheat, put it in there. Oxalate is critical for this fungus to do its damage. You knock out the oxalate, you don't get the damage. It doesn't mean the fungus can't maybe hang on and grow there for a bit, but it does not cause the big cankers and the damage that really are the death now of this tree.

As I mentioned, the ultimate goal is to put it out there. It raises questions like, well, who

owns it, is this going to be -- as Bill and I have talked, this is going one of those grandiose projects where by the time it's successful, everybody that worked on it is going to be dead. That's the simple truth. So, you have to have some foresight.

As I said, I have a brave heart and realize that all this effort, you'll never know if it really worked. But we do have some preliminary data from APHIS field permit that these trees are looking good and they'll continue to be bred with other American chestnuts that the foundation has identified.

So, APHIS would regulate this because there are plant pest sequences involved and the genetic engineering of the chestnut. Of course, we would look at it because it's a pesticidal mode of action for that transgene. FDA would probably look at in a voluntary sense. It's not clear since they look at allergenicity issues whether the use of a wheat gene might raise some issues with them. That's all still yet to be decided.

But we have had several meetings with this group, the three agencies, and certainly we think that the safe exposure to this oxalate oxidase gene, which is present in all kinds of grains but also a lot of dichod or vegetable species, things we eat pretty much

every day. So, there's no reason to think that the oxidase enzyme is a health issue.

So, general predictions, I mentioned they're trying to look out 5 to 10 years. But one thing that's clear, more complexity for sure, just the diversity of the types of organisms, but also the techniques used to create those organisms. This idea of sort of having A, C, D, and G for your nucleotides and your DNA and adding in a new one changes the language, literally, for the DNA. That's something new.

Having synthetic sequences where you replace the whole chromosome in a fungus, chromosomes that have never been seen before in a natural environment. Those are going to present challenges to the risk assessment. Certainly, there would be a lot more likelihood, I think, of probabilistic quantitative risk assessment and also based on modeling to try and understand this. I'm not sure some of the experiments could be done in a typical manner the way we do with acute tox studies, for example.

Also, the diversity, obviously pesticides, that's our interest. But these will run the gamut, I mean all kinds of products. There's some of them I wish I could tell you about I've been talking to. The

companies, of course, are very silent on what they want to do with some of these newer products. I mean, they touch your lives in all kinds of ways, not just on the pesticide side of things.

They also caution that the number of products coming in could really increase and that, as Bob mentioned, they suggested probably more training and, quite frankly, even possibly just more people to deal with these in the sense that if there aren't adequate people to deal with the risk assessments and the regulatory and legal matters, that it's always possible you'll hold up progress. So, that's a consideration from the panel.

So, the conclusions, as I said, this is very lengthy. I apologize for just taking one slice of this report. There's a lot more in there. Certainly, as I said, if you crack the cover on that file, you'll see what I'm talking about.

I think I've covered most of this already, so I won't say much more about it. We continue to look over the report, even though we've read it several times. Over time, the types of products we see will no doubt cause us to go back and reflect on what's been said in that report, and even the one before that, the one that I guess came out in 2015.

Fred Gould ran that panel on products of biotechnology as well.

So, we actually do stay in touch with some of the panelists and have a back and forth, almost a debate, about certain topics. So, this is a living document, so to speak.

So, with that, I guess we get back to the feedback area. We certainly would appreciate your input. Bob already went over some of these points, so I won't reiterate them, but we're certainly open to questions.

MR. MCNALLY: Maybe just to start, if you have any clarifying questions for Chris on the technologies, then, if you want, we can turn to the questions on the last page here to go through and get feedback and advice from you all. But any just general questions about the technologies that Chris could perhaps clarify?

MS. PALMER: Thank you. That was a tremendous presentation, really interesting. So, I appreciate your putting it together. I think that in particular the mosquito control technologies have real potential for human health. They may also have potential in the Hawaiian islands, the bird extinction capital of the world. We are very interested in those

technologies for the control of avian malaria.

So, I wanted to ask, it seems like the regulation of the Wolbachia is fairly straightforward as a microbial pesticide. But my first question is, with the Oxitec genetically-engineered male mosquitoes, you said that FDA has those now and the ones for suppression go to EPA. I'm wondering, once they get to EPA, what is the process and what can we expect when they get to EPA?

My second question is with regard to the gene drives. We do have more concerns, obviously, about those and potential global consequences. I'm just wondering is there some sort of international regulation or treaty or something underway so that we don't have to worry about what might happen in all the different countries developing those gene drives?

MR. MCNALLY: Thanks Cynthia. Let me handle the first question. Maybe Chris and I can do a tag team on the second.

I think your first question is what happens when it's sort of given to us in terms of the transfer from FDA. Basically, the company, just like the Wolbachia group, could pursue an EUP with us. There are possibilities for a Section 18 with us. Obviously, the reason you do a Section 5 and EUP would

be to perhaps get additional data that would support a Section 3 registration.

One thing we've committed to do in the previous administration is that for any of these novel technologies, we feel it's important to have an independent peer review with our science advisory panel. So, I can't prognosticate the future, but that's how we've handled things in the past with BTs and with RNAI. I think that would be something we would do in a similar fashion. So, to answer your question, the company could pursue a Section 5, a Section 18, and ultimately a Section 3 registration with us.

On the second question -- are you aware of anything in terms of internationally, Chris?

MR. WOZNIAK: I'm not aware of anything specifically intended to address gene drives. I would think, to some degree, the Cartagena Protocol on biodiversity and transfer, what they refer to as LMOs, cross country lines, might have applicability in some cases. But that's obvious concern, as I mentioned, that you can potentially cause an organism to go to extinction. Once it's released, how do you stop it from crossing a border.

There are considerations already underway

where people talk about various technical fixes, so to speak, remediation plans, that have to be in place before you even consider a release so that you can call something back. There are even some cases where people talk about protecting relatives of the species with a sequence beforehand so that if a gene drive somehow got into it, it would have no effect.

So, all of these are under consideration, but I'm not aware of a specific legal remedy yet.

MR. MCNALLY: Just a quick point from the report that we couldn't cover, I think there was a recommendation that we need to include, the social sciences. There are ethical issues here. That's something that was made fairly strongly when you're talking about gene drive and what that might mean. So, that's also another finding/recommendation from the report.

MR. WOZNIAK: One other thing I'll mention just briefly with regard to your first question is that a couple of us did work with FDA and CDC on the environmental assessment review when the Oxitec mosquito came into FDA over the last year and a half, roughly, two years. So, we have that experience jointly with those other agencies. FIFRA is obviously a little different than the Food, Drug, and Cosmetic

Act, for example, or the National Environmental Policy Act. So, what we look at in OPP may be slightly different, but the biology is the same.

MS. CLEVELAND: So, I guess I would like to follow up on Cynthia's call for international engagement. It looks to me like you're trying to still figure out what the US government is going to do and the different agencies. I get that. But as these are emerging technologies, the system will emerge all over the place. You already quoted several other countries.

So, I would have thought, and I'm not familiar with the report, that there should be something very strong in there about getting international engagement. I know EPA is always resource constrained. I get that. But boy, is this one very, very important to be at the table as the other governments around the world start to make their risk assessment policies, or regulations, or laws, or whatever.

So, there must be some format for international discussions on these as they emerge. It's very important for our government to be there at the table.

MR. MCNALLY: Agreed.

MR. KEIGWIN: Steven, then Gabrielle, then Nichelle.

MR. COY: Pretty basic question. With regards to the RNAi and -- I don't see where I was looking for that triggered my note, but there's a new biofungicide that the almond industry is using this year. So, with those type of things, are you looking at the effects on honeybees for those with the whole neonicotinoid thing?

After X number of years, now we're looking and going back and saying, hey, maybe we should look closer and a little more deeper. I just want to make sure that you don't forget those things could affect honeybees or all pollinators.

MR. MCNALLY: Yes. I guess as a general point, obviously, no matter what it is, we have the same sort of data requirements that people have to satisfy. So, the bee issue would be something that we in the biopesticides program look at currently and will look at in the future with all these novel technologies.

MR. KEIGWIN: Gabrielle and then Nichelle.

MS. LUDWIG: I'm moving away from just questions. Is that okay? So, one, I just want to say thank you for following up on some of the comments

from the last PPDC, basically saying you only looked at where we were, not where we're going. So, this has been very, very helpful to see how much thinking has been going on, particularly because of the NAS report, but reflected within the Agency. So, just thank you.

A couple things that I think -- I don't know where this belongs, but I second Cheryl's point that nothing we do sticks just in the United States anymore. So, how do we deal with that?

I think the other thing, and this comes up a lot, is really understanding the tradeoffs. Whether you're talking about the citrus and bee issue or talking about soil fumigants, talking about varroa mite control, these technologies could really be game changers in terms of pesticide use. So, being able to understand, okay, sticking with what I'll call a traditional technology versus these new technologies, what are the new risks, old risks? I think for OPP in particular, that's going to be a question that will come up a fair bit. How does this compare to what we've been doing in terms of --

I mean, this is not my personal opinion, but the more I've worked on pesticides, the more I've come to the conclusion that if we can make the plant resistance, the better off we are, because the way my

analogy is, it's like medicine but you take a shower in the medicine. When have you ever taken a shower and not a drop of water has not gone where you didn't want it to go? So, that's our issue with pesticides. So, if we can make it internal, that would be very powerful.

Again, our tradeoff -- and I do think OPP is going to have to struggle with how do we quantify that? That's again something new in this whole arena, because you're going to have people who are utterly against it for their reasons. People are going to be totally for it for their reasons. Really being able to understand what are the societal benefits and costs in terms of traditional pesticide use.

MR. MCNALLY: Thanks, Gabrielle. A quick point on that, just on the mosquitoes, one of the nice things about this technology is that those darned male mosquitoes find a way to find the female mosquitoes no matter where they are.

Now, if you're spraying a conventional pesticide, you're spraying where you think the mosquitoes are. So, there's actually, potentially, some additional benefits that some of these technologies have. Some of the points you made, but also in terms -- and we'll have to see the data over a

longer term, the success rate in terms of addressing the issue.

MR. WOZNIAK: Let me just add. I think one of the things that, I apologize, I should have made clear is that I think with all the technologies that I discussed, without exception, there's a higher degree of specificity involved. I mean, I think that's one of the key criteria for making these so valuable. That's, in many cases, defined by either RNA or DNA sequence.

But, in addition, we do always examine persistence, whether it's a chemical pesticide, a protein, RNA, whatever. So, that's the other side of the coin. Like with these RNAs, we already have some quantitative data on how long they tend to last in the environment. Compared to some of the synthetic chemicals, it's much, much shorter.

MS. LUDWIG: Just one other addition. Again, our other encouragement is for some of these conversations to be taking place with our research agencies. I have experienced about four years ago talking to both NIFA and ARS, and they were touting RNAi technologies like it's going to solve all of our pest management problems. I mean, I'm not kidding. That's pretty much what both of them said.

I, knowing the regulatory side, immediately said, okay, what's the regulatory status. They looked at me blankly. I'm going, okay, you're saying this is where our research should go, but you haven't stepped back and said where are we in the regulatory world.

So, my other plea is find ways, especially as these new technologies move forward, to have some conversations about what do you need on the research end to help you make good decisions. I think that would be helpful.

Again, similar to what Cheryl is saying, can we avoid some of the problems we've seen if we can have some dialogue in advance with the research community.

MR. MCNALLY: Chris can follow up on this in more detail, but it's as if you've read the report. That's one of the findings, to have better -- are you like a plant that Chris talked to you before to tee these things up? But yes, that's important. I think one of the things that Chris has done a great job in the four years I've been in this division is that we've had several meetings with the research entities.

We try to engage them, because they are sort of -- even the fellow research agencies are clueless about how to go down this path. So, one of the things

we want to do is to continue doing that but do a better job and have more proactive outreach to them rather than waiting for them to come.

Chris, I don't know if you have any from your own experience.

MR. WOZNIAK: Well, certainly. I used to work for ARS and I worked for the progenitor of NIFA, CSRE, years ago. As a matter of fact, I used to direct the biotech risk assessment grants program there, which we still participate in. So, that program is ARS money largely for a service to answer the questions regulators have. So, we have FDA, APHIS, and EPA there at the grant review for the proposals.

But, in addition, we also help write the request for applications to make sure that our questions are getting addressed. It is a competitive environment, so not everything we want necessarily gets funded. It's a small pot of money, but it is significant for us.

MR. KEIGWIN: Nichelle.

MS. HARRIOTT: I just have a quick general question about the mosquitoes and how this all works for the Wolbachia and the GE mosquito. These focus on the male mosquitoes. So, my question is, and this is

just a clarifying question for my education, how many females will these mosquitoes mate with, and how far do they fly to find these females in terms of that general efficacy of the technology?

MR. WOZNIAK: Well, the mosquito, now specifically with Aedes aegypti, but it's true of actually several other mosquitoes that vector viruses -- you're looking at a fairly small range. I mean, the maximum they probably would move, absent the tornado or hurricane, is about 200 meters. But, in most cases, it's actually significantly less than that.

So, when they're releasing, and I didn't point it out on that slide, but you can see somebody that looks like they're flying a large flute, they're blowing through a tube full of mosquitoes to blow them up into the air. Sometimes they do it out of the side of a van window with like a cylinder full of male mosquitoes. So, they'll go off and mate.

I don't know specifically how many times they can mate. There are some mosquitoes that will mate once after a blood meal and then move on. But there's just some really interesting work on frequencies of wing beats that control the attraction between the mosquitoes.

Some people are actually using this now as a possible way to disrupt this. There are mosquitoes that will mate multiple times, and some that are highly specific to a particular frequency mate once and go off. So, I don't know that I can answer your question simply.

MR. MCNALLY: We have about eight or nine minutes left. We can go through each of these questions. But if you just want to look at all those that we have on the chart, or any ones in particular, we want to make sure we hear from you today. If we run out of time, don't hesitate to contact us directly in BPPD. We'd love to chat with you more about these technologies, what they might mean to you.

But any other feedback on these questions from members of the PPDC?

MR. KEIGWIN: Richard.

MR. GRAGG: The second question on new concerns, I'm sure you're already doing it. But I think the public is probably one of those audiences that we want to help understand risk and the benefits, what this new technology is, because I think there's a lot of times people don't get the right information.

MR. KEIGWIN: Robyn.

MS. GILDEN: Obviously, being a nurse,

healthcare providers, nurses, doctors, various other public health officials need to be in the conversation on the health effects end.

MR. WOZNIAK: Any others? Oh, question down there.

UNIDENTIFIED FEMALE: I'm just curious, what is being done in terms of the health effects end? There's a lot of research in terms of -- we've heard a lot about how well these work and how well they can control mosquitoes. But what are the plans when we introduce these new technologies to be able to monitor the potential human health impacts of this technology?

MR. WOZNIAK: Well, what I can tell you is it depends on whether you're talking about Wolbachia or you're talking about Oxitec. They're somewhat different. I'll start with Wolbachia.

Wolbachia, as I mentioned, is in over a million species. There's no doubt that you have consumed it and will continue to consume it whether you are eating lettuce from the salad bar or fresh veggies from your garden or whatever. Wolbachia is in nematodes, all kinds of other arthropods. So, there's a very long history of safe use with that bacterium. There's no evidence for any sort of infectious nature, at least with mammals, or vertebrates, for that

matter.

As far as the Oxitec mosquito goes, again, the only differences are there's the red fluorescent protein I mentioned as a marker. That analysis has actually already been done 10 or 12 years ago by FDA. There's a document online. If you're interested, I can send you that. Looking at things like homology to allergens, homology to toxins, digestibility in a monogastric mammalian stomach. So, those are the kinds of examinations. I don't remember if there was an acute oral toxin of that particular state or not. With the other protein, the tetracycline responsive activation protein, it's a bacterial protein, an original derivation, would likely already be in your gut if you have E. coli as a resident of your microflora.

So, again, history of safe use, there's no known homology with any toxins or allergens. Again, unless you're riding a motorcycle without a helmet on, your chances of consuming these mosquitoes is probably pretty low. You could get an occasional one, but I think the exposure side is significant.

That's one of the beauties of both the systems, as Bob alluded to. Number one, they can get into places that we can't with a spray boom. But, in

addition, they're male species looking for a female of a specific species.

When we look at some of the conventional chemicals for mosquito control, one of the first questions is, we've got to test three or four species of mosquito. There's no point in doing that with this. They are pretty specific. The Aedes aegypti don't want to mate with Culex pipiens. So, the specificity I think is one of the strongest points of that. It's hard to fathom a way that they would be injurious to humans.

MR. MCNALLY: Just a quick follow up, we had the same data requirements for microbials for this stuff as we do for the other ones we deal with. So, the non-target populations that might consume the mosquitoes we'd be looking at as well for both of these types of technologies.

So, basically, we still follow the same process we do for anything else that comes before us to make sure it's safe for humans and also safe for the environment.

MR. WOZNIAK: As I recall, I think there was a fish study involved with the original environmental assessment as well. The predatory mosquitoes are actually mosquitoes that predate on other mosquito

larvae in aquatic situations. Those kinds of tox studies were run without effect.

MR. KEIGWIN: Well, thanks, everybody. So, we are about to break. We have four sessions this afternoon. A couple of them are pretty quick. So, let's try to be back in the room for 1:15. Thanks.

(Whereupon, a luncheon recess was taken.)

AFTERNOON SESSION

MR. KEIGWIN: Session 3, we've only planned for 30 minutes, so Anna and Garland will lead us through the presentation for about 15 minutes, and then we'll have about 15 minutes for questions.

Garland, are you leading us through this? Okay, I'll turn things over to you.

MS. WALEKO: I'm Garland Waleko. I'm a CRM in the Pesticide Re-evaluation Division. I co-coordinate the modernization efforts for the acute tox 6-pack with Anna Lowit. I'm going to talk about that.

For folks who don't know, the acute tox 6-pack studies are required for all new AIs and all formulation for purposes of precautionary labeling. So, the hazard category, the signal word, re-entry intervals, things like that. There's three acute studies, the oral, dermal, and inhalation, and then the eye irritation, dermal irritation, and dermal sensitization. So, those are the six studies we'll be talking about.

So, by way of a little bit of background, OPP developed a strategic direction for new pesticide testing and assessment approaches in response to the 2007 National Academy report on toxicology testing in the 21st century. This is about adopting integrated

approaches to testing assessment. AIATA is the acronym.

This is a hypothesis based, systematic approach to integrated exposure and hazard in assessing risk. So, it's more of a weight of evidence approach. The goal is to use a broader suite of alternatives, so computer-aided methods, also known as in silico, to better predict potential hazards in order to focus testing if testing is necessary, improving approaches in the current tox test to reduce use of animals, while also expanding the amount of information that we get, as well as understanding tox pathways better so that we can develop those alternatives.

Also, in response to the 2007 NAS report, OPP came up with guiding principles for data needs for pesticides. This is for EPA staff. The purpose was to provide consistency in identifying data needs while promoting the use of knowledge that we already have, and focusing on what data we really need to do risk assessment and make those decisions. The purpose is to increase efficiency and move away from a check-the-box kind of approach.

The purpose of this slide is to show that there is flexibility in implementing Part 158 data

requirements. For example, we can waive data. We can ask for more data than is specified in the CFR. So, there is room to accept alternatives.

These are the 6-pack studies that I mentioned. This shows how many we get per year from 2012 to 2015. So, you can see that's quite a few, each of those studies for every and for every formulation. Each AI could have many formulations.

So, last year, our former office director issued a letter to stakeholders reiterating our commitment to move to alternative methods and working with our partners, including other government agencies, which I'll talk about in a little bit, our industry partners, as well as the NGOs, particularly the animal welfare groups, and highlighting the three main activities.

So, critically evaluating, which studies we really use to make our decisions, expanding acceptance of alternative methods, and then reducing barriers to developing alternatives and also accepting them. So, some of those barriers include challenges of data sharing between companies, as well as international harmonization in acceptance of new methods. For example, if one country still requires the animal test, then registrants still have to do that test,

regardless of whether other countries accept alternatives.

So, internally we have an acute tox 6-pack workgroup. This has representation across the office. We meet generally biweekly to talk about recent progress, new projects coming up. Then, we also have an external stakeholder group. We meet regularly to discuss our goals and upcoming projects on how we can cooperate.

Our last meeting was at the Society of Toxicology meeting that was just in March in Baltimore. That month we also had two webinars, one on the eye policy or eye irritation and one on skin sensitization. We'll be having some follow-up calls about those. If you're interested in joining the stakeholder group, contact Shannon Jewell to get on the list and get the invites.

We also have a public docket where we put our draft guidance for comments. We also put our final guidance in there. The final guidance also goes up on the website. The docket also holds our meeting notes and minutes.

So, back to our other federal partners, ICCVAM, which is one of my favorite acronyms, is the Interagency Coordinating Committee on the Validation

of Alternative Methods. It's comprised of all 17 federal agencies that either require toxicity data or use it in some way to disseminate information for safety testing purposes.

The scientific support for ICCVAM is NICEATM, which is another great acronym, the NTP Interagency Center for Evaluation of Alternative Toxicological Methods, this is within NIH, and they do all the analysis or a lot of the analysis in modeling to support investigating these methods. They've been invaluable in this process.

Going back to the first activity, critically evaluating, which studies form the basis of our decision, the acute dermal waiver guidance was issued in March 2016. This is a collaboration between EPA and NICEATM to determine the relative contribution of the oral test and the dermal test to decide what category goes on the label.

After the draft went out in March, we finalized it in November. And we're already receiving waiver requests for the dermal study, given an acceptable oral study. We're even granting those waivers. So, currently, we receive about 200 to 300 dermal formulation tox tests every year. At about 10 animals per test, that's about 2,500 animals per year

saved through this one waiver.

So, here are the three other tests listing the OEC alternatives. They're on the right as starting points. Then I'm going to talk about the eye irritation BCOP, which is the Bovine Corneal Opacity Permeability Test. We have an eye policy in AD to accept the BCOP as an alternative to eye irritation for antimicrobial cleaning products.

Right now we're trying to expand this to conventionals. We have an in vitro/in vivo data set already provided by industry voluntarily that NICEATM is analyzing. Dave Allen, in particular, at NICEATM has preliminary results already and has shared those both through the webinars that we held in March and at the SOP meetings.

There are some gaps in the data, so we'll probably need to do some perspective testing, which we'll be discussing in an upcoming call in June to fill in those gaps so we can finish that analysis.

For skin sensitization, ICATM is a group of international regulatory bodies, so representing the United States. So (inaudible), part of ICATM, EU, Japan, CREA, Canada, Brazil, and China, and more than 20 other regulatory authorities met in Italy to discuss how to come to an agreement on potential IADAS

for skin sensitization and identify the obstacles to doing that.

One of the things to come out of that meeting, the alternatives, including in vitro, in chemico, in solico, so computer-based models, used in combination with each other were actually comparable or better than the animal tests, which is the LLNA, the Local Lymph Node Assay, in mice.

So, the United States, Canada, and EU drafted an SPSF, which I don't know what that stands for, it's something in French, to submit to the OECD. It's basically a project proposal to say, yes, let's go ahead and develop this performance-based guideline to accept alternatives. It's performance based to be more flexible, less prescriptive, and encourage more innovation. So, that was just accepted I think a week ago, so there will be a lot of activity on this one in the coming year.

So, the final area of activity is reducing barriers to adopting alternative methods. In early 2016, EPA released a process for establishing and implementing alternative approaches. This is meant to be a transparent way to evaluate approaches and then implement them in a step-wise process. One of the things this document addressed was the applicability

of 6(a)(2) reporting, which came up as a concern with alternatives, would it trigger reporting requirements from new tests that were being developed.

It's addressed in this policy in more detail, but basically, the Agency will only issue a policy on accepting alternatives if it's clear how we will use the data and how it fits in with the rest of what we already know.

Right now, we also have a pilot that started in December to collect both oral and inhalation formulation LD50s for chemicals, along with a GHS equation for that formulation. So, the equation is just adding up the LD50s of the components of the formulation. Then, the idea is to compare the two so that potentially that equation can replace both of those tests.

We're still collecting data, so this is a plug to submit data if you're a registrant. The equation is shown up there. I don't think it's that complicated, but it looks complicated. Like I said, that pilot started in December, and we'll run it until we get enough data to analyze.

Finally, we're also looking at potentially adopting the GHS categories for the hazard portion of the label. GHS stands for globally harmonized system.

It's what Europe and a lot of the world uses. We have our own test categories. The challenge here is adopting OECD guidelines that are in the GHS system for acute tox hazard categories so then we have to cross walk between our system and theirs, which is not straightforward for some tests.

One potential thing that could reduce barriers, but this would require a rulemaking process and it's pretty complex, the science and policy issues involved.

So, that brings me to our charge question to you all. In light of the resources required to write a rule and then move to a different system on the labels, all labels, what are the science and policy issues that EPA should consider? I think you were given a separate update just on this topic.

Kaitlin Keller in FEAD, Field and External Affairs Division, is leading a separate workgroup internally just to explore the possibility. I think in the Q&A session, we can talk about it a little more.

Are there any other questions?

MR. KEIGWIN: Gabrielle?

MS. LUDWIG: This is following up from what was in the written materials that were handed out

beforehand. You've indicated this was a lot of work, but what I couldn't quite figure out was how much would it shift current categorizations if you moved to the existing international one in terms of what you currently have? Is it just like a few compounds, a lot of change? I mean, I understand there's the bigger picture, but in terms of going from a moderate to a toxic or highly toxic to a moderate or something like that.

MS. LOWIT: I was looking for Kaitlin back there. The short answer is, at some point as we start -- I think one of the science steps is actually to do that analysis, which we haven't done. That said, the difference between the GHS categories and the EPA/OPP categories are not huge. There are a couple of exceptions to that. I think inhalation is just qualitatively different.

They're not hugely different, but that doesn't mean there aren't any chemicals that wouldn't change as we moved over. But I think it's also realistic to think about that there are tens of thousands of labels. None of that would happen overnight.

MR. KEIGWIN: Pat?

MS. BISHOP: Thanks, Garland, for the

update. I had a few questions and/or comments. First of all, on the dermal tox waiver, this, of course with EPA, is probably just a formulation. As you're probably aware, Health Canada Pesticide Management Regulatory Agency did a similar analysis looking at oral versus dermal. They came to much the same conclusion as you did, that as long as you had the oral data, you really didn't need the dermal because it was very rarely ever more toxic through the dermal route.

They also came to the conclusion that they could issue waivers for active ingredients as well, because they did the analysis for AIs and came to the same conclusion.

So, my question is, is EPA considering this to harmonize with Canada in this respect? If you're not, why not? That's my first question.

Secondly, I was just curious to know how many of the additivity equation data sets have you received? If you haven't received any, is there anything we can do to help push that along? I mean, we work with Crop Life on trying to send out an e-mail to registrants to try to participate in this. So, I was just curious to know if you've gotten any more since then?

Just finally on the GHS issue -- again, we're speaking more from animal welfare, trying to reduce animal testing. A lot of the alternatives are designed to work with the GHS system, as you know, versus the EPA system in which you have to do some major -- I don't know if it's major, but they do have to do some fiddling with the data to try to figure categories.

So, from our point of view, we certainly would like to see EPA move to GHS. I would think from industry's standpoint, having one system instead of two or more would be beneficial to them in the long run as well. That's just a comment from our perspective. Let me know the answers to my questions if you can.

MS. LOWIT: That was a lot. I'll take the second one first because that's the easier one.

So, your second question was about the GHS pilot. We've been running the GHS pilot since December. We're now into May. We have a whole number one submission. Dow AgroScience, a number of months ago, kindly provided the analysis of over 200 of their own products, so we have something, the Dow analysis, which has actually been recently published in the open literature, but only one submission under the pilot.

A number of companies keep reassuring us that we're getting some more big data dumps, but we haven't seen those yet. We're hoping that they do arrive pretty soon. We're open to anyone who has questions about how to do that, because we've had a few questions on that. We're happy to talk offline or via e-mail on how to make that happen.

The first one is the harder question. So, your first question was about expanding the dermal formulation waiver to the dermal active ingredient assays. You're not the first person to ask us that. In fact, Kate Willett from the Humane Society has been asking the same question. We've had some e-mail dialogue with her, too.

In the immediate term, we're not going to make that move. That doesn't mean eventually that we won't make that move, but right this moment we're not. That's almost entirely driven by our needs for our ecological risk assessors. As we continue to develop and evolve, particularly in the endangered species space, we need to ensure that the data are available that they may need. I think the ESA issues are continuing to evolve.

We're not going to move to eliminate that dermal tox study right now. That doesn't mean a year

or two years from now we won't be in a position to think about doing that, but right now is not the right time.

MS. BISHOP: Just curious, how is Canada getting past that? I mean, I don't know if you know, but how come they don't need the data but we do?

MS. LOWIT: I think you would need to ask them that question.

MR. KEIGWIN: Ray.

MR. MCALLISTER: I'm going to ask some basic questions just to make sure I understand things. The 6-pack is required on a formulation basis, is it not? Each formulation or different formulations generally require a new 6-pack?

MS. LOWIT: That's right. So, they come for the individual active ingredient but also for the formulation.

MR. MCALLISTER: And you have a separate similarity clinic to compare formulations and decide when it's different enough to require a new 6-pack?

MS. LOWIT: That's right. So, outside of this effort to modernize the 6-pack bringing in the in vitro studies but also some of the computational approaches. We have also recently improved our SIM Clinic approach. What's the SIM Clinic? The SIM

Clinic actually has a new name. It's a group of scientists who look at the acute tox studies and they look for opportunities for waivers.

So, the real point of that group is to compare formulation A, which exists, to formulation B which is new and see if they're similar enough that you can waive the study for formulation B, which is also one of the best ways to eliminate animal testing, is just simply to waive the study based on existing information. That's the function of that, and it's been working for a long time.

MR. MCALLISTER: So, I think you've answered my ultimate question, which is how do those two groups work together.

MS. LOWIT: They're actually working in concert together. There's actually a lot of overlap between the acute tox workgroup and what used to be called the SIM Clinic.

MR. MCALLISTER: Okay.

MR. KEIGWIN: Any PPDC members on the phone that want to speak to this?

(No verbal response.)

MR. KEIGWIN: Gabrielle.

MS. LUDWIG: So, I think two things. One is I appreciate that you point out that you're working on

this on a national level because if you don't have -- make life easier for the registrants or change the number of animals used in the testing. So, I think this is another case where working with OECD or whatever the processes are of the government is critical.

Then, I'm not a risk assessor so I don't get all of this. But I do work on international trade issues. So, from my perspective, anything that is harmonized internationally is better than each of us doing our own thing from an efficiency perspective. So, even though it may be hard to go through the transition, my gut reaction is to say go ahead and make the transition.

MR. KEIGWIN: I'm seeing lots of nods in the affirmative. Thank you both.

We're going to transition into our kind of what we've called in past years as updates in a minute type of thing. Kaitlin, why don't you come up to do the GHS one, since it's kind of topical given what we just discussed.

One point that I'll make, there are some updates in your packets which we're not going to take comments on. One of those I just wanted to provide an update to the update. That's the one regarding

glyphosate. Subsequent to us preparing materials for this meeting, Canada's pest management regulatory agency issued an update to their regulatory position on glyphosate.

I think the fact sheet mentions a June 2015 determination. They did reaffirm their determination regarding the lack of a carcinogenic potential for a glyphosate last week. So, the most recent date would be April 2017 for Canada's assessment.

With that, Kaitlin, do you want to just give us a very brief overview of where we're at with GHS? Then we'll see what questions we have.

MS. KELLER: Hello, my name is Kaitlin Keller. I'm in the Field and External Affairs Division here at OPP. As was already kind of discussed as part of the acute tox modernization, we have an internal workgroup that was established last year, specifically looking at the globally harmonized system of classification and labeling of chemicals. A lot of this stems out of the work that was being done and moved forward on the acute tox 6-pack, and additionally, just because of the harmonization that would result of it.

So, the workgroup has been looking at different options for GHS, implementation for

pesticide labels. At this point we've been looking just for adopting the GHS category use for the acute tox, the human health portion, and the physical hazards on the label.

As a little bit of background, GHS is a global initiative that stems out of the UN. It was adopted in 2003. It's for classifying and communicating chemical hazards on chemical labels and safety data sheets, including product identifiers, cautionary statements, pictograms, and signal alerts. It encompasses physical health and environmental hazards. Again, we're just looking at some of those categories that relate to pesticides now, so no new label elements, just converting those that are already on the label to be GHS compliant.

And so, at this point, you can kind of walk through the fact sheet. I think that was provided already. But one thing to note is that OSHA of course has already implemented GHS, so the SDS are compliant with GHS. The pesticide labels can often be inconsistent with that. So, that's one of the main reasons across federal government I think that there's an interest in harmonization there as well.

So, if there are any questions -- I'll just kind of leave it at that, but I can take questions.

MR. KEIGWIN: Ray.

MR. MCALLISTER: Crop Life has long opposed GHS implementation on pesticide labels. We haven't yet found a reason to change that position. I won't take the time to go into the reasons for that, but in light of the work you're doing now, we will look once more. But don't anticipate changing our position.

MS. PALMER: I just had a clarifying question. It says that OPP is not considering chronic health hazards that would add additional label requirements. So, is that just because it's too much work and too much trouble or what's up with the chronic?

MS. KELLER: I think that we were mostly just looking at converting what's currently on the label to GHS and not considering additional label elements. Again, the acute tox, a lot of that stems from the use of that from the science perspective as well and kind of moving towards OECD being able to accept OECD assays for those. So not requiring additional data and not requiring additional label elements behind it.

MR. KEIGWIN: Komal.

MS. JAIN: Thanks. Komal Jain from the Biocides Panel. I just want to echo the same concerns

raised by Ray. The Biocides Panel has been communicating on this issue with EPA for a number of years. We look forward to having some more detailed conversations about our concerns.

MR. KEIGWIN: Nina.

MS. WILSON: So, just to follow on, the biopesticide industry would have some concern moving to GHS because I think with signal word changes on some of our types of pesticides might lose some of that advantage that we currently have on signal words.

MR. KEIGWIN: Dawn.

MS. GOUGE: I just feel that a move towards GHS is the right move. It's the right direction to move. I understand that it may place burdens and additional work on both the Agency and industry, but I can't believe that it wouldn't be advantageous ultimately in the long run.

MR. KEIGWIN: I don't know if Steve Bennett is on the line, if the CSPA wanted to weigh in on this one or not.

MR. BENNETT: Steve Bennett. I don't think we have any specific comments that I'm aware of. I know this is something our members have paid particular interest in, but I don't have any specific comments.

MR. KEIGWIN: Cynthia, did you have another comment? All right, thank you -- certification and training. So, Jackie and Kevin are doing this update.

MR. KEANEY: You have in your package the fact sheet for both regulations. The existing regulation for worker protection has two implementation dates. Many of the provisions are in place, but there's a delay until January of '18 to make the full regulation implemented so certain training materials and compliance materials can be out and circulated.

We've gotten response from the states that they feel there's not enough time to adequately engage with stakeholders and prepare the folks that need to be prepared through compliance materials and training materials to be able to work within that time frame.

So, we've had a few petitions, requests, a number of states made requests, NASDA has made requests to essentially change the second date, push the date out. We acknowledged the receipt of the letters and receipt of the requests from NASDA and as yet have not reached a point where we are at a decision point for that.

The certification regulation is on hold as far its implementation date is subject to review. It's on hold until May 22nd. We've also gotten a

number of responses from major stakeholder groups essentially supporting what we did between proposal and final. In the proposal, we focused on 21 areas of change. In the final, as a result of the comments, very insightful comments from state groups, we moved away from the proposal position in 15 of those 21 issues.

The Association of Pesticide Control Officials have sent letters complimenting us on that essentially cooperative or collaborative federalism in making those changes and making it much more flexible and essentially doable in their assessment.

We've gotten that type of public support from the National Pest Management Association, and in a certain way from NASDA, and from the National Aerial Applicator Association. So, I think we've adequately responded to comments to create a much more flexible and appropriate time frame for implementation of that regulation.

The Pesticide Policy Coalition essentially supports the position we arrived at but had some concerns about the minimum age requirements. So, they were requesting an extension of the implementation date until we could address -- they were asking us to address the minimum age requirement.

So, there's a lot of things on the table for us with both of those regulations. Obviously, they'll be part of the response, I suspect, tomorrow as far as regulatory review. We're obviously open to the suggestions that have been sent.

MR. KEIGWIN: Thanks, Kevin. Question or comments on either of these? We'll start with Wayne, then Jim, then Virginia.

MR. BUHLER: Thank you, Kevin. I appreciate the updates. Comment on one and a question on the other. First the comment on WPS from a trainer perspective. It seems very difficult, challenging at the very least, to train on the implementation of the applicator exclusion zone.

I know that isn't an item until 2018 for full implementation, but I just want to go on record as perhaps an organization, and personally as a trainer, that it would be very difficult for us to be able to reach a point in which that could be communicated clearly. I think it would be rather onerous even from the enforcement standpoint. So, it's my hope that EPA would reconsider either removing or adjusting that.

MR. KEANEY: That has been raised by a number of commenters, and obviously we'll be considering that.

We do sympathize with the complexity of the enforcing or training on that.

MR. BUHLER: Thanks. The question for the certification rule is in the middle of the page you have a bullet item under final changes that non-certified applicators under supervision would go through an enhanced pesticide safety training or other qualification. What is meant by that? Is it a separate program? Is it something that's considered being developed by states?

MR. KEANEY: It's training that's quite similar to the handler training under the worker regulation.

MR. BUHLER: But it is separate and distinct?

MR. KEANEY: It's under the certification so it's separate and distinct, but it's essentially the type of training you get as a handler under worker protection.

MR. BUHLER: Okay, thanks.

MR. KEIGWIN: Jim, then Virginia, then Dawn.

MR. FREDERICKS: Thanks, and thanks, Kevin, for the report. On behalf of the National Pest Management Association, you mentioned our support of the final rule. I think that I just want to publicly commend the Agency for the process. I think in this

case the process worked. We saw a robust comment period and recommendations from various stakeholders. Many of those were incorporated in the final rule which allowed for more flexibility and a more workable rule. So, thanks for that.

MR. KEIGWIN: Thanks, Jim. Virginia, then Dawn, then Valentin.

MS. RUIZ: As a stakeholder who has been engaged in the rulemaking process for the WPS and also the Certified Pesticide Applicator Regulation, it certainly has not been a quick process. Personally, I have been engaged for 16 years in this rulemaking. Through that time, I've seen extensive engagement of very diverse stakeholders.

I would disagree that anything in these regulations are new or surprising or onerous. I strongly oppose any delay in implementation in worker protection. EPA is the only agency that has jurisdiction over worker protection for a work force that is very vulnerable, very much in need of enhanced information and training.

So, I would strongly urge the Agency not to delay implementation. I think 20 years is already long enough for this community to have waited for these improved safety provisions. I also think that

further delay in implementation would put the Agency at risk for violation of the Administrative Procedure Act and FIFRA. Thank you.

MR. KEIGWIN: Dawn, then Valentin, then Amy.

MS. GOUGE: Thank you. Kevin, I'm a bit worried at the prospect of a delay with regard to the minimum age. I just wondered if you wouldn't mind expanding just a little bit on the practical options for establishing certification programs in Indian land.

MR. KEANEY: Well, prior to this, there were some forced choices to be made for establishing programs in Indian country. They could work with existing state programs, and they felt that compromised their sovereignty. They could establish their own or they could work with EPA.

We made it more clear how we can work with the tribal programs, federal to sovereignty to sovereignty as it were. So, it's in the clarifying, clarifying what practice was a number of choices, some of them unfavorable to the tribal rulers.

MR. KEIGWIN: Valentin, then Amy, then Liza.

MR. SANCHEZ: Hello. As a former farmworker and as the son of farmworkers, I'm truly happy to see that we're continuing to look for ways to protect

farmworkers. I know that for 20 plus years there were no actions to protect farmworkers, including their family members. So, we have 2.5 million farmworkers. If you have family members, that's a pretty big number. Some of them are migrants; others are seasonals.

Also, a significant percent of them speak indigenous languages from Mexico and Guatemala. So, I think it is very crucial that we continue to look for ways in which we can protect them, because for many, many years they have been forgotten.

So, I just want to say thank you, and I hope that we continue down this road so we have some protections for farmworkers and their family members. Thank you.

MR. KEANEY: Thank you. I would point out that the revised regulations try to add more training elements that would be addressing take-home exposures and protecting families from take-home exposure. Also, we are committed to providing training in a manner that's understood, which means the language is understood. So, in the development of materials, it will obviously be in English and Spanish, but obviously as well in other languages that we know exist as labor segments that need to be reached.

So, we did have in the older regulation a couple of training packages for indigenous language speakers that were working on orchards. So, we'll continue that, obviously. We do have a long-term cooperative agreement with University of California-Davis combined with Oregon State to develop materials.

It's called the Pesticide Educational Resources Collaborative. If you go on their web site, you can see the pretty extensive array of training materials that have been developed and will continue to be developed. It's capable of being downloaded and used for anyone who needs them. That will go on and will expand into training materials for the certification regulation as well.

MR. KEIGWIN: Amy, then Liza, then Richard.

MS. LIEBMAN: Thanks, Kevin, for giving us the update. I just want to also echo a little bit of what Virginia is saying. I've been involved with a diverse group of stakeholders in a really important process that the Agency undertook.

So, starting in 2001, I was at a stakeholder meeting where there was industry, farmworkers, different groups all impacted by how pesticides impact workers. I continued as a stakeholder throughout the process.

In 2006, there was a subcommittee of the PPDC that was beginning to address worker protection safety. I participated in that, again along with a diverse group of stakeholders from many different perspectives.

So, while frustrated at times with the speed of the revision of the WPS, that process is incredibly important as we look at what we have today because we got so much input. The Agency got so much input along the way. It got input when you release the comments for public comments.

What you have come out with, really, is an important step forward for the workers who put food on our table. Quite frankly, it's a moderate step forward. It's not a radical new rule. It's not a radical revision. There are some really, really critical pieces, such as a minimum age, training, notification, all very, very important improvements that we can stand behind.

I would hope that every single stakeholder in this room would rally behind this rule that has come out and is designed and is the only one, as Virginia pointed out, that is protecting farmworkers. So, I'm a little bit baffled at the calls for some delays when we look at the painstaking process that

both stakeholders and the Agency went through to get a rule out. So, I really advise the Agency to move forward with the time table that you put forth. I think there's a number of stakeholders out there that are here to help you as you implement it.

There will be bumps. There will be some questions. There will be challenges. No one says it's easy. But if we're about protecting workers, which is what is required under the law, then we need to move forward on this. There should be actually no delay. I would hope that everyone in this room would rally behind this.

I mean, I'm dumbfounded that anyone is calling for a delay. It's really upsetting. I really want us to remember this process that you went through. Remember the science that's behind this and the data that's behind all this. Know that we have a rule that involves input from everybody, and we need to get it out there.

MR. KEIGWIN: Liza, then Richard.

MS. FLEESON TROSSBACH: Thank you. I have comments on both WPS and C&T. First of all with the Worker Protection Standard, I would agree. I don't think any stakeholder, and I know I can speak for state lead agencies, we absolutely support enhanced

worker protection, worker safety issues for farmworkers, for all occupational users and users of pesticides.

I think one of the issues for state-lead agencies and the idea of the implementation date is our ability to have access to the individuals who need to be in compliance. When the rule went into effect or was going through this process, we were told we were going to have the resource materials that we need in a timely manner.

Unfortunately, that process took a little bit longer. So, because of that, our ability to have access to your agricultural producers and farmworkers and those folks were delayed, and we did not have as much access. It's just not as easy as here's the information, go forth and start to implement this. There's a compliance assistance process that's needed.

We firmly believe in educated communities, a compliant community. State lead agencies are out doing inspections and doing those investigations, doing the work we need to, but it takes time to come into compliance and to bring people into compliance. While some of the issues or the changes may seem logical to us, there are concepts that are difficult for people to understand.

The AEZ is a perfect example. That was not included in the original proposal. When the final rule came out, that was a complete change, and it took us time to figure that out. So, now we're trying to make people understand how to do what they need to do and come into compliance.

So, it's not a matter that it's not out there and we're not working towards it, but it takes time. It took time to get the rule in place, and it's going to take time to get it fully implemented to get people into compliance. I think that's the perspective from the state lead agencies.

We're not saying don't implement the rule, don't put it into effect, don't make people start to work towards that. But be realistic in that it's going to take some time to reach those growers of agriculture producers out in the field.

So, states are out there doing it now. States have the ability to exercise prosecutorial discretion. I mean, we're doing inspections and investigations. But depending on the situation, there may or may not be action, because we understand -- we believe that you need to educate people first and go from there. So, that's for the Worker Protection Standard.

For the C&T update, I want to echo what many folks have said. We appreciate the Agency's willingness to work with stakeholders. The initial proposal to the final had dramatic changes. Much more flexible. Addressed many of the issues that state-lead agencies brought up.

As far as the delayed implementation, once again I think state lead agencies support enhanced competencies for applicators. Want to ensure that people are applying pesticides properly and providing for human health in the environment.

But there's a lot of uncertainty right now with state lead agencies. One, even though the certification training rule has been out since early December, it's quite complex. States are still going through the process of trying to determine what they will need to do in their own states to make changes to come up to that minimum baseline.

There are resources issues. Funding is uncertain for the state tribal assistance grants, which many states rely on to be able to have resources towards putting that into place. I think that comes into play.

I don't think that delaying the implementation is going to impact the ultimate result.

I believe that state lead agencies have had certification programs for many, many years, very robust programs that have evolved substantially, many of which are well beyond the current requirements or the requirements in the new C&T.

So, I don't feel like the program is going backwards in any way if there is a delayed implementation. The reality is that many states will have to go through the regulatory process, which, depending on the state, can take a very long period of time.

So, the current time frame, while it may seem like a long time to be able to come into compliance in government time, it may not necessarily be adequate. I think there are a couple issues that probably need some more discussion, like the minimum age requirement. I think probably in some circumstances you will have full support; in others, it may not be right for that particular state. I think some of those issues probably need to continue to be discussed.

So, in that particular case, I just don't think delaying is going to negatively impact the certification program on a national level, because I believe the certification program is quite evolved and

is doing a good job now. As we move forward, we'll even do a better job in the future. Thank you.

MR. KEIGWIN: Richard.

MR. GRAGG: I can appreciate all of the conflicts and different things that go into making all of this work. But I just wanted to say two things. I think the EPA is about protecting the environment and human health, then I would expect that the most urgent about protecting the people who are ground zero from these pesticides versus people who are on the consumer end that may only be getting a little bit.

Then, secondly, I think worker protection standards and certifications is even more important and urgent based on our previous discussion when we want to talk about pollinator protection. These are the people that are going to be spraying and manipulating and using the stuff out in the field. We're going to rely on them for the pollinator protection issue, ultimately.

MR. KEIGWIN: Okay, thanks, Kevin. So, the next update is on resistance management. Wynne and some others from BEAD will come on up.

MR. JONES: Hi, I'm Arnett Jones from BEAD, Biological and Economics Analysis Division. We have some background materials and would make ourselves

available for some questions. I'll give you an update on some of the work we're doing in resistance management.

As you know, resistance has become a very important economic and biological issue in terms of effectiveness of some of these compounds that we license for pest control. As a result of that, we undertook two initiatives. One was a general labeling initiative, which is an update of a 2001 pesticide registration notice, a PR notice. Nikhil can perhaps go into some detail on it if you want a little more detail.

But basically, it's a very strong encouragement for companies to put the mechanism of action on their labels in a very distinct and clear way so that growers would have access to that. That information would be very useful to them in terms of understanding the mode of action of their particular compound and how they may consider to choose to rotate their chemistries to practice some pest resistance.

Do you have anything to add, Nikhil?

MR. MALLAMPALLI: Hi, everyone. My name is Nikhil Mallampalli, entomologist with BEAD. This PR notice pretty much mirrors the 2001 PR notice. It gets into more detail with the guidance that registrants can put on their labels. It's limited to agricultural

pesticides. We've taken comments on this and the other PR notice that Skee will mention in a minute. We've got about 19 comments on this PR notice, very good comments that we think enhance the guidance. We're hoping to finalize the guidance sometime this summer.

MR. JONES: Thanks, Nikhil. The public comment was very important for that one, as well as for the second PR notice that deals with herbicides. That's guidance on pesticide registrants on herbicide resistance, management, labeling, education, training, and stewardship. Like the more general labeling notice, this notice went out for public comment. I don't remember how many comments we got.

UNIDENTIFIED FEMALE: Twenty-seven.

MR. JONES: Twenty-seven, thank you. Anyway, as with the labeling, the suggestions were very useful, and we actually changed some of the ways we were thinking about this in terms of how to more proactively manage resistance for herbicides.

If you think about where we are at EPA in terms of having basically a label as our instrument, we have made an effort to reach out to a lot of stakeholders and grower groups, Wheat Science Society

and others, USDA, trying to get sort of collective wisdom and to get the right people behind the initiative to get growers to be more active in practicing herbicide resistance.

Again, with herbicides, there basically hasn't been any new real mechanisms of action in something like 30 years or something like that. There's a lot of emphasis on the genetically-modified crops in terms of their importance in managing resistance.

There have been some unfortunate outcomes as a result of that. So, we're just trying to be more proactive and are trying to do it in a way that we think is responsible and will be effective in terms of getting the result that we want at the grower level.

Anything to add, Wynne?

MS. MILLER: No. I think the goal for that PRN, like Nikhil mentioned, is to try to release it sometime this summer.

Folks may recall for that herbicide resistance management PRN, we had suggested three categories that center around these elements of education, stewardship, training, and the labeling. Depending on which category you fell into, 4 elements would apply, or 8 elements, or all 11 elements.

Surprisingly, we got a lot of people coming back and saying hey, forget having three different categories. Let's just focus on one, focus on the high, and make it apply to all those modes of actions.

So, that's kind of what we're looking at internally, how to craft that. Again, we hope to release sometime in mid-summer.

MR. JONES: Are there any questions on that?

MR. KEIGWIN: Richard, I'm not sure if your card is up from before? All right, Robyn and then Steven.

MS. GILDEN: Thank you for the update. Just to clarify, this is all just for what the registrants are going to be putting on the label? Is there any other kind of techniques that are going to be associated with best management practices like trap rotation?

MR. JONES: There are two notices. One is a general labeling, and that is limited to labeling. But it also has some best practices as well.

Nikhil, you want to elaborate on that?

MR. MALLAMPALLI: We focus on the pesticide rotation, rotating modes of action. That's repeated for all pesticides. But we do mention suggestions to registrants. Registrants can choose to put whatever

other best practices they want to on their label. We make some suggestions, such as using crop rotation where relevant. Scouting is suggested throughout, things like that. I don't know if that is what you were getting at, but there is some of that in the PR notice.

MS. MILLER: Actually, for the herbicide resistance management PRN, it went beyond labeling. It also talked about thinks like resistance management plans as well. So, that's where we got into the stewardship, the training, and again beyond the labeling.

MR. JONES: There's also, if you look at some of our recent decisions, there are terms of registration related to reporting resistance, early identification, remediation, and things like that. So, again, we are limited to labeling in some specific ways, but we've really tried to leverage some other tools that we have, including the other organizations that put out the best practices, as well as when we think it's appropriate, the terms of registration on the stewardship end.

MR. KEIGWIN: Steven, then Marc, then Dawn.

MR. COY: So, I think that addressed some of my concerns. I was thinking, what did you do to

address the prophylactic use of insecticides? Herbicides are not so much used, but I know insecticides are frequently put on as a just-in-case type scenario.

MR. MALLAMPALLI: So, I think back to what's in our insecticide section. The general labeling PRN, of course, covers insecticides. We say that registrants should put on their labels that growers should scout before and after an application. So, as a suggested bit of guidance that registrants can put on their labels, we have put that out there in the PRN.

As biologists, we know that sometimes within the pest, they're going to need to apply on a calendar basis. So, that's something that extension would have to play a role in in advising growers. But to the extent that the label can have that, we would like the label to make sure to say to growers scout before and after. Don't just apply prophylactically.

MR. JONES: And these are pesticide registration notices. They're advisory in nature. One thing I will tell you, it's a timely question. Yesterday we met with the Insecticide Resistance Action Committee. We've taken on herbicides first because we had some painful examples of the

marketplace frankly not doing a great job in terms of managing resistance there.

But in terms of prescriptive stuff on the label related to prophylactic use, there's nothing like that. But we are trying to -- these are advisory documents. We're trying to raise a level of awareness. We took on herbicides first because that was the case that was calling out for it. We have thought about insecticides, but we haven't gone down the road with them the way we have with herbicides.

MR. KEIGWIN: Marc.

MR. LAME: So, I think you've answered a number of things that I'm concerned about, again which is we look at the registration, which, for all intents and purposes, is permitting and then monitoring for compliance, enforcement, and technical assistance. Because this is advisory, you're covering most of those things except for enforcement.

I guess at some point if I was remaining on the committee, I would like to hear more about, since this is advisory, what the different user groups or industries are doing with regard to some type of enforcement, market-based enforcement or something. Obviously not Agency-based because you guys aren't going there with resistance.

My expertise is in diffusion of innovation, how to get communities to adopt new things. I guess I don't see that diffusion process playing out here. I've seen some of the same old stuff that sounds nice but it's probably going to have to wait until things go away and maybe come back some day or never come back before something is done.

I think both for the growers and for industry itself, it would probably be best to have a more organized and well-managed effort to diffuse the innovation of prevention in resistance management. I'm not seeing it.

So, I would recommend that in the future as far as diffusion of innovation, particular to public health. I know that these are not public health insecticides. I mean, my colleague will mention this no doubt, but we're reaching a crisis stage. At what point does society say that we're going to get tougher on these things for human health.

My good friend Ray over here might be surprised to know that I do consider some of these pesticides as valuable tools. I would like to see them preserved. But it's going to take more than a tacit response. So, just my comments.

MR. JONES: I mean, we struggled with this,

okay. We've done the best we can in terms of trying to get the right people educated. We've seen some movement out there in terms of grower behavior. Somewhat related to what you're talking about, some of the registrations now are time limited. Part of the reason for that is because of the resistance potential for repeating the glyphosate experience, for example.

So, we're looking for creative ways to use the little bit of power that we have. I think we've been pretty successful in getting the USDA and resistance action committees and the Wheat Science Society and the Entomology Society involved in this.

But we hear you, and we'll take that into consideration. If you take a look at the terms of registration, there's a little bit in there. There's some books in there that are a little more solid. They have some teeth in them in terms of concern for the problem.

MS. KUNICKIS: I just want to respond. In case you weren't aware, there's a huge effort by some of the professional societies to do outreach on resistance management. For example, the Wheat Science Society, over the last year, have been holding listening sessions with growers and other stakeholders on how to implement and get information

out about the issue of resistance management.

Next week or the week after in Colorado is the Global Resistance Challenge. It's an international meeting where the whole week will be focused on resistance management. Lots of folks will be there. Lots of conversation.

USDA and EPA will be participating with the Wheat Science Society to do all kinds of outreach. A lot of documents have been prepared. Informational pamphlets, et cetera, have been put out and also by some of the grower groups. So, there is a lot of effort. We'd be glad to work with you or engage you if you want information about that.

MR. LAME: Well, I would be happy to help. I don't think I need much more information on it. As much as I hate to say it, this is less of an educator thing, as a former extension person and current entomologist, enthusiastic.

Peer development is the most important thing. So, the grower group thing is good. I'd just like to see a tougher response. Last time you mentioned the limits on registration. I think that's the best thing the Agency can do, or probably the only thing the Agency can do at this point.

MR. JONES: Thank you Sheryl for adding on

to that. The societies, you talk about behavior and economics being a big factor. You go to these meetings now and there's social scientists that are giving presentations (inaudible) sociology is back to sophomore college. But they turn out to be these extremely interesting talks about how to motivate behavior. I think the societies have done a great job in terms of getting the word out and spreading the word. We're starting to see it in the behavior now of the growers.

MR. KEIGWIN: So, I'm just going to go with the rest of the cards that are out. We've got two other topics to cover before the break. So, Dawn, then Donnie, then Gabrielle.

MS. GOUGE: Thank you. I just wanted to raise an issue. Marc alluded to the public health crisis not being resistant to mosquito adulticides. So, I wanted to put that on your radar if it's not already on your radar.

We have a small army of people around the country right now ramping up to do bottle bioassays to see if they can kill, having had at least a two or three years recently when it's been a very serious struggle to kill mosquitoes on the wing with, let's face it, two modes of actions that we have available.

I have an office next to Peter Allsworth (phonetic), who is a cotton entomologist, and he brags openly about the rules and regs that you have to stick to with regards to how many times you can use pyriproxyfen twice in a season. And he rotates it out with this, that, and the other. Meanwhile, the mosquitoes are being nuked. We try not to use the same thing for more than two years. Those applications can happen maybe 15 or 16 times in one season.

So, it's not that we're looking for resistance to be a crisis. It's already a crisis. We're trying to find pockets of areas. We just know that basically the choice that we have right now, we need to be relying on other things. No need to carry on doing what we've been doing. It's not working. Thank you.

MR. KEIGWIN: Donnie, then Gabrielle, then Ray.

MR. TAYLOR: This is more information than anything else. One of the soybean groups and the leading wheat scientists from across the United States has created a program called Take Action. Actually, the website is take action on weeds dot com. I highly recommend it. It's a great program. Talks about different groups and categories of chemistries that

are available out there.

MR. KEIGWIN: Gabrielle, then Ray, then Cynthia will be the last one for this session.

MS. LUDWIG: Just what I said I think the last time, just a reminder that we have the same issue in perennial crops. You can't rotate. They're kind of a little stationary. So, as you're thinking about things, keep that in mind.

Then I do think, and this is beyond EPA's scope, but as has been alluded to, the issue is how do you get growers to change when at the end of the day, they're going to go with what's most effective and/or what's cheapest.

In the almond industry, for us on fungicides, we've been drumming in rotate on herbicides. There are a limited number of tools that work against certain weeds. So, you kind of go back to them.

So, it is a more complicated issue. I think EPA is trying to do what they can from their perspective, but this is an issue that at least the ag groups have all been struggling with for quite some time. How do we get growers to rotate when at the end of the day whatever works well is going to be the first choice. So, we have to continue to educate on

that.

MR. JONES: If I could just respond to that quickly, one of the things that the grower groups can do is to reach out to the societies, to the entomology and phytopathology and science societies and try to make that connection.

We find that when we have the three different groups talking together, the wheat scientists, and the entomologists, and the plant pathologists that a lot of times there some connections that wouldn't be made otherwise. So, I would encourage the growers to reach out to the societies as well to help complete the loop.

MR. KEIGWIN: Ray.

MR. MCALLISTER: Just a couple of quick questions. What are the next steps for the PR notice on herbicide resistance?

MR. JONES: The comments have been incorporated. It's in final review now. It should be coming out this summer some time.

MR. MCALLISTER: Will there be an opportunity to see another final draft?

MR. JONES: Well, it's going through its final review right now. We've done the public outreach and the public comments. So, I don't think

it's scheduled for another review before it goes out.

MR. KEIGWIN: Cynthia.

MR. PALMER: So, echoing Steve Coy on prophylactic uses, I think it is a challenge with so many fungicides and insecticides built in the seed coatings. To recommend scouting or other best management practices sometimes the growers don't have that choice of simply scouting and then planting different seeds, because it's coated on to the seeds.

So, I'm wondering to what extent you're working with the seed industry to make available seeds for all the different crops that actually do not contain the fungicides and insecticides.

MR. MALLAMPALLI: That's an interesting thing to consider in the future. We're not working with the seed industry on this issue, as far as I know. The scope of the labeling PRN, I think both PRNs, is really intended to cover conventionally-applied pesticides sprayed, or genetically-modified herbicide tolerance crops would be covered as well, by the herbicide PRN. The seed coating issue is definitely a legitimate concern, I think.

MR. JONES: We did -- and that question has been raised about the seed coatings and resistance. We did talk to the insecticide resistance action

committee about that. We've also done some work. We can't find any direct relationships from the resistance side for some of the seed treatments that, for example, might be followed up by foliar treatment earlier on in the season.

But we are not working with the seed industry on that. I mean, we're considering this and we're considering resistance in a risk benefit framework because we're going through registration review and, when appropriate, we think in the new chemicals as well, new active ingredients.

MR. KEIGWIN: Okay, thanks. So, the last two topics, Anita Pease and Marietta Echeverria will lead us through those two discussions.

MS. ECHEVERRIA: Good afternoon, my name is Marietta Echeverria. I'm the director of the Environmental Fate and Effects Division. So, we are going to briefly go through two updates. We provided information in the packet. So, the first topic is around mixture toxicity or a.k.a. synergy.

So, this issue became prominent about a year and a half ago when we discovered that there were claims being made to the patent and trade office that chemicals in combination that we were considering for registration, the companies were making claims of

synergy.

We have had a longstanding practice in the program to evaluate single active ingredients in terms of our risk assessments. The reason being is based on the information that we have, actual synergistic interactions. They're actually a really rare occurrence based on the way that we regulate pesticides.

However, since these claims were being made, we felt that it was appropriate to consider the information and to determine whether or not it was a source of information that was relevant for risk assessment.

So, we've been piloting a process that walks us through a screening process to determine whether or not information supporting those claims is actually relevant for risk assessment purposes. To the extent that there is relevant information for risk assessment purposes, we have asked companies to report that information to us. Then we've gone through and we've actually evaluated that.

So, to date, we can report that we've looked at approximately eight cases on this issue. For the majority of cases, what we found is that those data are actually of little value in terms of risk

assessment. So, in the majority of cases, there's actually little underlying information that would actually make it into a risk assessment.

There's actually two cases where we saw potential relevance with respect to the information. In those two cases, we made a determination it was most appropriate to use our guideline testing methodologies to go to direct formulation toxicity testing. That does provide relevant information for risk assessment.

So, our goal is to continue piloting this process through the registration program and as we learn and we get a number of cases under our belt to actually make some recommendations and come out with a white paper and position in terms of the value of this data from a risk assessment perspective.

So, with that, I think we'll open it up for questions.

MR. KEIGWIN: Steven, then Nichelle, then Jake. Cynthia, I don't know if your card is up or not.

MR. COY: First clarify for me. These eight cases of synergy, were they cases that registrants claimed synergy for their product between different ingredients?

MS. ECHEVERRIA: Correct. So, they were

actual cases that we were reviewing applications under registration. We searched patent and trade office information and they were making those claims. So, there was a direct need to actually evaluate whether those claims and the data supporting those claims were relevant for risk assessment purposes.

MR. COY: Okay. So, this is not related to what the beekeepers usually bring up, synergy from tank mixes of two separate products?

MS. ECHEVERRIA: Correct. So, this was specifically where we had this source of information where these specific claims were being made. But this pilot does not address the tank mix situation that you're referring to.

MR. COY: Okay. And then, at the meeting in January, there was a presentation that indicated that at least one -- I don't know what the company was. But they were using an active ingredient of one product as a component of a separate product for the synergism thing. So, that's kind of what you're talking about in your initial eight cases?

MS. ECHEVERRIA: I'm not sure I understand. Can you repeat?

MR. COY: So, they were using -- I can't remember the product name. A researcher was doing

research and he said that an active ingredient for one product was an ingredient in another formulation. The reason they put that ingredient in there was a synergistic effect.

MS. ECHEVERRIA: Okay. So, I think that's a different scenario what you're talking about. There are some products where an ingredient is designed to be a synergist. In those cases, we understand how the synergist works purposefully to enhance efficacy of the product. So, I'm guessing that's what you're referring to.

But in these cases, there are actually claims being made to the trade office that said in combination two separate active ingredients, you would have enhanced yield or a better effect in the field.

MR. COY: Okay.

MR. KEIGWIN: Nichelle, then Jake, then Robyn.

MS. HARRIOTT: So, my question is similar to Steven's. So, the Agency is only evaluating synergy if there is an explicit claim being made, correct?

MS. ECHEVERRIA: Correct, for this pilot process. In these cases, we felt compelled that there is an actual claim out there that we needed to investigate, whether or not there is actual data

relevant for risk assessment that would actually change our risk assessment meaningfully.

MS. HARRIOTT: So, you mentioned that is a pilot. But in the future, will the Agency look at formulations that have more than one active ingredient for synergy as part of its risk assessment?

MS. ECHEVERRIA: So, for a product that is co-formulated, we do get formulation specific information, a typical end-use product when the application is made directly to water. So, we consider and we evaluate that information as part of the risk assessment currently.

MS. HARRIOTT: But it's not throughout the program? You said it's only for those applied to water.

MS. ECHEVERRIA: And also for plant toxicity. It's based on the formulation specific information. Also, field testing for pollinators is also formulation specific.

MS. HARRIOTT: Okay. So, the eight cases that you mentioned, so there are currently eight formulations out there that claim synergy on their labels?

MS. ECHEVERRIA: So, there were eight active ingredients that there was an application process for

which they were making claims to the patent office that we've run through our relevancy criteria and we've evaluated whether or not there was information to change our risk assessment.

So, it's not formulation specific here. So, it's an active ingredient A and maybe the company who has active ingredient A, or another company we've actually found out, and they're actually making claims in combination with another active ingredient in terms of a tank mix or some kind of use together, you would get enhanced yield or enhanced efficacy.

MR. KEIGWIN: Jake, then Robyn, then Sharon.

MR. VUKICH: You had mentioned that there's a process for screening and searching the patent office claims. Is that process available? Is it an SOP or is that something that we can see?

MS. ECHEVERRIA: Yes. It's a draft process that's available upon request. We have been giving out guidance as we've developed the process and learned as we've gone. So, we're happy to share that information. It is draft.

MR. KEIGWIN: Robyn, then Sharon, then Richard.

MS. GILDEN: So, could you just clarify for me. With the eight cases, you said most of them

weren't applicable because of a variety of different reasons. So, the data wasn't good or it was negative or it was missing? What made them not be usable except for the two cases?

MS. ECHEVERRIA: So, in some cases, there were no relevant data actually supporting the claim. In other cases, it was actually limited information. Then, in other cases, there was actually information but it was not robust enough to support a statistical analysis to support the claim. So, there's more than one sort of outcome.

MS. GILDEN: So, would that mean that where there was missing data or not good quality data, would you go back to those companies and say we need more data or better data?

MS. ECHEVERRIA: So, we weren't piloting this to impose additional data requirements. We were using best available information, as is our practice. So, if there was a data source that had the best available information there was evidence in that data source, we would want to use it. But we're not looking to expand requirements in absence of those data.

MR. KEIGWIN: Sharon, then Richard, then Cynthia, and I think Lori Ann, your card is up.

MS. SELVAGGIO: I've got a question about

this. Bullet number two refers to USGS ambient water quality data. It says in a predominant number of cases, the potential toxic risk is dominated by one to a few chemicals. That phrasing is a little odd to me, potential toxic risk. As you know, depending upon the watershed, highly agricultural or highly urbanized watersheds can very, very commonly have multiple pesticides detected in a single sample.

So, I'm wondering what else is EPA doing? It is common that you see mixtures that are often dominated by a few key chemicals. So, what else is EPA doing to evaluate the synergistic interaction, the potential for synergy amongst those frequently used pesticides that commonly show up in aquatic systems?

MS. ECHEVERRIA: So, for this pilot, we're evaluating the patent and trade information, patent and trade office information. To the extent that there is open literature data with respect to an active ingredient that is robust enough for us to consider for risk assessments, we do that as part of our re-evaluation process.

MR. KEIGWIN: We'll just take these last three because we still have one more topic and then the break. So, Richard, then Cynthia, then Lori Ann.

MR. GRAGG: Thank you. I think I just

understood what you were saying. So, if a company is claiming an interaction in effect to enhance the pesticide, then you're concerned that that could be tox interaction in terms of health. So, therefore, you're going to investigate it?

MS. ECHEVERRIA: Correct.

MR. GRAGG: Okay. So, are you using any of the 6-pack assessment to evaluate the potential?

MS. ECHEVERRIA: So, we considered that information from an ecological perspective to non-target mammals. This is in the context of ecological risk assessment. I should have clarified that. So, we are generally looking at non-target insects like the pollinators, birds, aquatic invertebrates, fish, and plants. Non-target plants has been a big one. So, it's really in the context of that kind of evaluation.

MR. GRAGG: Thank you.

MR. KEIGWIN: Cynthia.

MS. PALMER: I just have a clarifying question. I'm sure I just somehow missed the answer. So, on page one, it says a large number of U.S. patents have claims of interactions. Then, on page 2 we learn about these eight cases that you looked at in more depth.

I'm just wondering was eight the total universe of claims for which there is sufficient data or if not, how did you choose to focus on those eight?

MS. ECHEVERRIA: So, the eight had to do with applications that were in front of us for regulatory decision making. So, that's why we focused on the eight. We were actively working on those risk assessments in support of a registration decision. But there is this other body of information out there that has not been looked at systematically.

MR. KEIGWIN: And Lori Ann.

MS. BURD: Last July, we, at the Center for Biological Diversity, put out a report where we looked into the past six years of pesticide product approvals by four companies in the past six years. We found that 96 out of the 140 had pesticide patent applications for them.

Then we followed that up with a petition, because we found that going back to 2007, there was a regulation requiring pesticide registrants to submit that information. Then a regulation was removed. I think it was called unnecessary. So, we are still awaiting a response to that petition and eagerly look forward to it.

MS. ECHEVERRIA: So, as I mentioned, we are

in receipt of the petition, and we are working on the response right now.

MS. BURD: For folks that are interested, that report again is called Toxic Concoctions. It contains tables of pesticides we looked at.

MR. KEIGWIN: Okay, we'll do one more and then take a break. Maybe it will go quick. ESA. Not because it's yours, Anita.

MS. PEASE: Hi, everyone. I'm Anita Pease. I'm the assistant director of the Environmental Fate and Effects Division. Saving the best for last, I guess.

So, you've got your one-pager. So, I know a lot of you, this is a topic that is near and dear to your heart. For the past four years, we have been working with the Services, U.S. Fish and Wildlife Service, National Marine Fisheries, to implement the recommendations from the National Academy of Science Report that came out in 2013 to develop a common method for evaluating the risk of pesticides to endangered species.

We developed an interim method back in November of 2013. We agreed then that we were going to apply that method to five chemicals. Chlorpyrifos, diazinon, and malathion is the first

three. And then carbaryl and methomyl is the next two. We were going to do that in the context of nationwide biological evaluations, so the first ever nationwide consultations for endangered species based on pesticides.

Back in April of 2016, we released the first draft biological evaluations for the first three chemicals, which are chlorpyrifos, diazinon, and malathion. We sent those out for a 60-day public comment period. We received a lot of public comments. We got about 70,000 comments, most of which were a letter writing campaign to ban those chemicals. I think we had about 120 substantive comments mostly from grower groups, pesticide industry, and such.

After we received those comment letters, we had a stakeholder meeting in June of 2016, a two-day stakeholder workshop, where we got a lot of good recommendations on some of the challenging issues related to aquatic modeling, a weight of evidence approach, and seeking recommendations on further refinements, both spatially and nonspatially, to our risk assessments.

So, recently, in January of 2017, we did release the final biological evaluations, along with a response to comment document. It became necessary

because of our consultation deadlines, our court-mandated deadlines for the first three chemicals final biological opinions, which is the next document in the process. Those are due January of this year, 2017, for the first three chemicals.

It became necessary to bin all the recommendations that we received into those that we felt we could implement in the short term and those that would take longer to develop, having those discussions with the Services so we could come to agreement.

So, we released the final BEs, acknowledging that not all of the public comments that we had received we would have time to address. So, we did what we could in terms of addressing errors, working on some improved transparency for our modeling, adding and deleting species as appropriate, and also making some changes to our aquatic modeling approach to include some further refinements. So, those documents are now available.

Also, in mid-April, we received a letter from the registrants for the three chemicals, for Chlorpyrophos, diazinon, and malathion, basically making three requests to the Agency. The first request was they wanted us to retract the final BEs

for the first three chemicals, they want the Services to stop work on biological opinions, the next step in the process, and also for us to go back to the courts and request an extension on the court-mandated deadlines for the final biological opinions to allow us all more time to integrate all the comments that we've received.

Also, EPA has completed draft BEs for carbaryl and methomyl. Those have not yet been released for public comment yet. That's all tied up in consideration of the letter that we got from industry. I'll also mention that in addition to the industry letter, we received some letters of support from Crop Life America, from Rise, and also from the registrants for carbaryl, basically voicing support for the industry letter.

So, right now we continue to work with the Services on develop further refining the methods and also working on methods for step 3, which are the biological opinions. We're expecting that the Services will release biops, draft biops for the three chemicals in the beginning of the summer.

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

MR. KEIGWIN: Okay, Robyn.

MS. GILDEN: So, thank you very much for that quick update. After you're done with all of these pesticides, what pesticides are you going to target next?

MS. PEASE: So, next on the docket after these five are four herbicides. That's atrazine, simazine, propazine, and glyphosate. Right now, the commitments are for EPA to complete BEs by 2020 and for the Fish and Wildlife Service to complete the biop by 2022.

MR. KEIGWIN: Richard, then, Sharon, then Lori Ann.

MR. GRAGG: So, are the industry groups asking you to go back and redo what you've already done or approach it in a different way?

MS. PEASE: Yes. So, basically what industry is asking is that we go back and we refine the first two steps in the process, which are EPA's biological evaluations. So, if you're not familiar, the final BEs that came out had a large number of likely to adversely affect determinations. About 97 percent of the species for chlorpyrifos and malathion moved on to the biop as needing further evaluation by the Services. For diazinon we had about 80 percent of the species.

So, it's basically going back to the methods that we developed and including further refinements with exposure, the way we evaluate exposure, the way we characterize toxicity, and also how we evaluate geospatially the areas where pesticide use overlaps with areas where species occur on landscape. So, there were a lot of different recommendations.

MR. GRAGG: So, these were the methods they're wanting you to revisit?

MS. PEASE: Yes.

MR. GRAGG: Are these standard EPA methods?

MS. PEASE: They're new methods. They're new risk assessment methods. They make use of our existing ecological risk assessment framework, but we did develop a lot of new tools. We have a lot of new methods that we use in these BEs that we have not typically used in our normal FIFRA assessments.

MR. GRAGG: So, in what you have now and if you revisit it, when you revisit it, what implications will that have for human health risk assessments on these pesticides?

MS. PEASE: This is specific for --

MR. GRAGG: Yes, I know. I know, endangered species. I'm saying if you go back and revisit it for the endangered species, are there any implications for

the human health risk assessment?

MS. PEASE: Not that I'm aware of.

MR. GRAGG: Okay.

MR. KEIGWIN: Sharon, then Lori Ann, then Marc.

MS. SELVAGGIO: Thanks for all your work on this so far. I know these documents and this process is extremely time consuming and laborious. It addresses some big questions, though, which are what effects do pesticides have on the most vulnerable species in the nation, which is kind of similar to the question that we're asking when we talk about vulnerable people, such as farmworkers and children and those who are occupationally exposed.

It's really important that we consider the particulars of listed species when we look at pesticides through the process. So, I'm glad, even though I've only been working on this for two years, this whole process has actually been kind of underway, as you guys know, for over a decade.

I think it seems late in the game to get this kind of recommendation, because in the two-and-a-half years that I've been kind of paying attention to this, I think you guys have held at least four stakeholder workshops outlining your methods. It's

been open to the public.

So, I know that you've done a lot of work to try to make sure that the assumptions and the models and the scientific processes that underlie ultimately the conclusions are transparent and available to people to understand in advance. So, I appreciate that you have gone to that effort. I just think it's late in the game for a request like this.

When I look at the three requests, I guess my question for EPA is, since this first two batches are basically under settlement agreement, if you can't get a modification of the settlement agreement, doesn't that make moot the first two requests?

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

MS. SELVAGGIO: Okay. I just wanted to see if there was something I was missing. So, thanks.

MR. KEIGWIN: Lori Ann, then Marc, then Dawn.

MS. BURD: I'm going to echo a lot of what Sharon just said. The contents of at least the first letter -- I haven't seen Crop Life's or the other ones that you mentioned. The contents of these letters are all rehashing points that have been made in the multiple comment periods and the multiple public meetings.

This has been the most transparent consultation process in history with these long comment periods and many opportunities for stakeholder input. It's incredibly frustrating to see this Agency considering an 11th hour attempt to thwart a nearly half decade of progress on this.

The Center for Biological Diversity strongly encourages you to not grant this request.

MR. KEIGWIN: Marc and then Dawn.

MR. LAME: So, this was a fairly predictable game of delay that registrants and the associations play. They've kind of always done this, at the same time asking for sound science and transparency, which, again, I agree has been outstanding in this case.

I guess my question is, do you have an estimate of how many species will be going extinct in the United States before we get to do this again?

MS. PEASE: I don't have an answer to that. I think it depends on what their current baseline status is right now. Some species are recovering quite well that aren't still on the list. I look to Gina to clarify this, but others are in decline. So, there are some that are on the brink. These are criteria that are being considered in the biological opinion right now. Are the species trending up or down, and

that's part of the equation. But I can't even fathom a guess the answer to that question.

MS. SHULTZ: So, you're asking an open-ended question like what would the delay be. So, I can't tell you if there were a delay, how long it would be and how many species would go extinct during that time due to any of the pesticides that we're consulting on or other reasons unrelated to pesticides.

MR. KEIGWIN: Dawn, then Ray, then Gabrielle.

MS. GOUGE: Given that you're intimately aware as an expert team of the process that you've been through, if you were to go back, modify your process, and move forward, would you anticipate any different results at the end of the process?

MS. PEASE: I think we would. I think we would have a smaller number of likely to adversely affect determinations for species. I think some of the streamlining steps that we're considering right now, some of the recommendations from stakeholders, both registrants and grower groups, we agree with and we think those are good recommendations. We would like to implement them given the time to do so.

So, I expect that we would probably have a fewer number of species that would move forward in step 3, which is the Services biological opinion. We

want to be protective. We're not interested in just reducing numbers. We're interested in focusing our resources on a species that actually need and deserve protection.

When everything shoots through to the next level, that's not a very good screen. So, I think we acknowledge that. So, I think yes, we would expect different conclusions.

MR. KEIGWIN: Ray, then --

MS. ECHEVERRIA: Can I add one thing? One point I would make, I agree, we might expect different conclusions with respect to the step one and step two conclusions. But I don't know that we could say whether it would make an actual difference in terms of the biological opinions, which ones we determine are in jeopardy or not in jeopardy, or the regulatory RPAs are measured that we'd actually put in place. I don't know that we have that information. I do think it would make a difference in terms of our resources in terms of how big the consultation is to begin with.

MS. SHULTZ: So, I can confirm that as well. So, as we're drafting the biological opinion, there are species that were determined to have a likely to adversely affect. And after we've

done our step three review, we've concluded that actually they're not likely to adversely affect. So, we're not carrying it all the way through the jeopardy analysis.

But that's one of the many, many streamlining things we've talked about for the future consultations. It will be much more efficient if EPA uses that same bar that we've used in step three for not likely to adversely affect and then the consultation concludes at the BE stage.

MR. KEIGWIN: Ray and then Gabrielle.

MR. MCALLISTER: I think Anita made the point I wanted to make, basically. It's my understanding that the biological evaluations found some 87 percent of the species in the likely to adversely affect category, which doesn't bear any relationship with what we see in the field. These products have been used for decades and don't see declines in those species. So, I think it's worthwhile to reevaluate.

MS. PEASE: Yes, I just want to make a point. So, the effects are effects to one individual. So, I think that's important to note. That's what LAA means. It's not the population; it's at the individual level.

MR. KEIGWIN: Gabrielle.

MS. LUDWIG: From the grower groups' perspective, I've looked at the draft biological BE evaluation. I just want to say for those of you who say okay, this is all finished science, it really isn't. There's a lot of new stuff here. I don't claim to grasp all of it, but I will say that from our perspective, one of the issues really is --

I understand the reasons why, but some of the assumptions on how the products are used are absolutely worse, worse, worse case scenario. It would be nice if you not only had what I call the worse, worse --

I mean, some maximum label rates are like seven times what we actually use in the field, but also something where you looked at what I call a maximum normal use rate. So, you could really see how far off are we from things or where can we make some adjustments and maybe make some changes earlier on.

But I just want to be clear that this is really complicated. Having legal deadlines that short change the process and the public process for discussion about it really is frustrating. Again, it's not saying it's all going to end up one way or the other; it's just these things take time to try it

out, figure out what works and doesn't work.

I come back to having had the chance to observe EPA go through this process on the dietary risk assessment, on the human dietary risk assessment back when the Food Quality Protection Act got passed. Those first human health risk assessment showed substantial risk, actually for some of the exact same compounds we're talking about now.

When those risk assessments were made publicly available and grower groups could look at them and say no, that's not how we're using it, we're using it this and this way, and plus some other refinements in the risk assessment methodology going to a probabilistic methodology, using pesticide data program residue data, you ended up with a sense that okay, now we're dealing with the risks that really are of concern. Beforehand, everyone was like okay, this just doesn't make sense, as Anita was sort of saying, when you have everything being a problem, when it doesn't ring true.

So, I just want to say I realize there's a lot of different interests here. But from a grower group's perspective, not wanting to have things all right or all wrong, this has been frustrating in terms of having deadlines that didn't allow us to have that

really transparent process to move forward. So, I just want to say I don't think things are as settled as they seem to be.

But this has been a learning process. I mean, I do think EPA had to try this for better or for worse to find out what it takes to do every species between Maine and the Mariana Islands and barely survive it. Anyway, I just want to say that it's complicated, hard.

So, having the time does make a difference. Again, I'm not saying it's going to end up all one way or the other. I think there's additional information either way that could help inform this process.

MR. KEIGWIN: So, Sharon, you get the last comment.

MS. SELVAGGIO: It's just a question. I forgot to ask something. On your update sheet, it says EPA is exploring using species specific toxicity data earlier in the first step. If my recollection serves, you used like HCO5 from the species sensitivity distribution, unless you already had species specific data, right? I thought you already used that.

MS. PEASE: Yes, we do, but that doesn't come

into play until step two. If you recall, step one is the no effect/may effect call. That's right now only on geospacial co-occurrence. So, there's no toxicity information that's included in that step right now, other than the off-field transport part of it.

MS. SELVAGGIO: Okay, thanks.

MR. KEIGWIN: So, we're running about 15 minutes behind. Arnold has already set his timer for his talk, which isn't for like a half an hour or more. So, why don't we try to gather back here at 3:25. It gives you about 15 minutes. Thanks.

(Whereupon, a brief recess was taken.)

MS. MOSBY: -- and Melissa Panger who have been the co-chairs who have helped to facilitate and just get all of the information that we needed and advice we needed from the workgroup.

So, I'd like to just start with talking about -- just to refresh everyone's memory about the OPP goal, and just to mention that many of you remember that we started this workgroup, the PPDC incident workgroup, 18 months ago. The goal of the workgroup was to develop an electronic incident data system that is publicly available and useful to a broad stakeholder group. So, that was the goal of the

workgroup. We wanted to receive advice from the PPDC workgroup on this.

So, we set out to develop a new system to one, address the deficiencies in our current system. So, that meant that we were looking to have a system that would improve reporting by making reporting easier for both voluntary and for required incident reports, obtaining more and higher quality incidents for risk assessments, improving consistency in our reporting, also to enhance efficiencies by eliminating manual data entry, reducing time that we spent on FOIA requests, and also we wanted a system that would support quality science-based decision making, and also we wanted a system that would encourage data sharing within EPA and between other agencies and stakeholders. So, we were trying to solve a problem.

The problem I kind of stated in going through what we wanted, but the problem was that we had primarily flat files, no data. We have manual data entry. We have inconsistent information, missing information. Our data is submitted in various parts of the organization and also submitted in various forms. It doesn't talk to other systems.

So, the current charge that we had for the PPDC incident workgroup was to advise us on which data

might go into this new data system and to get input for system development. It's worth noting that the charge has evolved over time. We started out with sort of a start and finish, and we would have had substantial down time during system development.

Our current thinking is that the PPDC workgroup would help us on the front end, which is the data elements, and then we would go off and start working on system development. Then we will reconvene on the implementation issue. So, that's the approach that we are using.

The workgroup has been providing advice on what data might go into the system. So, that includes data elements, the number of data elements, also the thought of maybe we need a smaller number of elements for certain kinds of incidents. We talked about a trade-off between the cost and the benefit of additional data elements and when might some data elements apply. Yesterday, we had a facilitated meeting with the workgroup to talk more about this issue of when would certain data elements apply.

What we were trying to get at were some questions like should we strive to get all the data elements for every incident? What are the circumstances where we would strive to get all the

data elements? So, we got input on questions like that, just trying to figure out when do all of these data elements apply, what type of incident would they apply for.

So, we got that input. Then, the other part of our charge was input for system development. We wanted to hear from the workgroup on parallel databases. So, we talked about other systems that might help us in designing or thinking about what our system would look like.

Rather than to have the group be dormant for some time, we decided to dissolve the workgroup and come back to the PPDC for further input prior to implementing a new system. So, as I said, we received input on a host of data elements. I went through those.

We've got some work, and we've received just excellent advice and input that we'll take into consideration. But we need to go back now and look at the data elements that we have and then we would come back and start a new workgroup.

But what we would do in the future with the PPDC would be sort of implementation issues. It would be verifying and validating incident data in the database, protecting issues -- these are issues that

came up on implementation that we haven't come to some conclusion about -- protecting certain information, PII, and screening data for public release.

So, these are issues that we still have to address. Those are those implementation issues. So, we're at a place where we have received the advice for our initial charge, and we would like to, as I said, dissolve the workgroup and get back with you through another workgroup. We'll figure out the process for doing that.

I want to just thank the workgroup. You have provided invaluable input. We've got diverse input from a diverse group of stakeholders. As I said, your input has been invaluable. OPP appreciates the feedback already received by the PPDC workgroup. We look forward to taking your input under consideration as we move forward.

MR. KEIGWIN: Thanks, Jackie.

MS. MOSBY: You're welcome.

MR. KEIGWIN: If there are one or two questions or comments, we can take those. Cheryl and Liza.

MS. CLEVELAND: So, I appreciate being able to be part of this workgroup. I guess I really struggle with this constant discussion of data

elements for data elements sake without having broader context. Personally, I just struggle with it, so it was hard.

They'd say rank this or when do you need this. I'm like well, how are you getting this data? Is it coming from a public call? Is it coming from a search of another database? Is it coming from an EPA staffer that's going to backfill this? It was very difficult. I tried really hard to continue to stay focused on this.

That's what I just want to say. I think you did push through. We had a long list of data elements. But I think you need to consider them to be a little bit draft. Even in the car yesterday, there were some people discussing these data elements as if they would be somebody on the phone, taking a complaint call at a call center. And there were other people thinking no, it's a state investigation person that's following up on this. So, it's not clear how you're collecting, who is getting it.

We heard real clear that if you're talking to the public on the call, you'd only have a short amount of time, 6 to maybe 11 minutes keeping somebody on a call. That's it. So, if you want to push to get all these data elements filled, that's going to be

very difficult.

So, these other questions about when do you strive to get everything. That's a question. How much resource do you want to put into backfilling? How much EPA resource or other state regulatory resource do you want to put on to backfill things that you don't get the first time?

So, I would say we did bring forward some concerns last year where we stated that without context, some of this is very difficult. Mandatory versus voluntary, the data collection mechanism itself, the implications for a registrant 6(a)2 information, and then the verification and validation part of this.

We were only talking one part of the project. So, you had to start somewhere. Great. Consider them draft until you can answer some of those other questions. Thank you.

MS. MOSBY: Thank you.

MR. KEIGWIN: Liza and then Amy.

MS. FLEESON TROSSBACH: I think part of my question got answered by Cheryl, but just for my clarification, just to refresh my memory, this would be any type of incident? So, it could be a possible pesticide misuse or alleged adverse effects to

pollinators from pesticides. So, this could be any type of incident that involved pollinators?

MS. MOSBY: Yes.

MS. FLEESON TROSSBACH: Also, the report could come from anybody. So, the general public, state-lead agency, or registrant, any of those different groups?

MS. MOSBY: Yes.

MS. FLEESON TROSSBACH: So, I would just like to reiterate what Cheryl indicated, the concerns of state lead agencies, for example, in our business. We get a lot of complaints, a lot of tips, Complaints, and reports often have no pesticide related issue at all.

So, one of the concerns is that if that's reported as an incident, is it really an incident? There's not a finding of some type of violation or an actual adverse effect can be -- you know, there's some sort of causation there.

So, I would agree that verification and validation and then coming full circle. And then also ensuring that you're not double counting. If the general public reports it and I as a state-lead agency report it and somebody else, then you have these multiple things.

So, just to be thinking about in addition to which data elements are appropriate, how you're going to gather the data, verifying and validating. Is that full circle to make sure that you're not getting false data. Good data in, good data out. The opposite is true as well. If that's going to be used to inform decisions, we want to make sure that it's valid data. So, thank you.

MS. MOSBY: Thank you.

MR. KEIGWIN: Okay, we'll wrap up with Amy.

MS. LIEBMAN: I appreciate all the concerns that are being raised. I just wanted to say that the incident workgroup has really worked on a really important issue. I encourage you to continue the road that you're going down.

Quite frankly, if we're getting like extra reports, I just think that's great because we're not getting a lot -- we need to sort of figure out how to gather incident data. I understand the concern about possible double counting, but at this point, because it's so haphazard and there's not a good system in place, this is a start and a step forward and much needed.

I'll just put my plug that I put in for every single PPDC meeting, but we really do need a system

that's national where we can systematically report pesticide incidents. I would love to go the regulatory route on that, but I know that's probably not going to happen. But this is something that is greatly needed if we're to understand what's happening with pesticides once they've been approved.

MR. KEIGWIN: Okay, thanks, Jackie, and thanks to the workgroup that's gotten us to this point.

Now, what Arnold has been waiting for all day. This time I won't also forget to introduce Yu-Ting since she's a co-session chair for this one, so Yu-Ting Guilaran as well from the Pesticide Re-evaluation Division. And Bob McNally, he wasn't on the agenda. That one I have an excuse.

MR. LAYNE: Good afternoon, everyone. I'm Arnold Layne, Deputy Director of the Office of Pesticide Programs. I'm thankful for the opportunity to give you an update on Zika. I'm going to provide you, with the help of Yu-Ting, the status of registration reviews. With the help of Bob, we're going to talk about integrated pest management. Then, lastly, I just wanted to let you know that from the last PPDC meeting, we heard you with respect to your concerns and desires to bring together a workgroup for

public health issues. We'll talk about that.

To start with, an overview of Zika for those of you who weren't here last time. This is such an important issue. As you see in this slide, the former CDC director, Tom Frieden, highlighted the critical nature of Zika in his statement that you can read, as well as the statement or quote provided from the New England Journal of Medicine, which says it all, I think.

This next slide really breaks my heart, and it shows you the impacts of Zika on our most precious blessings, children. Zika is a public health concern, and it is a virus that is spread by mosquitoes that is known to cause birth defects in fetuses infected, and also Guillain-Barré Syndrome in adults.

Zika affects all of us through both health and emotional tolls that it takes on us, as well as it costs society. It's imposing. I have heard figures of up to $10 million for health care and just support for babies born with Zika. So, you can imagine the economics associated with that.

EPA is involved in a large and active federal response to prevent, treat, and gather data on Zika transmission. The Office of Pesticide Programs has a key role since we regulate mosquito control

pesticides and repellants, as well as advocate. We really do advocate first for integrated pest management methods for control.

I believe that all of us who work in the area of pesticides and human health, we must care deeply about how our expertise and interest can improve the lives and livelihoods of people by avoiding disease, protecting human health, and protecting the environment.

This particular slide here shows the number of Zika cases in the U.S. It is substantial, with most reported cases in Puerto Rico. While thousands of Zika virus cases are reported, most have been acquired through travel.

This map shows the spread of Zika across the U.S., with the darker filled areas showing higher number of cases. So far, only the Miami-Dade area of Florida and the Brownsville and border areas of Texas have confirmed locally acquired cases of Zika. In some respects, that's good news.

This next slide will show you some of the epi data associated with Zika. So, these numbers are from the 12th of April. I do have some updated numbers. I'm not sure that it matters. The fact is that the numbers are going up.

So, in the continental U.S., we're looking at right now, my latest figures, are 5,264; U.S. Territories 36,575. Of those 36,000 in the territories, only 143 of those cases are travel related. Of those 36,000 cases, 35,400 of those essentially are in Puerto Rico, 997 in the U.S. Virgin Islands, and 132 in American Samoa.

The pregnancies that have been officially report in CONUS is 1,762, and U.S. territories is 3,592. Pregnancy outcomes in the United States, so far there have been over 1,300 pregnancies that have gone to completion. Of those, 56 live born babies with Zika related defects, and there have been 7 pregnancy losses. Those babies that were lost did in fact have Zika related defects.

If you're wondering about the territories and the pregnancies, my data comes from CDC. CDC does not report pregnancy outcomes on the territories because of the methodology differences and how they're reported and/or tracked. CDC has a low confidence in the numbers from the U.S. territories. So, that's why they don't track those numbers. They are working with the U.S. territories to have that capacity. It used to be there and then all of a sudden it changed.

So, Zika is a virus that's been known since

the 1940s. There was a 2007 outbreak in Micronesia that resulted in an estimated 900 cases and a population of less than 8,000 people. Over the past two years, there's been more than 30,000 suspected cases of Zika that were reported from the French Polynesia and other Pacific islands. Just about two years ago, Zika was identified in Brazil and now in the Americas there are tens of thousands of known cases.

With insect season soon to start up again, and some places already have, there's a fair amount of concern by public health professionals that Zika cases may increase. We had a very mild winter this past winter, so we're expecting these numbers to go up.

Zika is closely related to dengue, yellow fever, Japanese encephalitis, and West Nile virus. As you know, it's primarily transmitted by Aedes aegypti or albopictus. The modes of transmission include intrauterine and perinatal transmission, sexual transmission, laboratory exposure. I think there's been one case as far as I'm aware of of lab transmission, and a number of cases of blood transfusion.

So, with the outbreak in Brazil, a connection was made between pregnancy outcomes and Zika virus. Subsequent studies have determined the

association between the disease and health outcomes, like microcephaly, brain calcifications, and other brain abnormalities. There have been sufficient cases of birth defects associated with Zika that there is now a condition called Congenital Zika Syndrome. So, if you hear that terminology, you'll know what it means.

So, this infection has been linked to a number of things, including eye abnormalities, hearing loss, limb abnormalities such as club foot, as well as impaired growth. Most recently, research is ongoing related to other health consequences that may be associated with Zika Syndrome, including such things as epilepsy in these children.

The other point I want to make is there are some babies who are born who appear normal. They have brain calcifications. And at the age of around six months, they begin to show signs of Zika. The brain begins to shrink and the head begins to shrink. So, you can have what you think is a "normal" child, but in time you find out that the child is in fact suffering from defects from Zika.

Yes, there is a correlation or there has been speculation of a correlation between people who have been infected with other diseases like dengue and

such, a correlation between that and Zika. So, in Brazil, there is a huge number of women who are pregnant and had a number of babies born with Zika. It turned out that they also had antibodies for like dengue and yellow fever and such. So, they believe that there may be some synergistic effect going on in the immune system. I'm sure there will be more research being done on that.

So, CDC leads this federal response effort. I'll say that again, CDC leads this effort. EPA and several other agencies, we help CDC and we meet regularly to discuss Zika and address Zika. We support CDC with information on integrated pest management and pesticide registration and use information.

Combined efforts show that in states where local transmission of Zika has been reported, such as Texas and Florida, mosquito control and public education efforts have succeeded in minimizing the impact of disease on human mosquito populations.

So, what that's getting at, as you'll recall this past summer, they were able to contain those additional infections by aggressive action with IPM as well as spraying of pesticides. So, while I think those areas still have what CDC considers yellow boxes

around them, the number of cases have not increased, for the most part.

Widespread public education campaigns address both residents and travelers to the area, encourage people in particular, pregnant women, to protect themselves from mosquito and Zika. Such measures include insect repellants on a regular basis, using window screens and other containment measures to keep these mosquitoes from coming indoors, which they love to do, discard standing water. Tire shredding, it's a huge issue in Puerto Rico, huge, tire shredding and removal, as well as avoiding areas where Zika transmission can take place. So, there are travel related warnings as well.

This next slide I sort of love because while the federal responses work to achieve comprehensive and sustained efforts on mosquito control, in light of Zika and other mosquito-borne diseases, and other diseases in general, the challenge remains. So, the black areas indicate those mosquito control districts that are active in those states that have not given up on mosquito control. So, they have active mosquito control activities going on. The white mass are those states that do not. So, this is a very poignant slide, I think.

So, not all parts of the country have a robust mosquito control program and/or adequate resources. So, some of the states used to have very active mosquito control districts. As their budgets got smaller and smaller, they decided to cut back on things like mosquito control in public health. So, as a consequence, they're not quite ready.

So, it's sort of patchwork here in the United States. There are more than 700 mosquito control districts in the contiguous U.S., but there are a large number of states where no local level mosquito control districts exist.

CDC and EPA are reaching out to states that provide help to do this. We need to control both larvae and adult mosquitoes, control surveillance of mosquito populations, their resistance, and increase personal protection largely through community wide approaches. We also need to establish vector control units in Puerto Rico. Of course, we're always looking for new tools and techniques that we can use.

Many of the efforts that are needed to reduce mosquito populations rely upon actions of property owners and residents to remove breeding sites. Folks, this is where the federal and state authorities have little control. So, we're talking

about your backyard. So, if you've got standing water, tip and toss. Teach your children how to do it. Those are breeding grounds for mosquitoes.

There's a bright side, and there's a bright future ahead, I believe. I'm going to be the optimist here. While EPA -- this not our area of work. I thought it would be important to put up a slide here on vaccine development. I'd like to report that vaccine development is underway and is looking promising. According to recent articles, it looks like there is promising news on the vaccine front. You can look up those articles and take a read when you get a chance.

Just so you know, phase one trials of vaccine development are ongoing, and they're looking toward phase two. During phase one, small groups of people received the trial vaccine. In phase two, the clinical studies expanded, and the vaccine is given to people who have characteristics similar to those for whom the new vaccine is intended. In phase three, the vaccine is given to thousands of people and tested for safety and efficacy.

At this point, the vaccine can be licensed. Even though there's still a phase four, which roles out ongoing studies of the vaccine. Use of live

attenuated vaccine is the best kind to give the best response. So far, the vaccine match seems to be very good for live attenuated vaccine. So, that's some good news.

The antibody response is reported stronger than response to the actual virus. So, good news there. All this means that we may have a viable vaccine. I don't want to throw out a time frame, but we're probably looking at a year to two years. I really can't put a time frame on it. Certainly, this is not EPA's area of expertise. This is certainly information from CDC.

In the meantime, especially starting this year and continuing, a strong partnership of federal, state, and local level officials have improved methods and approaches for controlling the mosquitoes and primary carriers of Zika. CDC and the states have strongly coordinated surveillance systems to monitor public health. CDC also worked hard during the winter, and I have to give them a whole lot of credit, to increase awareness and communications, closely collaborating with state agencies and mosquito control boards.

I mentioned that we meet with CDC on a regular basis, and this is one of the suggestions that

EPA provided CDC, that we use this winter as a time to prepare and train and develop and come up with community strategies. CDC has done just that. They have just been all over the place communicating, giving seminars and webinars and talking to states, et cetera, and communities. So, hats off to CDC.

Some mosquito control districts have ramped up as a result not only their own hiring, training, and preparedness, but also the information that they develop and disseminated in the communities. This is a community effort if we're going to be successful.

Because it is a public health emergency, EPA is also expediting registrations. You all are aware of that. We have expedited registrations, including emergency exemptions or Section 18s, and registration amendments for pesticides and repellants that have or want Zika claims.

At this point, I'm going to turn it over to my colleague, Yu-Ting, who is going to walk you through some of the eco and health risk assessments for mosquito control pesticides.

MS. GUILARAN: Thanks, Arnold. So, I have a couple slides to go through just to update folks on the pesticide tools that are available and are going through the registration review process right now.

As you can see, a lot of them, they are insect growth regulators with a couple that are on this slide. A few of the organophosphates are also on this slide. Then, the next kind of class of chemicals that we have here is pyrethroids.

They're in the various stages of the reg review process right now. For a good handful of them, the risk assessment is planned for this year. For a few of these, the risk assessment has been completed and has been published. We have gotten the comments from the public comment process. So, that spinosad and also malathion. And then we have ones that are planned this year in 2017. We have naled and DDVP. And then chlorpyrifos, obviously, the human health risk assessment was out back in November.

For the pyrethroids, we have the ones -- all the ecological risk assessments have been completed. The human health, a handful of them, did go out with the first batch. So, we're in the process of completing human health risk assessments. So, that includes the last chemical that's on the slide and all of the following slide, 15, here.

So, as you can see, some of these we have the assessment completed, and we will be soon extending the comment period once the Federal Register

notice is out, like what I said this morning, and then that will get another 60 days for people to submit comments to us.

So, our overall plan for the pyrethroids is that we'll come out with our proposed interim decision in 2018, following getting the comments from the public and assessing them and see if there's any change that we need to make. So, that's overall the schedule.

So, moving on to slide 16, just to reiterate that, the public input is really important to the reg review process. These are the chemicals that have been used for a long time. We know that a lot of times the label and use patterns drive the risk. So, it's really important for us to get feedback on detail use and usage information, especially data that will be the most helpful.

Then, geographic location of use can sometimes help us refine the risk. And then, also, after we have had a chance to look at all the risk assessments in terms of developing risk mitigation strategy, that's another area that we will solicit input and also work with the registrants and different stakeholders, USDA, then grower groups, or other CDC, for example, to figure out different ways to mitigate

a risk. Then, lastly, as an overall, the risk benefit balancing that I talked about this morning as well.

MR. LAYNE: Thank you, Yu-Ting. So, moving on to the next slide, I'm not going to spend a lot of time on it because you are well aware and knowledgeable about some of the things that we're doing that go beyond conventional pesticides.

We're also reviewing the new methods for controlling mosquitoes, currently assessing for safety and efficacy. That includes Wolbachia and Oxitec. So, I'm not going to spend a lot of time. I think Bob McNally and his group have done a fantastic job talking about that, so I won't spend a whole lot of time here.

I talked to some children, just to put a little smile on your face because it made smile. We had a bring your son or daughter to work day. I had to give an opening because my boss here didn't have time to do it. I was trying to be nice. So, I had a blast teaching them about many things, but of course I had to bring up Zika and mosquitoes.

So, one of the coolest things that they really appreciated and learned -- or actually two things. One is they will keep on their parents about tipping and tossing. Number two, they were amazed to

find out that just girl mosquitoes bite. So, I had a good time with them.

Anyway, the next slide on IPM. Bob, jump in at any time. You've done quite a bit of work in this arena. So, obviously, vector-borne diseases pose significant public health problems. We all know that. There's wide recognition that implementing IPM techniques is so critically important to successfully controlling disease vectors.

I want to stress that EPA strongly supports and is a huge proponent, and advocate for IPM, as we work with CDC and state agencies to monitor mosquito populations and target control measures, inform and engage the public and ultimately reduce vectors.

EPA plays a critical role in evaluating and streamlining registration process for many new novel and emerging pesticide technologies. We also provide guidance and expertise in safe and effective use of EPA registered pesticides as part of an overall vector management program. Obviously, when you're in situations like this, sometimes there could be quite a lot of misuse. So, we do our best to make sure that doesn't happen through education.

This next slide I'm going to hand it over to Bob. It's some of the stuff that he and his folks

have been doing in Texas with the IPM Center of Expertise.

MR. MCNALLY: Thanks, Arnold. So, as a lot of you know, we've talked before, we have an IPM Center of Expertise in Dallas. As Arnold alluded to, a lot of the benefits of IPM accrue as part of an IVM program. What we've done is supplemented the work of that group to include some IVM work.

We've added Ken McPherson, who was the region's sixth IPM coordinator, on a detail to the center starting this month. Ken's background is he was at the Defense Department before he joined EPA. He was sort of their expert on IVM and led efforts in the Pacific theater. So, we feel we have not only a national expert but an international expert to help us. I think where we help the cause of CDC is we bring the knowledge of pesticides to the table.

How do you combine that with IPM and an IVM program? To help some of those local communities that Arnold highlighted on the chart a little bit earlier that had the white space, that don't have an active mosquito control program, we think we can help with our expertise in those areas and others to help people deal with these issues as they come up, hopefully not this summer. But if they do, we want to stand ready

to be helpful.

MR. LAYNE: So, IPM partnership opportunities, CDC again is the lead federal agency for responding to public health emergencies, including vector-borne diseases. This also means that they are also the lead for recommending mitigation techniques to state and local agencies to address both disease and pest mitigation.

Recently, CDC awarded nearly $40 million to 4 universities to establish centers that can help effectively address emerging and exotic vector-borne diseases in the United States. Since there are significant regional differences in vector ecology, disease transmission dynamics and resources across the country, the centers are geographically disbursed and include the University of Florida, the University of Texas Medical Branch at Galveston, the University of Wisconsin in Madison, and Cornell University.

So, CDC has done quite a bit again. I can't thank them enough, and also their willingness to come together as a federal body. Several agencies came together, including the White House and others on this very important issue.

Next slide, please. So, that leads to -- and I can't tell you how much I appreciated in the

last PPDC, which is my first one in probably 15 years that I had been to, but just the overwhelming support from folks saying that they really would like to help in any way they can, help the Agency and help in this effort.

So, they wanted to bring back or reconstitute the public health workgroup. We took that back and we thought about it. We decided that we would like to move forward with that. So, with that in mind, we agreed.

There are some caveats, however, so that we do not get in trouble. One is there needs to be a defined time line. So, you're looking at a one to two year group. We really need to decide an area that we're going to focus on, or areas that we're going to focus on. So, sort of a finite set of areas that we would be charged with. It could just be one or it could be many.

I thought I would throw out just one up there. We are hoping to hearing from you, obviously, but I thought I'd get the conversation started. So, what we're proposing is -- and by the way, this is not just open to PPDC. We need at least one full-time member of the PPDC on this workgroup, and I imagine that I will not have a problem getting at least one

person, right, Dawn?

MS. GOUGE: I actually rotate out.

MR. LAYNE: Oh, you do? Oh, no.

MS. GOUGE: I'm afraid so.

MR. LAYNE: Well, you can still be on a workgroup. So, anyway, I'm sure there is at least one person staying on the PPDC who would be interested in helping us.

In any event, I thought that perhaps a discussion on Zika and other emerging pathogens, because they seem to be coming constantly, would be someplace to start. But there are a plethora of other topics that fall under this category of public health. So, we'd like to hear from you some of those suggestions and whether you're interested in serving on a group.

I will tell you that I would like to keep the group to no more than 20. Otherwise, it gets unwieldy. If you can send me or Dea, or actually send to Dea, your suggestions, A, if you want to participate and B, some areas for consideration that we can talk about and work on. That would be fantastic.

The next slide is just some discussion questions. I don't know if we still have time to do

that. I have 12 minutes left, and that was just from my presentation.

MR. KEIGWIN: Are you asking for a well done or something?

MR. LAYNE: Yes, and some water. Jackie professed to be from New York. I'm from New York as well. I think I went faster than her.

Anyway, we've got a couple questions for you to consider. Do you agree that the formation of a public health workgroup is ripe? I see some thumbs up. Yes? So, we want to move forward with that.

Again, please provide feedback and ideas on the charge that I proposed that perhaps we focus on Zika. But I'm open to whatever you think is most important and something that is well defined and that we will be able to complete within a reasonable amount of time. Send that information to Dea by May 17th.

What would be the benefits that EPA, and not just EPA, but everyone, could gain from this workgroup, focusing on Zika, if we were to go down this path? It's something to think about.

What other areas of public health and emerging pathogens would you advise would be appropriate for the workgroup to undertake?

Again, do you have any additional

suggestions for us to consider?

So, some discussion questions. With that, I open it up to you all.

MR. KEIGWIN: So, why don't we start with Fred, then Robyn, then Amy.

MR. STELL: Thank you. I just want to add that I think this formation of a public health workgroup would be -- DOD would be very interested in sending a representative from the Armed Forces Pest Management Board. We deal with not only items for the public health toolbox to be used on our installations, but also our overseas contingency operations, as well as some of the unique challenges that DOD faces with aircraft disinsection. That may also affect Department of Transportation.

We've seen with disinsection being implemented for public health purposes for entry into other countries, it's very important to stay engaged with those topics. We'd definitely like to be involved.

MR. LAYNE: Wonderful. So, we've got at least one PPDC member, so we can form a workgroup.

MR. STELL: This is supposed to be my last meeting, but my replacement definitely would like to be involved.

MR. LAYNE: Is there anyone here who --

MR. KEIGWIN: Everyone is going through membership.

MR. LAYNE: Everyone is going. Oh, geez.

MR. KEIGWIN: Some folks are term limited and couldn't apply for renewal.

Robyn, then Amy, then Marc.

MS. GILDEN: So, I've got to get myself together here because I have a couple of disparate comments to make. Yes, I think a public health workgroup is awesome. As for who can represent from the PPDC, you're losing three of the four existing public health representatives. So, Amy, it looks like it's going to be you. I mean, I'm hoping that you're going to replace the public health representatives. I'm willing to help, but I'm term limited off.

MR. LAYNE: Thank you.

MS. GILDEN: As for the IPM workgroup, I was privileged enough to serve on that for the six years that I've been on it. I'm very disheartened and disappointed to see that is not going to continue as the school IPM. I'm getting ready to give a talk to the School Nurses Association on Tuesday. I don't really see any follow up from the roundtable, which they were an important part of. So, I will continue

that conversation on behalf of the EPA.

I'm going to take the prerogative to talk about something that we weren't supposed to talk about because it's my last meeting. Just to say that on chlorpyrifos, the update that we were given, you denied a petition from March 29th requesting revocation of the tolerances that was submitted by the Pesticide Action Network and NRDC. Then you say that the neurodevelopmental effects are still unresolved and we're looking into it. So, you're not going to do anything further until October of 2022.

This is mind boggling. You say the neurodevelopmental effects remain unanswered, but yet you won't do anything to take it out of the food until it's answered. But then, you're still allowing it to be in the food. So, that's just my comment.

MR. KEIGWIN: Bob, did you want to address anything about follow up to the school IPM?

MR. MCNALLY: Yes, thanks, Rick. So, we are following up, Robyn, with the group. I think you guys were aware of the work that we did about this time last year. That work continues. We're trying to get a sense of what activities they are pursuing on their own and how we can help them in that follow through.

Our commitment last year was over a three-

year period to continue in that vain. I think the one thing within EPA is that I think, Rick, this year it's no longer on the list of regional priorities. So, the regions will not have that as something they can pursue. But our intention is to continue our efforts through the Center of Expertise in Dallas in the areas that we have control over here at headquarters.

MS. GILDEN: I know you've been working with NEHA, but I don't know how aggressive you've been working with the other participants that participated in the roundtable. The only nursing organization I'm aware of is the school nurses. I've not seen anything that they've been doing. I was invited to talk at this conference on Tuesday, and they asked me, we don't have anything on environmental health. Can you come present on environmental health? I was like okay, sure.

MR. MCNALLY: Thanks. We've be happy to meet with you and share some of the things that we're doing and some of the members of the roundtable who are following up on their own. I don't recall offhand all the different groups, but we're happy to talk to you about what they're doing.

MR. KEIGWIN: Amy, then Marc, then Dawn.

MS. LIEBMAN: Thanks, Robyn, for those

comments. Thanks for that presentation on Zika. That's a really important issue.

I resubmitted my application or nomination. So, if I'm around, I would be happy to serve on this. I do suggest, and this is a suggestion from the past, I think we should be careful with the term public health. I think it should be the public health and emerging pathogens group because it's a pretty broad topic and there's lots of public health issues relating to pesticides. So, I think that would help clarify that somewhat.

Then the other comment I wanted to make is in terms of the work that you're doing with CDC. I think that's great that you're such a strong partner with CDC. But one thing, EPA, believe it or not, is actually ahead of CDC in terms of clinician education regarding the recognition and management of pesticide poisonings.

I think that there's a lot of -- particularly when we're looking at the types of pathogens that you mentioned and Zika and the type of pesticides that are used to control mosquitoes and are being used to control mosquitoes and used to control Zika, that there's got to be a really important part of the outreach that you do to make sure that

clinicians are very much aware of the health effects of the pesticides that are being used. There's several organophosphates that are involved.

There's a community piece and the outreach piece, but in terms of advising CDC, because they tend to ignore this part of it, is that take note from what EPA has done in terms of trying to help educate clinicians. That should be a key piece of the outreach that they're doing in terms of the role that's used for Zika and other emergent pathogens.

MR. LAYNE: Thank you, Amy, for that. I will pass that along.

MR. KEIGWIN: Okay, Marc, then Dawn, then Gabrielle.

MR. LAME: So, I'm rotating off. This is an interesting workgroup. I'm pretty sure that Bob told me that the reasons they got rid of all the other workgroups and had this term period is to make sure that I'm not around to bother you people anymore. At any rate, I might say that as a parting member that this type of public service is very rewarding, and I appreciate the opportunity.

As far as this type of program, I think it's a smart move. When I heard, and I did hear that they were moving from school integrated pest management,

the center of the universe, to this, I actually thought it was a good idea.

My recommendation is to utilize the infrastructure that you already have in place. You have a vast infrastructure of a number of different governmental agencies, but also of change agents for integrated pest management that are well versed in this.

In fact, in my opinion, probably the best mosquito district, the most advanced mosquito district in the country, is New Orleans with Claudia Riegel. She was part of a team that Dawn and I were on that did education to public health folks throughout the country. Claudia is just the best. Her facility is the best that I know of. So, I'll volunteer her.

MR. LAYNE: Please do. And I assume that you're volunteering yourself as well, right?

MR. LAME: If asked, I will serve, but you've got to deal with your own folks.

MR. LAYNE: I have to hear from you that you're interested by May 17th, right?

MR. LAME: Yes, you'll hear.

MR. LAYNE: All right, thank you.

MR. LAME: So, what has happened both with

CDC and EPA with regard to integrated pest management in different ways is the digitalization of a wholesale approach to get information out. Where I see the value of that, to some extent, I think in this type of situation, you really have to do both. You have to go back to a retail approach going into specific areas with your experts and integrated team, as it were, and deal with situations. It will literally be saving lives at that point, rather than a theoretical thing about let's get out more information and count beans. So, I think that that's really important. This is something that Fred understands well when we get into that kind of stuff.

Then, finally, I would say that a strategic plan for the Center on Expertise is something that is definitely needed, would be probably in consultation with your administration, would be one of the most important first steps that you can take towards this. So, thank you.

MR. KEIGWIN: Dawn, then Gabrielle, then Lori Ann.

MS. GOUGE: Thank you. I am thrilled that you're forming a public health workgroup. Thank you so much for that. I'm disappointed that I'm not going to be here in person, but I will serve. Happy to

serve.

I did want to point out, as we recognize that school IPM, the Center will not focus on school IPM, I'm also very thrilled that they're going to focus on vector. I think Ken will be an awesome addition to that team.

But I did want to let everybody know that there is still a national school IPM steering committee and full workgroup, regional workgroups around the country, focusing on school IPM. So, we'll stay connected on what's happening.

I wanted to add a few sobering statistics to what Arnold shed in his report. That is if you add the microcephaly cases at birth with the post-partum cases that develop over time, it's close to 1 in 10 babies are impacted. If you look closer at those moms that had Zika in their first trimester, it's closer to 1 in 7. So, this is a really significant issue.

I would also like to encourage the new public health workgroup that yes, a focus on Zika for sure, at least initially. But we do have significant issues with ticks as vectors and also bed bugs, not as vectors. But I would really encourage even maybe if it's possible to form subgroups within your team at some point. And then, with regard to additional

suggestions, vector resistance issues, for sure.

Thank you very much. And thank you so very much for the experience and the ability to serve. I've really enjoyed it.

MR. KEIGWIN: Gabrielle, then Lori Ann, then Jim.

MS. LUDWIG: So, a couple things. I mean, public health is not necessarily my forte. Actually, Dawn, you mentioned some of the things I was going to mention. Certainly, as a hiker around this area, ticks and the diseases they transmit is becoming much more of an issue. I do think that whoever said we need to define this carefully --

Really, what we're talking about is mosquito control. It's not just Zika. You've got a whole bunch of other diseases that are mosquito related. Zika is just the one that's giving us the heebie jeebies, rightfully so, and so I think that definition of being clear on how we're defining it.

The flip side of it is, and I think since we're the PPDC, is you have this tension of the benefits of the pesticides and the risks of the pesticides. So, somewhere there has to be some more conversation about that. The risks are not only the human health risks or the environmental risks, but

there's even an ag risk that I think we have one almond load that supposedly got rejected because it had pyrethroid residue. We didn't have an MRL in the EU. That's being blamed on a mosquito spray. I don't know if that's totally factually true, but I'm just saying there's little things like that that can come up as well.

So, I think what I would like to see is help you get the advice of what are the things that you as the Agency need to think about as you're trying to find additional tools to help minimize the mosquito or tick or I've recently had to deal personally with bed bugs. So, I am quite versed now in how to deal with them, because I did not get professional help when I wanted it, so I had to figure it out on my own.

And then the full resistance management and dealing with the public on it is -- I haven't really heard a clear statement of how do we look at the risks and the benefits and manage that and the communications of it, given that we have a real public health risk from the mosquitoes and the ticks.

MR. KEIGWIN: Lori Ann, then Jim, then Nichelle.

MS. BURD: First a question and then a comment. Do we have any information about Zika? My

understanding is that a Zika mosquito needs to bite an infected person, and that's the way the mosquito gets infected with Zika. And it's not transmitted mosquito to mosquito. Is that correct? So, my question is whether the host could also be an animal. Just curious whether it could be a dog, cat, wild animal, primate.

MR. LAYNE: The hosts in the U.S. at least are humans. There are some primates that kind of also serve as a reservoir, but humans would be the only reservoir here.

MS. BURD: Thanks. My comment is because we know Zika is sexually transmitted, I would encourage the use of condoms and condom distribution as an IPM method, especially for women who are pregnant or may be pregnant who may be taking all the good measures we've been talking about, but may have a husband who is not being quite as cautious, to ensure that we're looking at all the modes of transmission and not just the mosquito-borne modes.

MR. LAYNE: We dealt with that issue with some of the U.S. territories. It is a very difficult issue because there's religion that comes into play. There's just a plethora of issues that come into play. I think there's talk about that.

I'll use Puerto Rico as an example. It turned out to cause some concern that kits were being passed out that contained contraceptives. Also, it gives a connotation that the husband may be doing something that he should not be doing outside of his vows. But, quite frankly, he could have gotten bit. Apparently, the virus hides in the male testicles. They don't know for how long.

So, you can encourage. I think that's all the concern that you've heard about telling women who are thinking of getting pregnant to avoid areas of Zika transmission, of local transmission in particular, and also in men. It's rare, very rare that I hear about the male part of this dynamic.

It's a real issue because the woman can do all she can if she wants to get pregnant and not realize that her partner actually had been infected until she gets that sonogram. So, that's a very touchy issue from a religious standpoint in some parts of the United States. But thank you for that.

MR. KEIGWIN: Okay, Jim and then Nichelle.

MR. FREDERICKS: So, not to diminish the importance of Lori's comments, I think it definitely has merit. But I like the idea of birth control being described as pest control. So, maybe if someone would

have explained it to me that way, I would have got the hint.

Then, also, if anyone finds themselves in a situation where, as Gabrielle did with bed bugs, we'd certainly be able to point you in the right direction of a professional having to do that.

So, from NPMA's point of view, definitely thanks to Arnold and your team for all the hard work that you've been doing with regard to Zika. For sure, I know that it's taken more time probably than you ever imagined, but it's important work, and we commend the Agency for it.

I wanted to also then just reaffirm the structural pest management industry's commitment to integrated mosquito management, IPM. We found ourselves in a unique position because oftentimes we don't think about mosquito control as being a structural pest management issue. But with these mosquitoes, with Aedes mosquitoes, oftentimes what you have is a mosquito that is uniquely adapted for living with humans and living around humans.

The structural pest management history has 150,000 trained technicians that are visiting between 8 and 12 houses a day. So, the boots on the ground in the backyards tipping and tossing. So, I'd be

happy to serve on the workgroup. I think I do want to echo the idea that right now Zika is important. It's up on the top of mind.

But we also shouldn't ignore some of the other public health threats with regard to ticks, obviously Lyme disease, as well as the other mosquito-borne illnesses, and the other public health threat that pests in general also present, such as transmission in food-borne illness, that sort of thing. So, thanks.

MR. LAYNE: Thank you. There's a new tick disease. There's one case in Connecticut that I just read about. I can't remember the name of it. So, it is definitely an issue, broad issue. So, ticks will be an issue this year as well. And this particular one hadn't been seen in quite some time. It's a lot more deadlier.

MR. KEIGWIN: Nichelle.

MS. HARRIOTT: I just have two very quick comments on this very important issue. With regard to the registration review of the pesticides that are registered for mosquito control, I am urging the Agency to take a very deliberate stance in conducting their assessment for mosquito exposures because it's very important that people have all the information

available regarding human health exposures to the use of the pesticides for mosquito control.

And then secondly, just echoing what has already been said around the room when it comes to public education. Again, it will be very helpful, especially for local officials who are tasked with making decisions for mosquito control, that they are aware of some of the human and environmental health risks when it comes to making these applications so they have all the information to make an informed decision.

MR. KEIGWIN: Are there any PPDC members on the phone that wanted to make a comment? We'll open up the lines.

(No verbal response.)

MR. KEIGWIN: All right. We have one person here in the room that signed up for public comment, and she promised me it would be no more than three minutes. So, Julie.

MS. SPAGNOLI: I just wanted to go back and touch on the GHS labeling issue. We looked at this many years ago. One of the issues is converting from the current pesticide labeling categories to GHS eliminates the caution category. There is no caution in GHS.

This would not be such a big issue just for registrants just to relabel their products and not have caution on their label, but there's a lot of implications. School IPM programs, municipal IPM programs, procurement programs, a lot of these programs utilize that caution signal word as a criteria. So, with the caution signal word going away completely, it could have implications. So, you would need a fairly robust public education effort to explain that.

In addition, also like extension programs that explain labeling to consumers, they'll often refer to caution, the caution category. So, one of the things to think about in considering GHS should that caution category go away, that could cause some significant downstream effects.

MR. KEIGWIN: Thanks, Julie.

Dawn, did you have a comment?

MS. GOUGE: Just a quick comment in response to that. So, there's already a great deal of confusion because the SDS signal words are harmonized or whereas the label signal words are quite often different. So, there's already a lot of confusion. So, I'm keen to just have it all the same. Yes, you're absolutely correct, some education would definitely be warranted.

MR. KEIGWIN: Thanks, Julie.

If there's anyone on the phone that wanted to make a public comment, we'll open up the line. Anyone participating over the phone that wanted to make a public comment?

(No verbal response.)

MR. KEIGWIN: Okay.

MR. HANSON: I'm Jaydee Hanson with the International Center for Technology Assessment. We have commented on the FDA's docket with respect to genetically modified mosquitoes. In those comments, we've actually recommended that the EPA, because of your better experience in evaluating insects, should actually be in charge of all of the genetically engineered, sterile insects, whether they're at FDA or whether they're at USDA. We believe that the EPA should be the first stop on that.

With respect to your new task force that you're talking about, part of my background is in bioethics. I think you're in some ways with the way you're dealing with Zika walking out on some dangerous grounds in ethics.

There are many things that cause microcephaly. I was personally born with one of them, cranial stenosis. Fortunately, it's one of the more

treatable. But alcoholism causes microcephaly. Toxoplasmosis causes it. There are many things. Part of the job that we need to be doing is making sure the public gets good information. A few years ago Alaska had the most cases of microcephaly. It's a serious illness. It's a serious birth defect. There are (inaudible) that cause it as well.

So, as the EPA and the CDC do their work, this is awful. No child should be born this way. But there are many other conditions, including a number of chemicals, that cause microcephaly. So, please be careful how you deal with that.

I would urge that your task force actually look at all of the arboviruses. There have been over 2,000 people die from West Nile disease in the United States since that epidemic began, one of my neighbors here in northern Virginia. So, I would urge you to look at all the arboviruses and educate about microcephaly in a more complete manner. Thank you.

MR. KEIGWIN: Okay, thank you. That concludes today. Thank you all for sticking through the entire time. Tomorrow we're starting at 8:30. I think I mentioned earlier we have a couple hundred people who have registered to attend in person, so that will make -- oh, sorry, 100 total. I overspoke.

Nevertheless, that still means getting through security will likely take you a little bit longer. So, please try to plan accordingly.

The other thing I think I should mention for PPDC members, because of the additional people, we will not have coffee here. So, bring some. You may need it. But factor that into your time getting to the building.

I think that's it. Thanks for the great discussions today and the input. We really do appreciate it. Have a good night.

(Whereupon, the meeting was adjourned.)

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