UNITED STATES

ENVIRONMENTAL PROTECTION AGENCY

PESTICIDE PROGRAM DIALOGUE

COMMITTEE MEETING

DAY ONE - NOVEMBER 1, 2017

Conference Center - Lobby Level

2777 Crystal Drive

One Potomac Yard South

Arlington, Virginia 22202

P R O C E E D I N G S

MR. KEIGWIN: Is this on? Now it is. Okay. So, we want to welcome you all to the new PPDC, Pesticide Program Dialogue Committee. I see a number of familiar faces, and some new faces around the table as well. So thank you all for joining us.

To kick things off this morning, I first want to introduce Dr. Nancy Beck, who is the Deputy Assistant Administrator for the Office of Chemical Safety and Pollution Prevention.

DR. BECK: Great. Good morning. How is everyone? All right. Nice to see you all here. I especially want to welcome the new members of our committee. Stepping up and volunteering is, you know, an awesome thing that public citizens can do, so I appreciate all the time you're going to take, because your engagement will really help us.

I encourage you all to be active and to be very vocal, because the more vocal you are, the better our outcomes will be in the end. And I look forward to the introductions and meeting you all over the next two days.

I also want to welcome members of the public that are here today. Your constructive input is also extremely important to us. It is through your feedback

that we're going to learn, we're going to grow, and we're going to ensure that we're putting forth the best regulations to protect public health and the environment, and to also ensure that we're maximizing the benefits of pesticides to ensure appropriate food security, which is very important.

I also want to introduce some other key members of our new team. To the right is Kate Bennett. If you haven't met her yet, she is from our Office of Public Engagement and she has been spending most of her summer with the agricultural community. After me you'll hear a little bit from Jeff Sands, who is our new agricultural advisor working in the Administrator's Office. And I also want to introduce Charlotte Bertrand. There we go. Charlotte is our new acting principal deputy assistant administrator. We stole her from OLEM, because she has a really strong background in risk assessment and program management, so she is an incredible asset to our team. So, thank you, Charlotte.

I'll just give you a little bit about my background, so you can understand where I'm coming from. I came to EPA in May with about 20 years of applied public health experience. I worked at the Washington State Department of Health, so I have a little bit of a northwest bias, and I came to D.C. to be a fellow in the

Office of Research and Development, where I worked on looking at how we can incorporate human susceptibility and variability into hazard assessments.

And then after about two years I went to the Office of Management and Budget, where I finally became an official government employee, and I spent about 10 years in the Office of Information and Regulatory Affairs. And this was really an eye-opening and amazing experience to be a career staffer on the White House grounds.

One of the many things I learned about is that there's lots of different types of science, right? So there's what I'll call exploratory scientific research, which helps us look at new ideas and hypotheses and helps us view where we should put our future research dollars. This is extremely important research, and I don't want anyone to think that I underestimate its value.

But the other type of research is the scientific research that's robust enough to support a regulation, and this is extremely important research. In these studies, we have to look at them a little bit differently. We need to ensure that they are sound methodology, we need to ensure that they're transparent. We need to understand that they're objective, right?

These studies have to be strong enough to support what could be potentially very expensive and costly regulations, and also regulations that could have extremely high benefits. So it is really important that we get these right, that we get this right, and that these studies be extremely strong.

The costs of getting it wrong are just too high. So, as you are aware, in EPA, we get sued quite a bit, and in the Office of Pesticide Programs, we get sued quite a bit. So I don't take this lightly. And so our priorities need to ensure that we follow the rule of law and that we're relying on the strongest scientific evidence to support our decisions.

So this is extremely important to the program, and your input on the strength of our studies and our valuations will be critical.

Throughout my career, which included working for American businesses and also working for four different Presidential administrations, I think it was Clinton, Bush, Obama and now the Trump administration, I have always worked to make sure that the science and technical assessments that the Government puts out are objective and transparent and sound, and I intend to continue to apply these principles at EPA.

There is already a very strong foundation within

the Office of Pesticide Programs. If you look at the guidance documents and the assessments they release, they're probably some of the best in the Government, if not the best. So I look forward to working with Rick and his staff to continue to ensure that the reputation of this program remains as strong as it is. And this is where you all can help with that.

I also want to say, it was an honor to be part of the team that made Rick official in his capacity in September. If you haven't heard, Rick is officially the director of our Office of Pesticide Programs now. So that is a -- I think a great thing for all of us.

The other part of the regulatory program that's important is where you all come in, because the decisionmaking, again, I cannot stress the importance of stakeholder engagement. So it is through coordination with you, our state regulatory partners, your engagement on the PPDC, that we can really come to a better understanding of what are some complex policy decisions to make sound decisions that are important to all our stakeholders. So again, I don't want to underemphasize the importance of your role.

I'm also a stickler for good government. I believe we have responsibility to communicate well in a clear and timely manner. That means we're going to

strive to get information to all of you in advance of our discussions so that you can digest it, so that you can think about it, so that you can be vocal and engage.

I'm also a stickler for timelines, so the 2022 PRIA deadlines, they stress me quite a bit. I'm sure they stress Rick a little bit. If you saw the draft strategic plan that EPA released last month, there are two strategic measures that are going to help keep our program on track. We want you to help us track them, and these are measures that help us keep our timelines under PRIA and also under FIFRA.

And then, finally, the other realism is that we have continuing resource challenges that we have to work with as we get towards this 2022 deadline. So again, this is where the committee comes in to get your feedback to help us on complex issues.

What are we going to do about dicamba in 2018? How are we going to approach the synergy issue? These are important things where your thoughtful advice is really needed and it's welcomed by me, it's welcomed by our team, it's welcomed by Rick, it's welcomed by his staff.

So I think OPP has put together a very robust agenda for you to help you understand some of our priorities and some of our challenges. There are more

than enough to fill two days.

So again, my schedule is going to prevent me from being at the whole meeting today. I will be here a little bit this morning. I hope to come back again tomorrow morning if all goes well, but if I'm not here, I look forward to hearing about how your discussions go, I'm sure I will get updates and briefings.

So, just before turning it back to Rick, I just want to once again stress the importance of your engagement and how important it is to us, and at any point in time, I welcome your feedback and feedback from Rick and his team so that we can keep ourselves on a good path to utilize you guys in the most efficient way to inform our decisions.

So, thank you all. Again, I appreciate your participation.

MR. KEIGWIN: Thank you, Nancy.

I also want to introduce Jeff Sands, who is our new ag advisor.

MR. SANDS: Good morning, and welcome to all committee members and public participants. My name is Jeff Sands, and I am the agricultural advisor to the administrator. I would like to thank all of you here today for your service to this committee.

Cross-functional constructive dialogue such as

the PPDC are critical for meaningful engagement between EPA and all relevant stakeholders. The groups represented at this meeting make for a diverse mix of perspectives and expertise that will serve as an informational platform in the regulatory process. Your collective input into this dialogue on complex policy issues equips us with information needed to make the best decisions in order to protect human health, the environment, and ensure our nation's food security through our actions here at the agency.

Your agenda over the next couple of days is quite full. I look forward to hearing all of the outputs from discussions, and again, I'd like to express my appreciation for your efforts in serving on this committee and all accompanying workgroups. Thank you.

MR. KEIGWIN: Thanks, Jeff.

Kate, did you want to give a couple of remarks? I didn't want to put you on the spot.

MS. BENNETT: Hi, Kate Bennett with the Office of Public Engagement. I just wanted to say thanks for the opportunity to sit in on your conversations. I see a lot of familiar faces at the table, and then others that I would like to get to know. We have an open-door policy in the Office of Public Engagement, so we work very heavily with Nancy and Rick and now Jeff, who we're

excited to have on the team, and any way we can be helpful, whether it's here, whether it's with the folks you represent out in the field, we're just eager to learn more and help facilitate stakeholder engagement with the Office of Pesticides, and also with the administrator himself. So, thank you for the opportunity to listen and learn today.

MR. KEIGWIN: Thanks, Kate.

So, like I was saying earlier, we have a lot of new faces, and so if we could go around the room, maybe start to my right and introduce yourselves.

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

MS. LIANG: Hi, my name is Charlotte Liang, I'm with U.S. Food and Drug Administration Office of Food Safety.

MR. HOFFMAN: Eric Hoffman, Deputy Director, Armed Forces Pest Management Board.

MR. WHITTINGTON: Andy Whittington with the Mississippi Farm Bureau Federation.

MR. PECK: Preston Peck, Policy Director of Toxic Free North Carolina.

MS. TROSSBACH: I'm Liza Fleeson Trossbach with the Virginia Department of Agricultural and Consumer

Services, and I'm representing the Association of American Pesticide Control Officials, or AAPCO.

MR. REABE: I'm Damon Reabe, president of Dairyland Aviation, a Wisconsin aerial applicator representing the National Agricultural Aviation Association.

MR. TAYLOR: Donny Taylor representing the Agricultural Retailers Association.

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

MS. FIGUEROA: Iris Figueroa, Farmworker Justice.

MS. LIEBMAN: Hi, Amy Liebman, I'm the Director of Environmental and Occupational Health, Migrant Clinicians Network.

MS. SANSON: Charlotte Sanson, head of regulatory affairs and compliance with Bayer.

MR. BENNETT: Steve Bennett with the Consumer Specialty Products Association.

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

MR. LAJOIE: Dominic LaJoie, I'm a potato grower from Maine, I'm representing the National Potato Council.

MS. ASMUS: Amy Asmus with Smith Farm Supply

representing the Weed Science Society of America.

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

MR. WAKEM: Good morning, I'm Edward Wakem representing the American Veterinary Medical Association.

MS. CALLIES: I'm Rachel Callies, I'm the manager of North American products registration at S.C. Johnson.

MR. TUCKER: I'm Tim Tucker, past president of the American Beekeeping Federation, I'm representing all beekeepers, not just those in our organization, and bees, hopefully.

MR. COPE: I'm Stan Cope and I'm the immediate past president of the American Mosquito Control Association, so a couple of presidents here. And that's the organization that I'm here representing.

MR. HOBBS: Aaron Hobbs of RISE, Responsible Industry for a Sound Environment, a trade association supplying solutions to golf, lawn care, pest control and other markets.

MS. McCURDY: Good morning, I'm Leyla McCurdy with the Children's Environmental Health Network.

MS. SELVAGGIO: Hi, I'm Sharon Selvaggio with Northwest Center for Alternatives to Pesticides.

MS. WILSON: Good morning. I'm Nina Wilson with Gowan, representing the Biological Products Industry.

MR. THOSTENSON: Good morning, my name is Andrew Thostenson, I am a pesticide program specialist with North Dakota State University, and I represent the American Association of Pesticide Safety Educators.

MR. McLAURIN: Good morning. My name is Allen McLaurin, I'm actually a cotton farmer in North Carolina and I'm here representing the National Cotton Council.

MS. BISHOP: Hi, everyone, I am Pat Bishop with Humane Society International and Humane Society of the United States.

MS. BURD: Lori Ann Burd, Center for Biological Diversity representing all life on Earth, but especially endangered species.

MS. HARRIOTT: Nichelle Harriott, Science and Regulatory Director, Beyond Pesticides.

MS. PALMER: Cynthia Palmer, Director of Pesticides, Science and Regulation, American Bird Conservancy.

MR. VROOM: Good morning, I'm Jay Vroom, President, CropLife America, the trade association representing the Agricultural Pesticides and Crop Biotechnology Industry.

MR. ALARCON: Good morning, Walter Alarcon, I

work with the SENSOR pesticides programs, we track acute pesticide poisonings and I work for CDC and NIOSH.

MR. GORMAN: John Gorman, I'm with EPA Region 2 and I'm the chief of Pesticides and Toxic Substances.

MR. KEIGWIN: And then I think we have one or two members who are joining us by phone. So if you're a PPDC committee member, would you please introduce yourself.

MS. SHULTZ: This is Gina Schultz from U.S. Fish & Wildfire Service. Could you hear me?

MR. KEIGWIN: Can you hear us, Gina?

MS. SHULTZ: Yeah, I'm sorry, yes, I can hear you.

MR. KEIGWIN: Okay, great, thanks.

And then is Dan Kunkel on the phone?

MR. KUNKEL: A lot, and I kind of -- (poor connection).

MR. KEIGWIN: Dan is going to be able to join us intermittently. Dan is with the IR4 program based at Rutgers University.

(Operator interruption.)

MR. KEIGWIN: Let's review the agenda for the next day and a half. As Nancy, Kate and Jeff said, it's a very ambitious agenda, we probably could have put more on here, but we only had a day and a half, but these are

some issues that we as a program could really benefit from the collective input of all of you. So we're going to start the morning with a presentation from Jim McCleary. Jim is from the part of EPA that oversees all of the federal advisory committees for the agency, and because so many of you are new to the PPDC, or maybe haven't been on the PPDC for some time, we thought it would be helpful for Jim to come over and just remind us of all -- all of us about what our roles are as being members of a federal advisory committee.

We will then take a break, and then Mike Goodis, the Director of our Registration Division, will lead a session and a report back from the Pollinator Protection Plan Metrics Workgroup that has been working on developing some measures to evaluate the effectiveness of the managed pollinator protection plans, and this will be a topic where we will want to get your input on the feedback from the workgroup and see if you all think that that's a path forward that the agency should be considering.

We will then break for lunch, and then in the early afternoon, we're going to give you, again, led by Mike and his staff, an update on what's been happening with dicamba and some recent regulatory changes that we've put in place for the 2018 season. And then we

will have an update on the work that we've been doing to evaluate claims of synergy and how we're incorporating that science into the registration program.

After a break, we've sent around to you all in advance a number of one-pagers on some topics that we had heard you all were interested in hearing about. We've reserved about an hour for you all to ask questions about those issues, and if there are others and time permitting we can take those as well.

And then we'll end the day with giving you all an update on where things are with the Pesticide Registration Improvement Act, our progress under the current statute, and some of the changes that could take place were Congress to re-authorize the program.

And then tomorrow morning is almost exclusively dedicated to getting your all's feedback on the Worker Protection Rule that was promulgated in 2015 and the Certification of Pesticide Applicators Rule that was finalized at the beginning of this year. Many of you were here for the May PPDC meeting and the regulatory reform public meeting that we had a subsequent day, and there were a lot of comments that we received relative to those two rules, and now what we really want to do is get you all to have a dialogue about what we heard and we'll summarize those for you and then see if we have

some consensus advice for moving forward on the implementation of those two rules.

And then in the middle of all of that, Arnold Layne, who is Deputy Director for Management here in the Office of Pesticide Programs, will give a brief report out on yesterday's first meeting of the new Public Health Workgroup.

So a pretty packed day. In order to do this effectively, particularly for tomorrow, we're going to start at 8:30, not 9:00. So the guards were really moving you all through rather quickly yesterday, so I want to thank Dea and her team for helping to facilitate that. I think that was the fastest we've ever gotten people into the building for a meeting, but that's because you all showed up so early, maybe because you're used to how long it takes to get into our building. So do that again.

So a couple of housekeeping things before we get going. PPDC members and members of the public, if you have not signed in at the desk as you came in, please do so that we have a recording of your presence here. Your tent cards, when we open it up, just, you know, put it up on its side so that I know that you want to speak or make a comment.

For those of you who have been in this room

before, you know that we do our best with the audio system that we have, so we did do a tech check last night; it was working great. So I have all the confidence that it will continue to work great, but just remember that if you see the red light on your mic', that means you're live. For people on the phone, to hear you and anything that you want to say, your mic' has to be on, otherwise they're not going to be able to pick up the conversation. And then when you're finished speaking, if you could just turn the mic' off.

For those of you participating via teleconference, we currently have a global mute in place. We can control the muting and unmuting, so please don't unmute your line unless we ask you to. And then at the end of each day, we will have a 15-minute public comment session. If members of the public are interested in making a comment during those sessions, please sign up at the registration desk out front.

And so with that, let me ask Jim to come up.

MR. McCLEARY: Good morning, everyone. Thank you for showing up this morning, participating. Let me just grab my notes for a minute, because I can't read that screen from here.

Okay. This was an overview of the Federal Advisory Committee Act at EPA, how we implement it here.

The Federal Advisory Committee Act requires us to set up procedures for every agency who has even a single federal advisory committee to uniformly manage them, and this is how we do it here at EPA.

First of all, welcome. And this is -- let me see. Dea? How do I advance it? That's okay. Thank you.

Okay. Welcome on board. You're all volunteers, and I can't tell you how much we appreciate that here at EPA. We could not afford to buy the type of experience and the points of view that are in the room today, so thank you for that. I know it's a big commitment. And thank you also to the organizations that you represent for giving you time to be here with us today. We're excited that you're here with us and we look forward to hearing your comments and your participation throughout the meeting.

The Federal Advisory Committee Act was established in 1972 and it governs the establishment, operation and termination of federal advisory committees. FACA may apply when EPA utilizes and convenes committees to obtain group advice. So if we were going out to find individual advice from any one of you or from any individual around the country, anywhere, we wouldn't need to invoke FACA, but the fact that

you're all here today giving us group advice means that FACA applies, and that's why we've done what we've done by setting up this federal advisory committee.

FACA requires that we have a charter. The charter is filed with the Congress of the United States, and it lists the objectives and descriptions and duties of the committee, the period of time for which the committee will do its work, officials to whom the committee reports, and the estimated number of meetings and the costs associated with it.

Charters are generally good for two years. We renew the charter for the PPDC every two years, and you are currently fully chartered and up and running.

FACA requires specific things about membership. Members, all members of all federal advisory committees throughout EPA serve at the discretion and the pleasure of the administrator. Committees must be fairly balanced for the points of view represented and the functions to be performed. And as you were going around the room today, I noticed that this is a very well-balanced committee. A lot of different points of view are represented here, and that's a great thing for this committee and the EPA.

Now, EPA appoints members depending on whether the member is being asked to represent the point of view

of a group, which is a representative member. Everyone here today is a representative member. Or provide the agency with their best independent judgment and expertise, and those are special government employees. Special government employees, or SGEs, are a separate animal from what everyone in here is today. They're actually paid, often times paid for their participation, and they represent their own personal expertise. Many times they're scientists or other specialists in their field.

Being a representative member is different, it means that you are representing the point of view for the group that you're representing. FACA also requires public access. We have a healthy number of members of the public here today, and that's a good thing.

The transparency that FACA provides allows the members of the public to see the process, to see the work that this committee is doing and thus the work that the agency is doing.

We have to publish meetings in the Federal Register. This is a public notice requirement. Meeting notices have to be published in the Federal Register at least 15 days prior to the meeting. And opportunities have to be provided for the public to provide their own comments so that their voice is also heard at the

meetings.

Openness and transparency, we've touched on it a little bit. Detailed meeting minutes and committee documents are available to the public, and I know that meeting minutes aren't available yet. They will be -- they have to be certified by the committee chair within 90 days of this meeting being completed. And the meeting documents have been already published to the website.

Requirements apply to all meetings, including face-to-face meetings, teleconference meetings, videoconference meetings, and any other electronic medium that we may come up with in the future to hold federal advisory committee meetings here.

Okay. The DFO -- let me tell you, DFO stands for designated federal official. Dea Zimmerman is your DFO, and I have to say she is one of the finest DFOs the EPA has. She's terrific. She is your link to the agency. If you have questions, you should approach her with them. And Dea will reach out to me and to others to find the right answers for you.

EPA must designate a federal employee, that's Dea, to be your designated Federal official for each committee. DFOs manage the day-to-day operations of the committee and the DFO must attend every meeting, approve

the agenda, call the meeting to order and adjourn it, if it's determined to be in the public's interest.

What about you? What are your roles and responsibilities as a member? We ask you to participate. Nonattendance impacts the efficiency and effectiveness of the entire group. You were asked to be on the committee for a reason, that's because we want to hear your voice.

We ask you to study and review the materials in advance. That's the come-prepared-to-class requirement. We ask you -- we do send the materials out in advance and we ask that you review them so that you are prepared to engage fully at the meeting. And then to speak up. We want to hear your views during the course of the meeting.

We ask you to represent your interest group or organization and work towards consensus, when appropriate. It's not always possible, but when it is, we ask that you try to reach consensus with your fellow members and we ask you to provide feedback to your chair. The chair provides leadership to the committee and works with the DFO to develop committee agendas, schedule committee activities, coordinate work and obtain consensus.

We ask you to collaborate to accomplish the

committee's charge. Serve your appointed term. If you develop a conflict and can't serve, please let your DFO know immediately. If you can't serve your term, it may affect the balance of the committee, so it's possible that the committee wouldn't be able to meet again until your point of view on the committee is reappointed to someone else. And we ask you to have close communications with your DFO.

Okay. There are some travel and ethics considerations that you should be aware of to keep everyone out of trouble, and we want to help you do that here. EPA may pay travel and per diem for members on official travel. So all of you here who traveled, I think it's greater than 50 miles from here, are probably on an official travel status, and you've worked with Dea and her staff, her colleagues, to coordinate that travel.

We ask you to refrain from any language or activities that could compromise the civility of the committee and maintain an environment that promotes participation of individuals, regardless of race, color, national origin, age, sex, religion, disability or sexual orientation. This is our plays-well-with-others requirement. And if you have children in kindergarten, you've seen that before. And with people on this

committee, I expect no problems with that here.

The next one is a big one. Members may not lobby Congress in their capacity as an advisory committee member. We've had some committees where we've had some trouble with this in the past. It is not okay for you to go up to Capitol Hill to meet with your member of Congress or other members of Congress or Congressional staff to lobby them on behalf of this committee. You do not represent the committee to Congress.

There is a process by which EPA will communicate with members of Congress and the legislative branch. It is not by individuals going up there.

Now, while I say that, by being members of this committee, you don't lose your rights as a citizen. You can still meet with your member of Congress in your own capacity. We call that "on your own time and on your own dime." So please don't leave the meeting today or tomorrow and go up to Capitol Hill while you should be participating in the meeting to meet with your member of Congress, but if you want to meet with your members of Congress or anyone else up there in your own capacity as a private citizen, you are welcome to do that.

This can sometimes get a little tricky, so if you have any questions with it, speak to Dea or me and

we will help you navigate these sometimes treacherous waters.

EPA employees may not direct or encourage members to contact Congress with concerns of pending legislation, so that means that no one at the front here, myself included, can ask you to go up to Capitol Hill and say, hey, we really need you to speak to this member of Congress about this issue, please do that for us. We can't do that ourselves as Federal employees and you can't do it either as members of the committee.

Committees provide advice and/or recommendations directly to EPA, Congress and the President. Your advice here goes right to the OPP staff, I think most staff members are here with us today. This is a dialogue committee, so you don't produce written reports. That's why it's so important for your participation today, to be present, to be engaged and active in the proceedings of this committee.

With EPA approval, committees may form subcommittees and gather facts and draft documents to assist the parent committee, and I know that PPDC does utilize subcommittees and workgroups from time to time. Subcommittees must report their findings directly to the parent committee for full deliberation, approval and discussion. So subcommittees can't go directly to the

OPP staff with their recommendations, it has go through PPDC in general.

Okay. At EPA, our subcommittees follow the same requirements of FACA, including guidelines for openness, transparency and membership. So a subcommittee at EPA goes through the full membership process, and the same openness and transparency process, the same notice and registering -- notice in the Federal Register that the main committees would do.

Committees may also form workgroups to conduct research, perform studies or gather facts. Working groups are small, informal meetings. These are -- we call workgroups here they're for a specific purpose and a limited term. So if there's a specific project that the committee needs done and they want to put a small group of the general committee members to work doing it, we call that a workgroup. Workgroups are not required to follow the same openness requirements, the same notice requirements as committees and subcommittees are.

Working groups are also not subject to FACA. I just said that, I'm sorry. Okay.

Additional resources for you. Your DFO is your best point of contact for any questions that you have. Dea, as I said before, is terrific, and she'll reach out to me and others to get the answers that you need to do

your jobs here.

We provided a link to the Federal Advisory Committee Act in case anyone is interested in reading it. We have attorneys here that do that, so you don't have to if you don't want to.

We have also our FACA page. This is the page of my office on the Internet site that will give you some more general information about FACAs at EPA, not just PPDC, but the other FACAs here as well. Our telephone number there for the Federal Advisory Committee Management Division is there. That will give you our general number and they can get you the resources that you need within our office.

And that's it. That's the end of my presentation. Again, I would like to thank everyone for your participation at the PPDC, you're making the process better because of it. I can entertain any questions that anyone might have now.

Yes?

MR. KEIGWIN: Stan, then Cynthia.

MR. COPE: Are there any occasions where there's a formal vote by the committee, and if so, is it majority rules or how does that work? Thank you.

MR. McCLEARY: Good question. The OPP staff runs the committee meetings. I don't believe that this

committee, the dialogue committee, has any votes. We're here to hear your dialogue and to hear what you have to say and we are looking for everyone's point of view, but this is a committee that does not utilize a voting process.

MR. KEIGWIN: Cynthia?

MS. PALMER: Thanks. I'm just curious if there are specific metrics or criteria in that distinction between a subcommittee and a working group. I know it's already been an issue in the Public Health Committee with its workgroup. And I'm just wondering, I mean, are there certain numbers? Or I mean you say small, you say limited term, what exactly does that mean?

MR. McCLEARY: Okay. I guess there's a slight amount of room for interpretation there. Workgroups cannot continue on indefinitely, like the PPDC continues on. We renew the charter every two years for you. Workgroups can't do that. It has to have a specific purpose and a limited duration, so usually these are research projects or writing projects. PPDC doesn't come up with a written project, so we wouldn't need it for that, but if there was a research project that we needed to occur, that may be reported out at the next meeting, that's when we might utilize a working group for the PPDC, this committee. There is a slight amount

of wiggle room there, I guess, but not a lot.

Any other questions?

(No response.)

MR. McCLEARY: Okay. Well, I will linger through the break in case anyone wants to reach out to me privately, and thank you very much for your time today, and thank you for your service.

MR. KEIGWIN: All right. Thanks, Jim.

So we are running way ahead of schedule, which is great, so we're not going to take a break. So I'm going to ask Mike Goodis to come up and we'll go just right into the next topic and we'll take a break after that.

MR. GOODIS: I'd like to introduce myself, my name is speaker corner. There we go. All right.

So, definitely running ahead of schedule. That's good. All right.

So, again, my name is Mike Goodis and I'm the Director of Registration Division. It's a pleasure to be here with you this morning. I want to lead a discussion regarding the workgroup, the PPDC workgroup, on Pollinator Protection Plan Metrics. For some of you who may recall, this was put in place a year ago with the goal of writing a recommendation to the full PPDC membership in this meeting, so it's a year term, and the

membership -- and we'll get into some of the details of this later.

The workgroup -- and it will be Andy Whittington and Rose Kachadoorian will be making a presentation on the work -- on the workgroup and their progress and their recommendations to the panel. And so -- and that's, as Rick mentioned before, you know, this is a recommendation to the panel for support for our recommendations to the EPA for consideration.

So I know we have a lot of new members to the membership here, and so just for a little bit of background on how this all came about, this is, again, regarding pollinator health, and specifically use of pesticides, you know, for controlling various pest issues. A lot of this really started back in 2014 with the President's Executive Order asking for federal agencies to work together to develop a strategy on how we can help improve pollinator health overall.

And so that was an effort that was co-chaired by the EPA and USDA, and that strategy was published I think in 2015. But in that, again, federal agencies committed to various actions, and so the EPA, and specifically for EPA, germane to this conversation, was measures to try to restrict products that are known to be toxic to bees under certain conditions for commercial

pollination, but also to work with states and tribes in developing pollinator protection plans. And this was really building on the success of some states, Mississippi, North Dakota, Florida, Colorado and California, where they have led the effort in working with their stakeholders in identifying opportunities for beekeepers and growers to have a better understanding and communicate intended actions regarding pesticide applications and also pollinator activities as well.

And so we thought that was a great concept that we wanted to continue to support, and so as part of the EPA's effort, the EPA finalized our mitigation policy regarding acute exposure to bees, and that was completed in January of 2017. That, again, the scope for that work was mainly limiting the -- restricting the use of certain pesticides under conditions where bees are being brought in for commercial pollination services during bloom time. And we acknowledged there was some exceptions for those particular uses.

All other uses outside of that scope, again, we were relying on and encouraging states and tribes to develop these pollinator protection plans. And but we also acknowledged that we needed to monitor the progress of those plans and, to some extent, the effectiveness of those plans to see if that was really a good model that

was going to result in some improvement of pollinator health in reducing pesticide exposure to bees.

From the very beginning, there were questions like, well, how do you intend on measuring? How do you intend on evaluating whether the plans overall are actually achieving its objective? And at the time we really didn't have a full understanding of how best to do that. And at the same time, too, we didn't want to lock in states and tribes in structuring their plans to just meet whatever the measures were that we were looking at here at the EPA at a national scale.

I think what we observed and recognized was a lot of diversity across the country regarding use of bees and the types of crops that are out there. There are some states that are more targeted for commercial pollination, some of the states are more for honey production, some states are maybe neither, there may be more hobby, urban type of pollinator use. And for some states, I think they recognize, too, that maybe their priority in working with their stakeholders were more about habitat and forage development and protection.

So we thought really that's why flexibility was important for the states, and in developing those pollinator protection plans and working with their stakeholders. So again, we didn't want to limit, you

know, what the scope of those plans were. Nor did -- we were requiring them. Again, this is all voluntary efforts by the states themselves. And so -- but again, the challenge was how do we look at whether these pollinator protection plans at a national level are actually effective. Are they actually improving, you know, the potential reduction of pesticide exposure to bees, which would help contribute to general pollinator health.

And so that's where this came about, about a year ago we felt it would be a great opportunity for PPDC to establish a workgroup and to provide a recommendation to the agency. And so, again, you'll get more information from a report out from the workgroup, but, you know, at this point -- you know, and again, I think the -- just from my observation, too, again, I was the EPA lead for the workgroup during the course of the year. You know, I thought the -- it was great participation from the workgroup members. We met monthly, mostly in conference call and in some cases in person, in conjunction with these meetings, and I think the group is at a place to make a recommendation to the full membership.

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

MR. WHITTINGTON: Thank you. And thanks,

everybody, for being way ahead of schedule, because I was planning on studying this during the break. So this will be a fun adventure for all of us.

So, this is going to follow very closely with what we just listened to from the attorney because I think this workgroup did function very much like the workgroup is supposed to. So the workgroup was convened to come up with some process to try and measure the effectiveness of state pollinator plans on a national scale. And that process involved the problem definition, a review of the MP3 plans that had been developed, a look at what a national-level metrics guide would look like, and then looking at what an implementation plan would look like. And then we would come back and present that to you for your feedback. And I'm like him, I can't hardly see the slides to follow you.

All right, so the expectation of the workgroup or the charge of the workgroup is to make a recommendation for EPA to use in evaluating the effectiveness of the pollinator protection plans at a national level, and a means to monitor how they're doing overall, a strategy to communicate that effectiveness to the public, and we refer to the public in the broadest sense.

The agency will view the outcomes of this work as a long-term effort and an ongoing effort in looking at trends versus any specific target. Like I said, the workgroup commenced on November 2016, with a deadline of November 2017. So we did have a very specific time frame.

I don't necessarily know that the workgroup was small. There were 24 members of the workgroup, but it was over a very broad base of stakeholders. And I'm not going to go through everybody that's involved with this, but you can see it's a very diverse group.

So the process was the problem definition and the problem was how do you develop this set of metrics to evaluate these plans, and they are stated tribal plans. Mary Clock-Rust at EPA worked with the tribes to -- and is working on their plan, but I think most of what we've done would be very easily translated to the tribal plans, as well as the states.

The plans' purpose is to reduce the exposure of pesticides and developing some mitigation measures to reduce those acute exposures. And then EPA will develop those metrics evaluating the efficacy of the plans nationally.

So in the review, and I don't remember the exact number of plans that were reviewed, but it was -- there

were a lot. Most states at this point have completed their MP3, or their pollinator protection plan. We looked at the commonalities between all of those plans and do the state MP3s have some process to identify metrics within those state plans that we could adopt in a national plan.

So we identified the metrics that could be used at a national level, we identified specific metrics to recommend to the PPDC, and identified a process for gathering that information for national level evaluation. And then implementation would be to identify process to the states and tribes to get feedback on the metric process, develop strategy to communicate the national-level metrics to the broader public and identify a possible timeline for evaluating the metrics.

So of the plans that were reviewed, there were some common themes that were identified. We want to focus on the communication between stakeholders, focus in on education and knowledge between all the groups, pollinator groups, and the cropping community. And then identify whether they identified the best management practices or a set of standard operating procedures.

And we looked at the differences, and there were several, and most of those differences were based

basically on the geographic or the regional differences in the pollination use in those states. Some areas are specifically devoted to honey production, some are more geared towards pollination services.

Some of the other themes were the -- some of the MP3s were much more comprehensive than some of the others. Some typically just focused on the beekeeper and pesticide user components. And then all the state plans are voluntary and rely heavily on local cooperation between and across stakeholders, and we wanted to look at how people were involving other stakeholders in that process.

So we developed this five-step process. We are going to go over steps 1 through 4 today, and step 5 will take place post-survey. And those steps are one of the considerations, which is what do we need to look at for a national-level survey; assessment of the categories, which was identifying those categories that were common amongst the state MP3 plans; there will be a survey of the states, of their MP3 plans; and a survey assessment. And then step 5 will come post-survey.

So, national-level metrics guide. One of the considerations, we need to have a mechanism to evaluate the effectiveness of these MP3 plans at a national level. We need to have comparable measures across the

states, but we don't want to compare states against each other, we want to compare them against the measures that we've identified. The assessment will be at the national level -- I just said that.

The survey tool will be used, and there is a need to have a group to conduct the survey and collect the results and then communicate the effectiveness of the plans to the broader public.

And in the assessment categories, these are the categories that we identified that were common amongst the vast majority of the MP3 plans. One is communication, best management practices, standard operating procedures, the involvement of the stakeholders, education, the progress measures or behaviors.

And now I will turn this over to Rose, assuming she has gotten on.

MS. KACHADOORIAN: Can you hear me? Yes, can you hear me?

MR. WHITTINGTON: Rose, we can hear you.

MS. KACHADOORIAN: Hello? Great. Great. So I'm Rose Kachadoorian with the Oregon Department of Agriculture, and Mike Goodis and Andy covered a lot of really good information. So what was mentioned was a survey, and I'm going to be talking a bit about the

survey, and then also five assessment categories were provided to you. I'm going to kind of go through those categories, and also provide some information just regarding process. And so on to slide 13, it would be step 3, state MP3 survey.

So the workgroup worked with state lead agencies, and these are basically the agencies that are responsible for pesticide regulation on development of a survey. This included your AAPCO rep to the PPDC, Liza Fleeson. And AAPCO, again, stands for the Association of American Pesticide Control Officials. We also worked with the chair of SFIREG, and this stands for the State FIFRA Issues Research and Evaluation Group. And also the chair of AAPCO's pollinator committee, or the co-chair of it, and I'm also a co-chair.

We're hoping that this survey that we've developed will also be able to be modified or adapted in some way for tribes and territories, so that was also something that we thought about. It's our intent that EPA receive the information once the states complete the survey and that the responses to the survey will be transparent. And there was a lot of discussion about that, whether it would be transparent or not, but we're public agencies, and basically everything we do is transparent and available to the public. So I think

many states will be really proud as far as what they do with pollinator plans. Plus it will really give an opportunity for a state that's just trying to figure out like, you know, what more can we do, if they're able to look at another state's plan and maybe get some ideas and contact that state and say, you know, how is that working out for you? And so I think that it can really benefit the entire country as a whole.

Next slide. Communication was mentioned as one of the assessment categories, and this was really how are states increasing communication between pesticide users and beekeepers. And not only just pesticide users, but let's -- I heard that somebody from the Aerial Applicators Association is there. You know, what do we do in the situation where you have a farmer who has contracted with a beekeeper, how do you get that communication to maybe an aerial applicator that can't see whether bees are foraging, get that information to even somebody who's going to be applying pesticides by ground who maybe is unaware that that grower has bees or maybe the neighbor has bees. So just what is a state doing to kind of facilitate that entire communication process.

We also have an assessment category of just best management practices, or standard operating procedures,

and I think a lot of states are really kind of focusing on this and are really strong. You know, what kinds of methods can they use to reduce pesticide exposure, or pollinator exposure to pesticides. Can the states provide a list of their best management practices or standard operating procedures, and in this -- a lot of times these really encompass a lot of aspects.

They encompass like the communication, what kinds of pesticide risk might be associated with certain pesticides or might be particular for a particular crop. Let's say a crop when it's in bloom, unfortunately gets maybe a high pest level at that time and needs to have plant protection products applied. And how have they included crop producers, beekeepers, and I think it was Mike that mentioned the pollinator forage and habitat, you know, especially for some states that just have crops planted fence row to fence row, they might be focusing in their pollinator plan of, you know, putting in some more pollinator habitat, and other states who maybe have a lot of pollinator habitat might be focusing more on how to reduce drift to those habitats, whether it's during seed planting or during either a ground or aerial application.

Next slide, please. Education. So how are states coordinating, or who's developed the program,

because sometimes it's not actually the state lead agency, but how are they coordinating with other agencies, and these could be other state and federal agencies. I can think in my own agency, the Oregon Department of Ag, that we are working with our Department of Forestry and our Department of Transportation, and other federal agencies, just how are people reaching out, are they working also with their cooperative extension, their university people, are they being brought in.

And also, there are a lot of non-governmental organizations out there that are really doing some great work, and is there coordination and collaboration with those entities, and if so, how does that look.

Also, on outreach. Is outreach being conducted in how bees are exposed to pesticides, how growers and other pesticide users might select pesticides. Are people being taught about residual toxicity or, you know, which pesticides are systemic and when you might use those and then when you might not use those. And also, pesticide label comprehension, are people being tested like before their training on label comprehension, then do they receive training and then they're retested to see really an increase in their comprehension.

Also just some of the methods that people are using for outreach. Are they just putting something on a website or are they reaching out through radio ads and television? I know for our own agency, we're doing public service announcements on Spanish language TV, and we're going to be doing radio, again, with Spanish language. And just what kinds of educational materials are out there. And again, some states are really doing some innovative things.

And another big important aspect of this would be stakeholders. Who's being reached? Is it just agricultural? Are maybe some of the urban applicators being reached? The certified and then non-certified? Are homeowners being reached? Just how -- and not only just reached, but are you sitting down as a state agency or whoever is coordinating the pollinator plan, are they sitting down with them talking to them about their communication, their knowledge level in all of those aspects.

And also, you know, we have on this slide yearly stakeholder meetings. There might be some states that have more frequent meetings and other states have less frequent meetings, depending on the stakeholders, but are they kind of revisiting it and kind of keeping it alive? I think none of us want to see a system where,

you know, we go through all of this work, we develop something that's really useful, and then people forget about it in a couple of years. They're like, you know, how are people keeping this alive?

Next slide. Progress measures are behavioral changes. Are we seeing a reduction in related verified bee kills? We have verified bee kills on there because -- pesticide-related, because at least in our state, I've talked to other states that we get a lot of calls about bee kills and they're sometimes associated with nutritional stress or disease or some other aspect that's not pesticide-related. And those it's really important to identify that to assist those beekeepers in understanding a little bit more about the factors that can kill bees.

Also it can be a little distortion as far as how many bee kills are actually pesticide-related. And we do want to actually capture those that are pesticide and also non-pesticide related.

Also, have states developed some potential measures of exposure to bees. Some states I've spoken with have talked about possibly measuring pesticide levels in pollen, just like they would measure pesticide levels in surface water, just to kind of get an idea of what's out there. Are we seeing a certain pesticide at

a higher level than others? Are there some pesticides that might be of concern or of interest; and if so, what kinds of educational programs can we put into place to get those levels down? And then if, you know, you can't get the levels down through education, then to look at other avenues.

Also a method -- again, measures or methods to assess pesticide exposure, and also methods to assess maybe how we've increased communication or how effective our educational efforts have been. We also would like in the survey try to get an idea what measures the state is using, because the states, it's not only EPA, but states want to know if they're doing a good job, where are they being effective, and how are they doing that? Are they looking at the national honeybee surveys? Are they conducting their own state surveys, whether it's through the university or the state agency themselves or another entity? Are they seeing an increase in, again, tracking that increased adoption of best management practices and other considerations?

Also we have on here the last bullet point, funding for listed measures. There's -- you know, there are many people who want to do a lot of great things that there isn't funding for, but if people are getting funding for certain projects, I think it would be good

to have that reflected and the group thought it would be good to have that reflected in the survey if there were sources of funding and what kinds of projects were being funded that might benefit the nation as a whole.

Next slide. So again, and I think both Mike and Andy covered this, that each state had a lot of flexibility in developing their own plan and therefore they're diverse. There was some talk at the beginning of the group about some of our meetings as far as having a rating system where we were comparing one state to the other. And that was actually deemed not really viable because, again, you have states with different levels of resources, but a lot of different types of crops and different types of issues.

So if you had a state that was more urban without a lot of commercial beekeepers, they were doing one thing, versus a state that was more about honey production, versus, you know, a state like ours where we have over 220 crops that were doing something different.

So a determination was made, and I think it was a good one that really if we were going to convey what was happening nationally, that it was actually more accurate to look at kind of an aggregated assessment of what was going on in pooling those data, and that would kind of normalize that data and kind of give us a more

accurate reflection of what was going on.

And so again, the states, even though the results of the survey results will be transparent and available for each state, if EPA is going to do some kind of numerical assessment, that that's something that is not really going to be done on an individual state, it's going to be done for the country as a whole.

We are planning on using a survey tool, and I'm going to talk a little bit more about that and kind of the role of the state lead agencies in assisting EPA in getting the information that they need, and again, we have a number of questions that we were thinking about for that survey, and again, looking at the percentage of the tallied results -- responses.

Next slide. So again, a little bit about that assessment system, we're looking at total number of responses; for example, let's say 80 percent of the states have a certain kind of communication system, 30 percent have something else for some other factor they're measuring. So they're looking at -- we would be looking at the total number of responses. So we have a table here that's -- it's blue on my slide.

So, for example, if we're looking at communication, maybe that first question where you have a yes or no response could be for does your state have a

method to increase communication between pesticide users and beekeepers, yes or no. If you answered yes, well, what are you doing? And so the state lead agency or whoever is implementing the pollinator protection plan would indicate all of the different ways that they are increasing communication.

Next slide. So we're on to step 5, which is data collection and the results. And so AAPCO is offering to utilize SFIREG to facilitate the distribution of a survey. SFIREG has regional representatives for each EPA regional office. For example, the regional office I'm in, it would be for Oregon, Washington, Idaho and Alaska. And so then the regional SFIREG rep would give those surveys out to each one of the states and kind of birddog it and make sure that those are submitted.

This way the state lead agencies who are busy and doing a lot of different things aren't just kind of sent these random surveys and they'll kind of get around to filling it out when they have time. No, this is going to be actually a lot more strategic. And so we're really grateful that SFIREG is kind of stepping up to the plate and has offered to do this.

So then the regional SFIREG reps will be turning this information, AAPCO will be assisting with the data

collection. If there are some -- we're thinking about maybe using something like SurveyMonkey, which has some kind of basic stats associated with it. And then we would just provide this information to EPA so they could conduct their assessment. So we would provide the raw data to them and then if the survey tool had any kind of basic statistics, we would also provide that information.

Next slide. Oh, next slide is not mine, but let me talk a little bit more about my slide 19, then. It's really our goal that all of this information be available to beekeepers, to pesticide users, to NGOs, and that we'll all be able to learn from this. We're looking -- we're thinking about these periodic types of surveys so we can see how these programs are progressing over time where, you know, I think everybody's hope is that, you know, there are changes over time as our program matures and as you identify new needs or you fulfill kind of holes that were there that things naturally progress.

And so the states will be working in conjunction with EPA to identify whether any changes will be needed over time, and again, that will be a very transparent process.

So I think it's Andy who has that last slide.

So thank you, and we'll be answering questions after that.

MR. WHITTINGTON: Thank you, Rose.

So I'd like to say we had a very large committee that worked extensively on this. I probably will not answer Caydee Savinelli's phone calls again for several years, but there has been a lot of thought and a lot of effort put into this. We feel like we've come up with a reasonable and fairly comprehensive way for EPA to begin to take a look at the national metrics for the pollinator plans, and at this time I think we'll take feedback from the committee.

MR. KEIGWIN: Okay, so let's first see what questions you all have for the workgroup. Let's see, Cynthia, Lori Ann, and Pat.

MS. PALMER: Hi, Cynthia Palmer, American Bird Conservancy. When I think of pollinator protection metrics, I think of things like the kill rates for bees, the incidents of dead birds, the state restrictions on the worst pesticides for pollinators, such as neonicotinoids and chlorpyrifos.

The efforts, the extent to which states have made an effort to get farmers off the pesticide treadmill and employ sustainable agricultural techniques.

The extent of clean habitat available for pollinators. I'm not sure that filling out a survey -- I think it's a worthwhile effort, but I'm not sure that that truly captures the success of the pollinator protection efforts in that state.

And I'm also worried about the risks beyond the managed bees. We know that a single seed coated with neonics or chlorpyrifos is enough to kill a songbird, and we know that many native pollinators are at risk as well.

So I'm wondering to what extent do these outputs truly capture the effectiveness of the pollinator protection plans, and I'm wondering if we should reframe it more as a survey of communication guidelines, which are worthwhile, but they're not really metrics.

Thanks.

MR. WHITTINGTON: So, and all of those are significant concerns, but as we were looking at the pollinator protection plans, most of them are designed to mitigate those acute exposures. And they're pretty much limited to that. So I mean, there are other methods that we have that will be utilized through EPA and through FIFRA that will address a lot of the other concerns, especially through risk assessments that are ongoing. But specifically for the pollinator plans,

when you're looking at that one piece of the entire pollinator protection puzzle, I think this will be an effective way to measure what those plans are specifically addressing.

I think in the beginning we looked at the pollinator problem as addressing it as how do you eat an elephant, it's one bite at a time, and well this has been several bites at the elephant. But we acknowledge that there are ongoing issues that will have to be addressed at other times, but they may not be specifically addressed by pollinator protection plans.

MS. KACHADOORIAN: Hi, this is Rose Kachadoorian. Is it okay if I talk right now? Okay, I will talk.

I'm very sensitive to the issue of the native pollinators. They are actually really essential for pollination in a state like ours. And, in fact, we have an education -- we have an entire Oregon bee project, not just a pollinator protection plan, and our agency is out actually monitoring for native bee populations and we're going to be using that, at least in our state, as kind of one of the metrics. It's not something a lot of states can do, but it just happens to be what we can do. And so that information is going to be reflected in our survey results.

We also are traveling across the state and working with different groups to learn how to identify native pollinators, too. So I think that these plans, even though many people are kind of geared towards an acute exposure to the European honeybee, there are a lot of states that are also looking at native pollinators, and that will be captured in these surveys.

A lot of the BMPs, also, will help reduce that kind of sublethal, possibly chronic exposure that goes on, or possibly could go on to bees. So I think that these issues will be captured in the survey. But as far as the issue with bird deaths, probably not in the pollinator survey, but I know that state lead agencies report that information to EPA. So that information isn't lost, it is captured, but in another venue.

MR. KEIGWIN: So, Lori Ann, Pat, and then Charlotte.

MR. GOODIS: A quick interruption. If I could also ask, as I see some of the workgroup members in the audience as well. Ray, I see you. I think Caydee is back there, and there may be some others, too. It might be helpful to -- for -- because this was a group effort and it's really a recommendation from the workgroup. Maybe if we do have a mobile mic', if at times to help answer questions, the upcoming questions, I would

encourage workgroup members to provide their input in response as well. Thank you.

MS. BURD: Thanks, Rick. I'm going to echo some of what Cynthia said, at the risk of sounding like a broken record, some of us at every single opportunity are raising our concerns that we keep using honeybees as the metric and there are 4,337 species of solitary bees in North America that have very different modes of exposure and needs than honeybees, and while we care very much about our honeybees, the needs of the solitary bees are not being addressed in this, and in a variety of ways.

And what might be an acute exposure for a -- or a nonacute exposure for a honeybee could very much be an acute exposure for a native solitary bee and could result in the loss of an entire group, and so catastrophic losses that we're seeing in those populations.

So while I recognize and am happy about, you know, what Rose mentioned, that there are great efforts happening in some states, these metrics don't capture any of them, and they don't establish any guidelines, mechanisms, anything that even addresses them. So it's great that, you know, some of that could get mentioned in the surveys, but it's not built into this, and I'd

like to see that happen.

MR. KEIGWIN: So Pat, then Charlotte, then Stan.

MS. BISHOP: You know, I sat here listening to this, and I'm still a little confused as to what you're actually surveying and the data that you're collecting. So I'm understanding that there's these plans, and they probably have certain elements in them. So there's an opportunity, I think, to evaluate the plans themselves, do they have the proper elements, communication, so on and so forth.

And then there's the issue of implementing the plans, you know, how well is this state implementing it. And then, finally, is it doing anything? Are you seeing results from it?

So I'm not quite sure what your survey is doing, and what parts is it surveying? Are you surveying how well the plan was developed? Is it surveying -- are they implementing it? And then, finally, is it surveying what is coming out of the plan? Is it doing what it's supposed to do?

So could you just clarify that a little bit for me?

MR. WHITTINGTON: I'd say yes to all of that. I do believe that the survey will capture what the -- what the individual states are doing. And I can only speak

on behalf of my state, Mississippi. We do have our annual meetings, we do have constant communication with our beekeepers and our producers. And what you want to see -- what you want to see going forward from the pollinator plans is you're going to notice it in a couple of years. You're going to see a change in behavior, we hope, from the people that you're now communicating with, because this has been an issue for -- in basically the time frame relatively recently between -- it's relatively recent communication that we've had between beekeepers and farmers.

So I think we are starting to see that communication and that education take place, and behaviors changing, and the result of that should be a reduced exposure, which is a reduction in the number of bee kills that we see.

So I think we start capturing that as what are you doing, and are you implementing what you have laid out in your plan, and then from that, we should start to see at least a reduction in the acute exposures.

MR. KEIGWIN: Charlotte, then Stan, then Damon.

MS. SANSON: Thank you. I just wanted to say I think it's the -- I think it's worth commending the group for the progress they've made in the past year on coming to consensus. I can see that it's a rather broad

group of folks. And my question, Rick, I think this is maybe something you can answer, because I think we heard earlier that this panel is not a voting body, so after the discussions today on this topic, what is the mechanism for adopting the recommendations by this workgroup?

MR. KEIGWIN: So once we're done with the questions, I will pose a question to you all so you can start thinking about it. But it will be something along the lines of, you know, notwithstanding some of the concerns that we heard thus far as we've gone around the table, would it be the PPDC's advice to EPA to as a first step begin pursuing the use of these metrics in evaluating managed pollinator protection plans as we continue to assess risks for pesticides as related to pollinators.

So it will be something along those lines, but, you know, this workgroup was set up with a very discrete charge, and I think they've come back with where they can get based upon that charge, and so what the agency will want is advice from the PPDC on whether or not we should be moving forward with the recommendation posed by the workgroup.

So Stan, then Damon, then Liza.

MR. COPE: Thanks. Stan Cope, American Mosquito

Control Association. Outside of private industry, there are roughly 900 and some tax-based or municipal organizations that do mosquito control. Being new to the group, I don't know if you had any input or if you're going to get any input on your survey from the mosquito control groups, but many of them have long-term, very sophisticated communication and public outreach plans when it comes to pollinators.

So I guess my question is, is mosquito control involved in part of this, and if not, would you like them to be?

MR. WHITTINGTON: Does the lady in the back of the room want to speak up? Here we go.

MS. SAVINELLI: I'm Caydee Savinelli, I work for Syngenta and I helped with this committee, and Andy, you will take my phone calls, whenever you are. Okay?

Anyway, just to answer the questions about the -- well, let me just step back for a minute. So the charge of this group is really looking at the plans nationally, so that's really what our charge is. And within the stakeholders as part of the plan, the mosquito boards are part of the stakeholder groups that the states have reached out. So that's part of the metric that is, you know, as you list all the various ones, unfortunately we can't get into all the various

details, but certainly stakeholders are very important in the whole MP3 process within the state, and the mosquito control boards are very important as part of the stakeholders, depending on the state, of course.

So that's where it falls in. It's not necessarily the question specifically related to the mosquitos, because we're really trying to look across all of the plans, and as you can imagine, being so diverse, trying to come up with the metrics that make sense across a diversity of plans, and that's why we have those categories, because they seem to be the categories that were most common communication, education, stakeholders was one of the categories.

So it is included, but in a different subset of the questions. Oh, yeah, we didn't -- no, mosquito control boards are very important. And keep in mind, too, that within each state, it's really up to the state to engage all of the various stakeholders, and I know in some cases, in some states, the stakeholders didn't feel engaged, so it's really important to go back and we encourage the stakeholders to be engaged.

Thank you.

MR. KEIGWIN: Okay, Damon, then Liza, then Jay.

MR. REABE: So, as a Wisconsin aerial applicator, we perform insecticide applications to

cranberry crops, and there was a study conducted by the University of Wisconsin that I'll forward to Dea for everyone's review, and what they -- what they were studying was pollinator health at the cranberry production sites, as well as away from those pesticide application sites.

And there was a surprise finding in that study where they found that there was greater native bee populations and greater species richness at the application sites than there was away from the application sites.

So while this survey doesn't -- may not meet the needs of or the goals or the interests of some of the people in these -- in this room, I think that that's an interesting study that should be forwarded.

Also, in regards to the survey work, to the pesti -- or excuse me, the pollinator protection plans, what they do for us as applicators is raise awareness of pollinator habitat in general. Not just honeybee habitat, but also other pollinator habitat, and these plans are effective in communicating those concerns to applicators.

MR. KEIGWIN: Okay, Liza, then Jay, then Sharon.

MS. TROSSBACH: Thank you. Again, I represent AAPCO, which is a national association of pesticide

regulatory officials from the 50 states, tribes and territories, and as one of the other members said, I do want to commend the workgroup on their work.

This was a very daunting task given the inherent challenges in trying to come up with national metrics for very diverse plans. I think that the proposal that has been put forth does meet that need and does the best it can to allow for the diversity and the flexibility in the plans.

While there are many issues related to pollinator protection, I think that this group has done a great job of looking at the Presidential directive. It was very narrow, very focused, gave EPA a very specific -- a very specific directive to reach out to states, tribes and territories to develop voluntary pollinator protection plans which looks at one piece of a very huge puzzle of issues related to pollinators and pollinator health. And I think that they did a good job.

I think the fact that this is a long-term evaluation that, you know, many plans are now complete, some are still in process, some are in the beginnings of implementation, but you have to start that data collection, and I think this does a good job. It leaves it as a living document or a living survey that can

evolve over time as plans evolve. And again, I think it allows the states to have that flexibility and that diversity.

It was mentioned some states are very -- you know, they focus on honey production and others have a lot of contracted pollinators. Some have hobbyist beekeepers, some have many more commercials. So the ability of states to provide information about what they are doing, the unique things they're doing, there are commonalities. I think the proposal looks at those commonalities as things that were put forth about communication and best management practices and standard operating procedures, but allow states to also provide that additional information.

I think states, tribes and territories would be willing to, you know, provide that information, want to provide that information. You know, many states put in a lot of hours and a lot of work. I know in Virginia, this has been an 18-month process that involves a lot of stakeholders advisory committees, a lot of meetings. We want our plan to be successful, we want to protect pollinators.

As pesticide regulatory officials, we're not proponents or opponents of the use of pesticides, simply if you're going to use them, use them properly. And

since pesticide use is legal, we have to allow for that, but at the same time, we all support, you know, pollinator protection, and I think that the state plans are a great way to allow states to represent their apiary industry, their cropping systems, the type of pest management and pest control they have, and also protect pollinators.

And so on behalf of AAPCO, I support the proposal, I support the approach to the survey, and, you know, again, I just want to commend the workgroup on a very difficult task.

MR. KEIGWIN: Okay, Jay, then Sharon, then Preston.

MR. VROOM: Thank you, Rick. Wow, Liza just said what I was going to say, except she said it so much better. I would add that I think this work of this workgroup is an extension of everything that was devised in the President's pollinator protection directive that Liza just mentioned, but it's important, also, to remind everyone that the President, President Obama, empaneled a very comprehensive group of federal agencies and authorities to come together under the co-chairmanship of the deputies from USDA and EPA. And to me, overarchingly, this is a great model for a way to address so many issues that certainly are on today's

PPDC agenda and in future agendas for consideration by this federal advisory committee.

The last thing I just wanted to mention is back to Cynthia's original comments, Cynthia, I'm not aware and haven't been able to discover any registered uses of pure chlorpyrifos as a seed treatment, so if you know about that, I would love to talk with you offline.

Thanks.

MR. KEIGWIN: Okay, Sharon, then Preston, and then Tim, is your card up? And then I think at that point I want to put the charge back to the group about next steps.

So, Sharon?

MS. SELVAGGIO: I am Sharon Selvaggio. I wanted to say that I think that the survey instrument will be useful, especially if it is, indeed, periodic and repeated and used for adaptive management, if the states are open to modifying, increasing their efforts through pollinator protection based on the results of the survey, what they find from other states, et cetera, where appropriate.

So my questions are primarily about the survey and I have a couple of questions. So, Rose, you mentioned a couple of times in the PowerPoint about the transparency of the survey, and I'm wondering is the

survey draft available now, will the responses be available to the public state by state, or just the aggregated responses.

Another question I have is regarding that the issue that Pat brought up about implementation monitoring as opposed to effectiveness monitoring, and so my question is, who in the states would be filling out the survey, and how will they get information from people in their state, whether they be farmers, mosquito control districts, et cetera, about whether, in fact, these recommendations, these voluntary measures that are in the MP3s are being implemented. There was some stuff in here about communication effectiveness, some potential for actual empirical data collection on direct pesticide exposures through pollen measurements, bee kills, et cetera.

I'm just wondering, given that the level of intensity of those kinds of measures depends upon funding and all of this is voluntary, I'm a little concerned that there won't be an ability to really test and report upon the effectiveness of these measures in a national way. I certainly think state-by-state information on those will be very useful.

I guess my last question, and I'll move on to somebody else here, but is that the pesticide-related

verified bee kills, Rose, you had mentioned that it's hard sometimes to differentiate a pesticide-related bee kill from those that are caused by nutritional issues or disease, and we've seen in the literature that disease and pesticide impacts can be interrelated as well. So I'm wondering how the group is differentiating between disease or pesticide-mediated disease kills, if that is the right way to capture that. Thank you.

MS. KACHADOORIAN: This is Rose. As far as differentiating whether it is a pesticide-related bee kill or not, there actually are EPA enforcement guidelines for pesticide investigators and how they should investigate bee kills, and I know at least our state, and I'm sure other states do this also, is that we actually collect the bees and we analyze them for the presence of pesticides and also work with experts from the university to see exactly what the problem is, is it some kind of protozoan, a varroa mite, or nutritional, or is it, indeed, pesticide. I mean, we have had pesticide-related bee kills, as you're aware of.

And so there is a whole process designed for that. Let's see, and what were some of your other questions? Oh, as far as assessing. You know, it has always been a challenge, I think, if you talk to anybody who works with extension, and I used to work with

extension for 10 years myself, to know what your -- if you're conveying information, are people assimilating that information, are they understanding it and are they putting it into practice.

And so a lot of states, what they do is they'll use even survey, like the people who have attended their classes, like do you understand what we've told you, have you changed your practices from the last time you've been here.

And so it's going to have to be a lot of kind of getting back to those particular pesticide users and beekeepers and others to see exactly what practices they've changed and meeting with stakeholder groups to see if there's any kind of change so the survey results are accurate.

As far as transparency, you know, we have a lot of AAPCO surveys right on our website, and I -- you know, I'll have to -- I'm president-elect of AAPCO, but I'll talk to our president to see if it is possible to have all of this information in one source so people can go to it. And so if people want to know what's going on in various states, they can.

We currently have an Excel spreadsheet on the AAPCO website with the names of all of the contact people who are coordinating their pollinator protection

programs, and some of the components of those programs, and then that information is actually being used by other groups that we're in the process of updating that Excel spreadsheet. In fact, I think it may be yesterday or the day before yesterday, kind of an email was sent out to the state lead agencies saying, you know, have you made any progress, and if so, please update your information so we can have that on AAPCO's website.

So that will -- and I imagine that EPA will have information. I don't -- we would have to talk with EPA to see if they would have the state-by-state information on there. Does that answer your question? Maybe somebody else can kind of help chip in here, too.

MS. SELVAGGIO: Yes, that helps, thank you.

MS. KACHADOORIAN: Um-hmm.

MR. KEIGWIN: So Preston, then Tim.

MR. PECK: Thank you. And it's good to see a lot of different people in the room that I know.

I represent an organization that has multiple initiatives within various programs, some of which relating to pesticides, some of which relating to pollinators and farmworkers as well, so I'll be wearing a couple of different hats while on this committee from our perspective. But I also -- I see a lot of different survey questions, and I'm very new to this, so this is

the first time that I'm kind of going through the survey. So I look forward to talking to other workgroup members about it, but I see different limitations on the survey, and I don't disregard the survey as a useful tool, but I just am bringing up issues on its limitations, such as the related verified bee kills from pesticides are limited by detection of equipment that the state department of ags have.

I know in North Carolina, it's relatively -- it can -- it's not as sensitive as it could be, and I have spoken with our state apiarists about that as well. Obviously things like Cynthia and Lori Ann brought up around native pollinators, there's limitations there. I just think that we've seen limitations within surveys in general with bee-informed partnership surveys. You're taking a voluntary BMP and asking people to take a voluntary survey on that. So I would just, you know, caution on how we use the survey.

Also, as I do support communication between applicators and beekeepers and other people, but again, within the organization, we've seen various limitations on that. Especially relating to farmworkers, you know, that's one of the key things is, you know, communicate with farmworkers what is going on and where it's going on, and we've seen that that just hasn't worked in the

past and has continued to not work.

So I look forward to the discussion tomorrow. So I'm skeptical about how effective communication will be to reduce exposures, to reduction in acute exposures, I think there's a lot of assumptions in there, and a lot of gaps.

I had one question for Liza, as far as is the surveying group that will be conducting the surveys independent of AAPCO?

MS. TROSSBACH: So, it's SFIREG, right? It's SFIREG, and that is an evaluation group that is under the umbrella of AAPCO. If AAPCO, which is the -- the broader group, they have a group that's SFIREG that does the work of AAPCO, and through that, there are regional representatives. As Rose has said, there's one state lead agency representative from each of the ten regions, and then they are able to provide information to the states. So it's just a mechanism, a framework to be able to get information out to the state lead agencies and collected.

Again, in this particular case, that mechanism, that framework, is long-standing and has worked very well in the not only dissemination of information, but the collection of information from state lead agencies, and that was one of the questions that Sharon had

brought up is how -- you know, who's going to respond to that information, it would be the agency that was responsible for the drafting of the particular plan. So it was an offer on behalf of AAPCO to say this is an existing mechanism that has a long history of working to collect information and that we're willing to utilize that just to assist in the collecting of the information and then forward it to EPA.

MR. PECK: Thank you. And just one thing along that line, I know that we have received very different information when evaluating state policy based on how outreach is conducted and who conducts it and where they're looking. So you're going to get very different answers.

For example, within North Carolina, we looked at best management practices on who to notify when it comes to pesticide application and how far that radius would be, and within that what is our limitation on prior notification. And our state Department of Agriculture did a really good job of reaching out to the state beekeeping association; however, the people that participate in that survey were one group that was surveyed and we in conjunction with many other partner organizations conducted our own survey and got very different answers.

So just to be aware of who you're asking and stakeholder input on how to conduct outreach. Thank you.

MR. KEIGWIN: And Tim?

MR. TUCKER: Thank you, Rick.

First of all, I'd just like to commend the committee that worked on a very daunting task. I thought originally it would be extremely difficult to come up with metrics to really define this program, but I think it's a first good step in the right direction, and anything that we can do to increase dialogue on a national level between the states in evaluating these programs that are working in some states, like California, where they work very effectively for a long time, and improve the communication and awareness, you know, that we were talking about.

And I totally disagree, I think that if we can communicate better between applicators and beekeepers and anyone with a perspective in this that wants to protect pollinators of any kind, we have to do a better job of that. We have to find out what's working and what's not. And I think that this does provide us with a -- you know, a measure of assessing that.

So I'd just like to thank the committee again, and those that could participate to a greater degree

than I could. My job sometimes limits me to being involved, but I think the industry really feels that communication and dialogue is very important between all parties with our different perspectives. So thank you again.

MR. KEIGWIN: Well, Lori Ann's card went up after I said Tim was the last one. So if there's something to add to this quick, because I want to put the charge back to the group.

MS. BURD: I have a question to follow up on the comment that chlorpyrifos has not been registered for seed use. I believe it has been registered for seed use not in significant crops like corn, cotton, sorghum, wheat, is that currently the state of chlorpyrifos as a seed treatment? And I figure the experts are here.

MR. KEIGWIN: We can certainly confirm it at a break. We don't have it all in our heads. But we'll get back to the group after lunch to confirm that.

So I think the way Tim kind of teed things up would probably have been the way that I would have done it, so as a first step in terms of measuring the effectiveness of these plans, does the PPDC support the workgroup's recommendation to begin to employ this survey instrument moving forward as we continue to build upon the dialogue, improving the dialogue with

stakeholders, and as we continue the re-evaluation program? So kind of a thumbs-up type. Sort of neutrals or anyone in defense?

MR. WHITTINGTON: There's the broad concepts, and then I think there would still be some fleshing out of the exact wording of what those look like.

MR. GOODIS: I'll just add to that, too. You know, I know the group mainly focused on their approach, and I think what was provided in the presentation and sort of the framework of the questions. And so there are some draft questions, but recognizing I didn't want to spend too much time on that until there was an accepting of the general approach, I think that's something that the agency would take a look at those questions too and working with SFIREG and others to make -- probably fine tune those to make sure we're getting the right information for our needs.

MR. KEIGWIN: Okay. So, thank you to the workgroup. I think we've got a path forward. All right. So now -- good job.

(Applause.)

MR. KEIGWIN: So now we're running behind, but that's okay. So why don't we come back at 11:15, and what we'll do is we'll start doing part of what's currently session 5, so the questions and answers. So

we'll do a few of those topics between 11:15 and when we break for lunch, and that will give us a little bit more time for some of the afternoon topics. So we'll come back at 11:15. Thanks.

(Whereupon, there was a recess in the proceedings.)

MR. KEIGWIN: I just want to check to make sure that Gina Schultz is still on the phone.

(No response.)

MR. KEIGWIN: Yeah, I knew she wasn't feeling well.

MS. SHULTZ: Hello. I'm on.

MR. KEIGWIN: So, what we'll do for the next 30 minutes, so that we can get back on track, and you still have enough time for lunch, is we'll start to do parts of the question and answer session for session 5.

So why don't we start with the status of the ESA consultations. For the PPDC members, there should be a one-pager in your packet that summarizes where we are with the current pilot ESA consultations. So let me just quickly see if there are any questions about those.

Tim, is your card up for ESA?

(No response.)

MR. KEIGWIN: So, Sharon, Cynthia, we'll start there.

Sharon?

MS. SELVAGGIO: Okay, I've got a couple of questions. In reading this, there was no mention of the resolution of the Dow April letter to withdraw the BE stock that was on the BiOp to modify the settlement agreement, so I'm wondering kind of what happened with that. We were expecting the draft BiOps for chlorpyrifos and the other OPs in May and those haven't come out yet. It says here that once they're released a public comment period is expected before finalization and the due dates. So the finalization is December, so there's not much time left.

And then we were expecting the BEs for carbaryl and methomyl I think in May as well, and I don't think it says anything in here on that -- about that.

MS. ECHEVERRIA: Thank you. My name Marietta Echeverria, I'm the Director of the Environmental Fate and Effects Division. So thank you for those questions. I will provide as much information as I have, and as I'm able to.

So with respect to the letters that we received earlier this year, to my knowledge, there has been no response to those letters. So they were received, we acknowledged the receipt, that request was to withdraw the biological evaluations. Those biological

evaluations have not been withdrawn at this time, so we continue to collaborate with our partners at the services on step 3, which is actually the biological opinions. So we continue to have discussions with them and to give input on those biological opinions as they're being developed. That's what we've been doing.

With respect to carbaryl and methomyl, you're correct, we did not meet our May time frame. What we have been doing is considering all of the public inputs that we've gotten in the first three pilots through the stakeholder engagements that we've had, the stakeholder meetings, and through the formal response to comments.

And what we've been doing internally, and as we've said all along, was to consider refinements to the process to make it more efficient and to bring in additional refined information earlier in the process. So we've internally been thinking about how to do that, and our hope would be to apply that advanced thinking for carbaryl and methomyl, which are the next two that are currently on the schedule.

MR. KEIGWIN: Okay. Cynthia?

MS. PALMER: Actually, that addressed both of my questions as well. I had looked at the handout from May 3rd, and noted that the language was almost identical to the one that we just received the update with the same

aside from the paragraph included in May about Dow Agrosciences letter. So I think this answers my questions to the extent possible.

MR. KEIGWIN: Okay. Any other questions on ESA, the update that's in your package? Going once, twice.

(No response.)

MR. KEIGWIN: All right, so Yu-Ting Guilaran, who is the Director of the Pesticide Re-evaluation Division, will come up. So there are a couple of things -- a couple of one-pagers in your packet, one relative to where we are with progressing towards meeting the October 1st, 2022 registration review schedule in the statute, and then there are some specific chemical-specific updates for three chemicals.

So, questions for Yu-Ting?

(No response.)

MR. KEIGWIN: So, why don't we start first with the general status update for registration review. Any -- so, Cynthia.

MS. PALMER: Thank you. So these are impressive large numbers, and I'm just wondering if you're able to tell us what percent of these reviews are receiving a thumbs-up or a thumbs-down from EPA. Are some of these applications sort of not making their way through the process, and do we have metrics on that?

MS. GUILARAN: Thank you, Rick. I'm Yu-Ting Guilaran, the Director of Pesticides Re-Evaluation Division, and just so that I can understand your question a little bit better, what do you mean by thumbs up or down?

MS. PALMER: Approval from EPA.

MS. GUILARAN: On what exactly are you referring to?

MS. PALMER: That we have, for instance, 457 conventional pesticides cases making their way through the system, are they all getting a full approval or are they approved with restrictions, do we have metrics on sort of where -- you know, what's the outcome?

MS. GUILARAN: Okay. So if you go down a little bit further on the status update. For the conventional, we have about 40 percent remaining on the draft for assessment, and we have proposed already 40 percent of the interim decision, and then finalized another 30-some percent of those. So it was really a mix of whether or not the labels are fine as they are, or there's additional mitigation that we need to put on the labels.

In general, for the more recent years, we're trying to work on different efforts such as spray drift reduction as kind of a way to reduce the footprint of pesticide, and also more recently resistant management,

which is another piece that just recently went final are some of the ones that were going to the mitigation. But it's a mix bag of both. And we do have a data -- database that's being developed right now for decision capture, and we are anticipating to roll that out probably more toward the beginning of the year.

MR. KEIGWIN: That database is being developed in anticipation of re-authorization of PRIA, which would, among other things, have expanded reporting for types of changes that are made as part of registration review.

MS. PALMER: Thank you.

MR. KEIGWIN: It will be an internal database, but we will be doing as part of our annual reports to Congress on PRIA, should PRIA be re-authorized, then the data would be made available as part of that annual report.

Other questions from PPDC members on the general registration review updates?

(No response.)

MR. KEIGWIN: Okay. Then Yu-Ting also has her team up here for three chemical-specific cases. So why don't we start with the easiest one here, chlorpyrifos.

Nichelle?

MS. HARRIOTT: So, in your handouts, you have

here, "despite several years of study, EPA has concluded that the science addressed in neurodevelopmental effects remain unresolved, and that further evaluation of the science is warranted to achieve greater certainty as to whether the potential exists for adverse neurodevelopmental effects."

Now, in your last Human Health Review, I think it was 2015, the risk assessment that you published seemed pretty clear on the neurodevelopmental health effects regarding chlorpyrifos, and the agency had come up with a proposal to revoke food tolerances as a result of that assessment.

Further down in your paragraph here, you then say you are hoping to come to a clearer scientific resolution on those issues, which are the neurodevelopmental issues. What specific issues still need to be resolved when it comes to evaluating the neurodevelopmental effects of chlorpyrifos, given that we have over 30 years of data showing that chlorpyrifos is highly toxic to the children's brains, to neurodevelopmental health, and EPA has over the course of reviewing chlorpyrifos taken action to try to mitigate the health impacts of chlorpyrifos?

So, for example, we in 2000, I think you guys said -- you removed indoor residential uses of

chlorpyrifos. We've had buffer zones to mitigate bystander exposures, you've hand a volatilization assessment. So what more needs to be done to give a clearer scientific resolution of these issues?

MS. GUILARAN: Thank you for your comment and question on this. So thank you for talking about the history of the different things that we have put forward, and they're indeed just proposal as what EPA was thinking about at the time, and one of the important things about a reg review program is that different from re-registration, with all the transparency in the process, and also soliciting public comment, it's an important step. That's why we have three different phases as we're going -- as each chemical going through reg review, we get public feedback on.

So for this particular one, the things that you have talked about, number one, the science has never been -- we went through SAP several times, so it's not -- even though I'm an engineer, I'm not a toxicologist or human health expert on risk assessment, the science is complex. So that's why we have gone through the SAP several times trying to hone in on what are the effects of chlorpyrifos.

So the proposal in 2015, also a notice of data availability in 2016, were just what the EPA was

thinking about at the time. We received a lot of comments on both sides, so that's why the science is still unclear on whether or not what we were proposing is really there the path forward for the agency.

So that's where things are. We do intend to complete a review by the deadline of 2022.

MS. HARRIOTT: I have another question.

MR. KEIGWIN: Okay.

MS. HARRIOTT: So I would like to know what specifically is unclear. What studies are now needed to resolve these issues? Are there studies that you have identified, that you need to help resolve these issues?

MS. FRIEDMAN: Sure. Hi, this is Dana Friedman, I'm also in the Pesticide Re-evaluation Division, I'm a senior regulatory advisor. I wanted to clarify that some of the specific issues are really wrapped up in the incorporation of the epidemiology studies that we do have available to us. We have had a lot of comments from the public, both with regard to the availability of the raw data, that's one of the issues that we've been -- you know, discussed -- have been discussed in public comments a number of times.

Some of the issues around the incorporation of epidemiology studies has also come up in a number of SAPs. In our last Revised Human Health Risk Assessment,

I believe it was 2016, I think it was November, we utilized the data in a way that we thought reflected what the SAP had suggested we do in evaluating the report and additional comments that we received from the public, there is still great uncertainty there.

MR. KEIGWIN: Okay, Iris and then Amy.

MS. FIGUEROA: Hi. So I just actually -- thank you, Nichelle, for the question, that was a question I was going to ask as well, and just to highlight the vulnerable populations that can be affected by this delay, particularly farmworkers and farmworker children, of course. And five years is, in our view, a very long period of time for potential harm and for the long-term health effects that that could have, that exposure.

MR. KEIGWIN: Okay, Amy, then Leyla, then Lori Ann.

MS. LEIBMAN: So, thank you for some of the initial comments, and that echoes a lot of some of our thinking, but the process regarding this is really disturbing, and problematic. And I don't understand how all of the sudden the agency thinks that the science remains unresolved.

This is -- this is probably one chemical where we have the most science to underscore the impact that this chemical has on children's brains. And then let's

not forget about workers, because we always forget about workers, but, you know, workers are continually exposed to this chemical.

I was just out in Hawaii looking into an incident in January 2016, this year, in California, there has been numerous exposures of workers to this chemical. And all of the sudden, EPA changes the rules of the game. And so what -- I don't understand with the science that's there, the process. And if this is going to be the process, is it money? Is it profits? Is it that we don't care about the population that is going to be impacted?

I mean, okay, so we can throw away the workers, they're Latino, they're poor, they don't speak English, and we don't care? I mean, that is the population that's going to be impacted the most by these changes in the game. And it's not acceptable and it's really -- it's really upsetting and it's very -- it goes against the mission of what the EPA is all about. And that is to protect human health.

And so what is happening here is not that the science is unresolved. We have more science on this issue. And so what happened is that the rules of the game have changed, and this is going to impact a population that puts food on our table and their kids

and the populations that live around them.

So that is now on your plate and this is really a very poor -- poorly made, poorly done process, and a very dangerous decision.

MR. KEIGWIN: I realize, Richard, you had had your card up sooner, so Richard, if you could go now.

MR. GRAGG: Okay, I have two questions. I guess my first one has to do with the going to 2022. So how can the EPA -- how do you intend on revising, updating, or coming up with some new type of evaluation that it took you 30 years to get to, how are you going to do that in five years? So that's my first question.

My second question is, you say here that you received a request to remand the biological evaluations. If somebody can explain that. And then you say you have not issued draft biological opinions.

MR. KEIGWIN: All right, so let me take the second two first. So as they related to the ESA evaluations, we did receive a request earlier this year to -- it wasn't a remand, it was a request for us to withdraw the biological evaluations for three organophosphates: Chlorpyrifos, diazinon and malathion that we had submitted to the U.S. Fish & Wildfire Service and the National Maritime Fisheries Service in January of this year.

MR. GRAGG: Right.

MR. KEIGWIN: That initiated consultation under the Endangered Species Act, so we received requests from external stakeholders to withdraw those biological evaluations. We have not withdrawn those biological evaluations. The biological evaluations are still with the services and we are actively engaged in consultation with the services.

The next step will be for the services to provide us with draft biological opinions that we will make available for public comment. We're still working, as Marietta said, with the services in the development of those draft biological opinions. Those are products of the services. These are very complicated evaluations for them to do, the first nation-wide biological opinions that we're doing in tandem with the services. And so that work continues to be ongoing. So there has not been a remand and there has not been a withdrawal of those.

MR. GRAGG: Okay.

MR. KEIGWIN: Okay? In terms of the next steps with the human health evaluation. Yu-Ting, do you want to?

MS. GUILARAN: So, part of what we're doing right now is going through the comments that we have

received from the 2016 Notice of Data Availability, along with the Revised Human Health Risk Assessment. I was just checking with Dana on how many subsequent comments we received. It's 200, and then the mass mail is more than that.

So we're going through the comment process working with the Human Health Effects Division to basically trying to figure out ways to address the comments.

MR. KEIGWIN: Okay. Did you have a follow-up, Richard?

MR. GRAGG: Yeah. So just for my clarification. So EPA goes through a process where you come up with a result or analysis, you put it out for public comment, and so these public comments are -- or these questions have led you to not conclude the human health portion because you got these comments, is that how the process works?

MS. GUILARAN: So kind of going back to what I was saying originally, that we -- EPA was attempting to address what the SAP's recommendation was to the agency. So the feedback that we have received, wide ranging from whether or not the agency did address or did not address, and this is how it was insufficient or sufficient, we have on both sides. So that's where

we're trying to go through the information that we received as part of this process through reg review. Trying to see what more modification, if any, we have to make to the science piece of it.

MR. GRAGG: I guess I'm going to stop, so it's going to take you five years, you estimate, to get there?

MS. GUILARAN: I guess I'm citing the five years because that's the end of the first round of reg review.

MR. GRAGG: Um-hmm.

MS. GUILARAN: I'll try to do the best I can for you.

MR. GRAGG: Thank you very much.

MR. KEIGWIN: Okay, Leyla, then Lori Ann, then Preston.

MS. McCURDY: Thank you very much. I'm not going to take too long. I want to say that I concur with the statements made by my colleagues before me, Nichelle, Amy, Iris, and Richard, and I agree with the questions that they posed and I feel like they have not been answered in the way that satisfies me.

So I just want to re-emphasize that we at the Children's Environmental Health Network are very concerned that this decision to postpone is putting children in harm's way, and we hope that the process can

be expedited. Thank you.

MR. KEIGWIN: Lori Ann, then Preston.

MS. BURD: First I want to acknowledge the many EPA employees who put years into working towards the chlorpyrifos ban. I thank you all for the work you did and recognize that this decision was out of your hands, unfortunately.

I have a few questions. Number one, as you guys go about this process, are you working with estimates of anticipated poisonings that will occur in the five years that it will take for us to apparently get certainty? That's pretty good numbers, it seems like we should be upfront with them.

MS. GUILARAN: So, our -- so we continue to monitor any of the incidents that occur related to all the pesticides that's in the market right now, so that's how we would keep track of the incidents.

MS. BURD: Okay. We know there's no such thing as scientific certainty, but we are pretty certain about what chlorpyrifos will do, and as many of my colleagues mentioned, there's abundant research on chlorpyrifos and why this ban would have been well substantiated. I'm wondering if as part of the additional research that you all are looking at and incorporating whether you are studying and monitoring the people that are currently

being poisoned by chlorpyrifos every year as this decision continues. It seems like that would be a very good group for additional research.

And also, I guess I'd like to know, you know, a little bit more about the plan of action for the next five years. We're not getting a ton of information here about exactly what will happen in these next five years.

MS. GUILARAN: So first I just want to -- if folks are interested in looking at the comments that we have received just the diversity of that and to kind of underscore what we're talking about when we talk about the scientific complexity and uncertainty, I will welcome you to our docket, because they are all available for you to take a look at the issues that we have to grapple with from here on out.

So step number one is to look through all the comments and make sure that we understand them, and then to see which of the comments are substantive, that may or may not change our risk assessment. Obviously if it's going to change our risk assessment, that will take HED time to work through that. And at that point, if there is a change, I mean, I'm looking at my boss, but we may have to have another comment period, or -- so I think that's why it's really hard to predict.

I think first is just really to wrap our hands

around what's the kind of information that's come in and what we need to do to respond to those comments. And I'm sorry for not being able to provide even more detail at this point, but we did receive a lot of information, and I encourage you to check our dockets.

MR. KEIGWIN: Okay. Preston, then Donny, then Cynthia.

MR. PECK: I will support the comments that have been said thus far so far as the potential exposure over this time period, but I also heard at the beginning of this meeting, and I don't remember who, I believe it was an agency official speaking to the importance of government to have clear and concise messaging when talking to the public. And I think that we've acknowledged that this has caused a great deal of confusion.

And we've seen in North Carolina, and the people that I met during the break from North Carolina will probably back me up on this, a great deal of confusion coming from coal ash being spilled into the Dan River, and our Department of Environmental Quality and the Department of Health and Human Services going back and forth, and I'm sure EPA was brought in on this, on levels of hexavalent chromium, so forth and so on. In the mean time, the people of that area are being exposed

and being very confused by the process of whether they can drink their water or not.

So just to highlight the lack of clarity on this decision and the impact that that can have on people and the confusion and still distrust within different agencies that not to just focus on the EPA, I think that time and time again I hear not necessarily from people sitting around this table, but people from industry speaking on touting these newer classes of pesticides such as neonics that's safer alternatives to the older class; however, in these same breaths and the same moments, I don't hear much from industry on advocating to get these other chemicals with this much data off the shelves.

And so I would encourage industry to speak up in times like these and to acknowledge that there are concerns to be made here and do what you can to help out agency and regulatory officials. So, thank you.

MR. KEIGWIN: Donny, then Cynthia.

MR. TAYLOR: So, can you all educate the committee on what impact an external deadline has on you performing your work?

MR. KEIGWIN: So, let me ask you a clarifying question. We have lots of external deadlines. Do you have specific ones in mind?

MR. TAYLOR: I understand, but you can use this as your case study.

MR. KEIGWIN: So if what you're referring to are court-ordered deadlines --

MR. TAYLOR: In this particular case, if that's the deadline.

MR. KEIGWIN: So in this case, we were under a court order to come to a decision by a certain period of time. I should note that after the agency received the report from the FIFRA Scientific Advisory Panel, the agency asked for additional time because of the -- or in light of the advice that we had received in trying to figure out a path forward based upon that advice.

While we did get some additional time, we did not get the length of time that we had sought, and so the scientists here in the Office of Pesticide Programs did a yeoman's effort in my personal opinion with the time that they had to revise a risk assessment, seek public comment, understanding that it was the best that we could do with the time that we had, understanding the report as we understood it at the time, and that, you know, one of the values of public comment periods, in general, I'll just pivot to that a little bit, is that as great a job as we do, and I was very thankful and appreciative of the comments that Nancy Beck had earlier

about the strength of this program's assessment. We don't always get it right, and there is great value to us in getting feedback on the assessments that we do. We don't oftentimes get a lot of feedback on the assessments that we do, so 200-plus very substantive comments on an assessment is a lot of information to go through and to make sure that we're making the best decision that we can with the best available science that's before us.

MR. TAYLOR: Thank you, because I think under the deadlines that you were given, I think you had to do what you had to do and everybody doesn't understand that science sometimes takes longer than the deadlines that are put in place.

MR. KEIGWIN: Cynthia?

MS. PALMER: Thank you. First of all, I concur with the comments of Nichelle, Amy, Iris, Richard, Leyla, Lori Ann and Preston, and I would like to state that the science on smoking has likewise been very complex, and yet when you look at the message and the weight of the evidence, it's rather clear-cut that smoking is bad for you. And I think there are parallels.

And third, I just had a clarifying question about Dow's requests to remand, because it comes up in

each PPDC update that they have made this request, and you've stated quite clearly that EPA has not done this, they have not granted that request.

Is that the same as saying that EPA has rejected that request? Have you turned down Dow's request, or do we still need to be nervous that you might actually say yes? Thanks.

MR. KEIGWIN: So we received that request many months ago, and we have not withdrawn the BEs, and I think that's a pretty effective message. I think the fact that we have not withdrawn the BEs, that is the agency's current position.

MR. KEIGWIN: Richard, you're -- or Donny, anymore? Cynthia, anymore?

(No response.)

MR. KEIGWIN: All right. So, I suspect that given that the next two chemicals aren't exactly -- why are you looking at me like that? All right, you all have a choice. We can either -- I will give it to you all. We could either try to get through both glyphosates and the neonics before lunchtime, that is like the -- that's -- let's practice this consensus thing a little bit more this afternoon. I think I heard no, pretty resoundingly. Jay might suggest otherwise, I don't know if that's why your tent card is up.

So, my suggestion based upon the groans in the room was we will break now. I will give Jay a minute to intervene with what he was going to say.

MR. VROOM: Just with respect to the suite of pest control available to farmers and other pesticide users, at the intersection of EPA's trying to apply very complex laws like the Endangered Species Act that has been referenced here, written completely separately from the pesticide law, and, frankly, even though the Food Quality Protection Act amended both the Food, Drug and Cosmetic Act and FIFRA in 1996, you still struggle with trying to make sense out of those two laws.

And so as an example, conversations here this morning about chlorpyrifos largely pivot around the petition to revoke the tolerances of chlorpyrifos, which is a process that in the pure sense of the two statutes are completely disconnected. And, frankly, doesn't make any sense.

And so I just wanted to make the point that farmers and other pest control users have a lot of needs, and if you look at the actual facts of the evolution of the way the agency regulates, especially all of the insecticides that we're talking about principally here, and use patterns that have responded, I think we've seen a tremendous amount of risk avoidance

and mitigation that is a combination of the serious efforts of applying science and very disparate policy framework handed to EPA, and the user community, and everybody else that sits around this table.

So I think we ought to pause and celebrate the fact that we have made a lot of progress around risk mitigation in the last 20 years. And that there's a profound commitment that we heard today from EPA to continue to lead with regulatory efforts to apply science as it evolves, and help to also provide a pathway for new, safer products to get to the marketplace. Thanks.

MR. KEIGWIN: Okay. It is ten minutes to 12:00. Why don't we reconvene at 1:15, plan accordingly to get through security so that we can start right on time, and what we'll start with at 1:15 is the discussion about dicamba.

(Whereupon, at 11:50 a.m., a lunch recess was taken.)

AFTERNOON SESSION

(1:15 p.m.)

MR. KEIGWIN: Just one thing before we move on with the afternoon agenda. It's been brought to the agency's attention that there may be PPDC members that are tweeting out the discussions at today's proceedings, and I've been asked to remind everybody that, as Jim McCleary went through with us this morning, that it's important for all of us to refrain from any language or activities that would compromise the civility of the committee, and at least one PPDC member has brought to my attention their reluctance to speak because of the tweeting. So I would ask and just remind all of us of the role and responsibility that we have in these proceedings, and to act accordingly.

So, thank you for that. So this morning we had a very robust conversation, and I would imagine it will get even more so. So I'd like to introduce Reuben Baris, who is the Acting Branch Chief of the Herbicide Branch in the Registration Division, and Dan Kenny, who is the Acting Associate Director of the Registration Division, to give you all an update on a recent decision that we made relative to dicamba.

MR. BARIS: Thank you, Rick. And thank you, PPDC members, thanks for the opportunity to present

today on a little window into essentially how my staff and I have spent our last few months. And actually, honestly, many people in this room have spent the last several months investing a whole host of energy into finding workable solutions. This has been an enormous undertaking that represents the efforts of individuals at all levels within the EPA, coordination and cooperation from state lead agencies, university weed scientists, USDA, and the pesticide manufacturers of dicamba products approved for use on dicamba-tolerant soybean and cotton. It is an extremely high-profile and significant situation. It has drawn on the resources of our regulatory partners, focusing attention on investigating incidents and developing practical solutions.

The role of these efforts is to minimize off-target movements and reduce instances of crop damage in the 2018 season, while recognizing the importance of these products as a tool for growers to manage weed resistance. It was and continues to be our intent to inform growers in a timely manner, allowing them to make informed choices for seed purchases for the 2018 growing season.

The next few slides will walk us through a very high-level synopsis of these issues and provide a

general update on the areas of the labels that were modified for the 2018 growing season.

New uses of dicamba for use on dicamba-tolerant soybean and cotton were registered in November/December of 2016. Three products are currently registered. That's Monsanto's XtendiMax with VaporGrip Technology, BASF's Engenia herbicide, and DuPont's FeXapan herbicide with VaporGrip Technology. These are the only products that are registered for over-the-top uses for dicamba-tolerant soybean and cotton.

As the 2017 growing season was ramping up in the mid-south, EPA quickly became aware of the rapidly increasing number of crop damage cases alleging off-target movement of dicamba. These incidents of off-field movement were reported to the state departments of agriculture as early as April, after which allegations and investigations were brought to the EPA's attention as early as May, stemming from the Bootheel of Missouri and Arkansas.

As the 2017 growing season progressed, recorded incidents rapidly increased in frequency and geographic distribution across the southern states, northern Missouri, and eventually spreading into the midwest and Dakotas.

The next few slides are a little bit updated

than the slides that you actually have in your packet, given that when I gave these slides for approval and submissions for you all to actually have printed out and available to you, new information was brought to our attention about finalized numbers and cases. So these will be posted to the PPDC's website, I can get confirmation of that, so they will be available as soon as that happens.

So out of the 34 states where dicamba-tolerant soybean and cotton uses were registered, 25 states reported estimates of soybean crop damage. As of October 15th, 2017, 2,708 official cases were reported to the state departments of agriculture, totaling over 3.6 million acres of soybeans. These figures only represent the official incidents reported to the state departments of agriculture in May and, in fact, underestimate the extensive crop damage incidents since we are aware that approximately one in five cases were actually reported and documented.

Throughout the 2017 season, estimates such as these represented our current understanding of the evolving issue, but as this issue was extremely dynamic and difficult to really get perfect information on, as soon as these figures were gathered and presented or reported, they were actually outdated.

The map on this slide and the next were compiled by Dr. Kevin Bradley of the University of Missouri, where he pulled representatives from the state departments of agriculture quantifying the number of formal complaints of soybean crop damage.

And then this map estimates the total acreage of soybean damage this year as reported by state extension weed scientists drawing from their involvement directly with growers. While these estimates focus on soybean acreage, we are also aware of cases involving tomatoes, watermelon, cantaloupe, vineyards, pumpkins, vegetables, tobacco, residential gardens, trees and shrubs, and other plants that are sensitive to dicamba.

As the issue evolved this year, EPA -- next slide, sorry. As the issue evolved this year, EPA engaged state lead agencies and university weed scientists in a series of conversations gathering information that could help remedy the unacceptable dicamba-related incidents reported in the field. The EPA approached the issue cooperatively with our regulatory partners in affected states and collected information from experts in the field to better inform any potential federal regulatory action.

Our objective is to minimize off-target movement and reduce the number of incidents in the 2018 growing

season, but we recognize the utility of the benefit of dicamba-tolerant technology through weed-resistant management. With this in mind, the EPA developed workable solutions with the pesticide manufacturers to amend the pesticide label application directions to address issues that rose to the surface of possible explanations for the unacceptably high number of crop damage incidents.

In our discussions, there were five common issues that surfaced in almost every conversation, suggesting the potential root causes of crop damage related to dicamba applications. These were: Physical drift, contamination, temperature inversions, volatility and misuse.

In reaching an agreement with Monsanto, BASF, DuPont -- and DuPont on measures to further minimize the potential drift to damaged neighboring crops from the use of dicamba formulations used to control weeds and genetically modified cotton and soybeans, the new use requirements for the use of dicamba will allow growers to make informed choices for seed purchases and weed management for the 2018 growing season.

This slide summarizes the major changes to the label for the next growing season; however, the labels have been revised significantly compared to the original

registrations. Namely, there are no longer supplemental labels for the uses on dicamba-tolerant soybeans and cotton. The supplemental labels have been integrated into the main label which the registrants have voluntarily agreed to designate as restricted use, meaning that only certified applicators may purchase and apply these products, which also includes permitting those under the direct supervision of a certified applicator to apply these products.

Dicamba-specific training is mandatory for all applicators who intend to apply these products, emphasizing that there may be state-specific requirements for training, and applicators must follow the state requirements before applying.

Additional restrictions have been implemented to limit when applications are permitted, reducing the maximum wind speed from 15 miles per hour to ten, and limiting applications of the dicamba between sunrise and sunset.

Language was added to enhance directions for sprayer system cleanout in order to prevent cross-contamination, and in an effort to increase awareness of the potential risk of damaging neighboring crops, label directions and documentation was added requiring applicators to identify potential sensitive

crops or plants neighboring the application site to further emphasize the compliance with downwind buffer restrictions.

And, lastly, the restricted use pesticide designation on these three products carries with it the requirement for the applicators to keep and maintain certain records regarding the use of these products. Keep in mind that product labels are very different from the labels that the growers may have become accustomed to in the 2017 growing season. It is important for applicators to be trained before applying these products and follow all label directions.

All three registrants are undertaking a process to get the labels in the hands of growers in time for the 2018 application season. This effort is intended to appropriately manage product that is currently in the channels of trade and relabel it so growers are using the correct label. While each registrant may have slightly different processes for implementing the new label, the intent is to ensure that applications -- applicators and growers have the new label and are following the correct label directions for the upcoming season.

EPA will monitor the success of these changes and help inform our decision whether to allow the

continued use of dicamba on dicamba-tolerant soybean and cotton after the 2018 growing season. And I think one of the things that we will hear today that I hope we can enter into the rest of the hour would be looking to the committee to -- and open it up for suggestion and discussions about how best to monitor the success in the 2018 season and beyond.

Thanks.

MR. KEIGWIN: So, questions on that presentation? Andrew, Preston, Charlotte.

MR. THOSTENSON: So, my question, basically now we're trying to figure out what success looks like in 2018? Would that be a fair assessment of what we're going to try and do over the next few minutes?

MR. BARIS: Yes, I think that's one of the objectives, and how best to measure that.

MR. THOSTENSON: Okay. So, you know, one of the thoughts that I have in working with applicators, and we've engaged with our Department of Agriculture about what success might look like, and we just threw some ballpark numbers out and said if we have 50 percent of this off-target movement in North Dakota, would that be acceptable in '18 or not? And our department universally said that wasn't acceptable. That would have been a failure.

So then we said, well, maybe 25 percent. Maybe 10 percent. So I guess I'm grappling with what the success looked like. I mean, we are going to have problems, it's just a matter of how much problems we'll have.

I assume that what has happened with the new labels will mitigate some of it, but how much? And that's what we're grappling with in North Dakota right now is trying to describe what success looks like in 2018.

MR. KEIGWIN: Okay, Preston, then Charlotte, then Cynthia.

MR. PECK: Thank you for your presentation. I have just a couple of technical questions. With the point on the underestimation of crop or plant damage, the approximately one in five being recorded. How did you derive that estimation?

MR. BARIS: That was based on conversations with stakeholders, state lead agencies, university weed scientists. It's not a precise estimate.

MR. PECK: Right.

MR. BARIS: It's an approximation. It was just really the only information that we have, formally, are the cases reported directly to the state departments of agriculture.

MR. PECK: Yeah, I was just a little curious on the methodology. And then one other question, is the plan with the rollout of the new labels, is this being coupled with any kind of educational efforts on letting people know that there are label changes besides, you know, is EPA working with the state departments of ag on kind of a robust education campaign and awareness building on this?

MR. BARIS: I think yes is a fair statement, but there is a mandatory training requirement on the label, and it opens -- it gives a nod to the states that actually do have a specific requirement in their state, and many states implemented that requirement through 24(c)s, and the 24(c) labels, in the 2017 season.

So the idea was to recognize that some states already do have that requirement in place and may continue that moving forward, but there is an opportunity there for states to decide whether or not they want to implement their own specific requirement.

MR. PECK: Thank you.

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

MS. SANSON: Thanks, and thanks, Reuben, for the presentation. Preston stole some of my questions, so I'll move on to my next one, although I did have a question on slide 4, as Preston did, approximately one

in five cases, if that is -- if that is an assumption, I think perhaps it would be better to state that as an assumption, rather than approximately, because if that number doesn't have a firm basis to it, maybe it's an assumption.

MR. BARIS: That's fair to say. It is an assumption. I mean, it's anecdotal information.

MS. SANSON: Yeah, okay.

MR. BARIS: It's not an official agency position.

MS. SANSON: Okay. And then on slide 5, the one with the map. I see that you have updated it since the version we have, which is fine, but I was curious as to an explanation on the zeros in some of the states. Is that where it's registered but there were -- no, I think it was that one. I think is that where it's registered but there were no official incidents reported? Is that how to interpret that?

MR. BARIS: That's correct. The state was polled, dicamba is registered in those states for over-the-top uses, but no official complaints or incident cases were reported in those states.

MS. SANSON: Okay, thank you.

MR. KEIGWIN: Cynthia, then Jay, then Liza.

MS. PALMER: So, this is worrisome in terms of

the volatility and the drift issues with dicamba. I sure hope it works in the next growing season. I'm wondering what steps EPA would be taking to protect the neighboring growers, and what these neighbors can do to become whole. It seems like they will have no choice but to buy dicamba-resistant seeds from Monsanto in the future and we're sort of further along on that treadmill.

I'm also wondering if with these label changes, if there is like a Cliff's Notes version or something, for the growers, because like I read that the Monsanto XtendiMax with VaporGrip label is 4,500 words, and if we're adding a few more, I'm hoping that there's a summary version available for farmers. Thanks.

MR. KEIGWIN: So, as part of the training that Reuben mentioned, and some of the label changes, there have been -- there has been additional information put on the label relative to what the sensitive crops are. And then the enhanced training that will be provided in many states, as Reuben mentioned, did do fairly extensive training, and in a number of those states, the extent of training perhaps even correlates with some of the states where there were relatively low incidents, or in the case of Georgia, no reported incidents.

And so we're trying to build upon the success of

that effort. As Reuben also mentioned, now these products are restricted use, and so there's recordkeeping, and so some of the recordkeeping requirements that have been put in place in effect help to walk the growers through the label, and then they're recording how they have met that label requirement, so we think that that helps to reinforce important parts of the label.

Liza -- no, sorry, Jay, then Liza, then Andy.

MR. VROOM: Reuben, on slide 4, where you talked about that was revised to 3.6 million acres of soybeans impacted, so this is the composite of the reports you got from the state regulators. Is that right? So it would be an estimate of what they knew or had reported in terms of the field size, right, for each complaint incident?

MR. BARIS: So, that's partially correct, it incorporates those figures; however, that 3.6 million acre estimate is actually a poll from university weed scientists extension agents on their best guess at what --

MR. VROOM: So it would be a whole field estimate, and in most of the cases, the impacts would have been, you know, near the boundary of the field, so this 3.6 million number estimate would be the total

acreage of fields for which complaints are anticipated or have already been filed.

So it's -- the point I wanted to make is it's probably an overstatement of the total acreage, and this is out of I think 22 million acres that were treated this year with over-the-top dicamba applications.

MR. BARIS: That's correct, 22 million acres were treated.

MR. VROOM: So, again, it's early days. You know, our advice to the agency was to wait until more of the state investigations had been concluded. We understand that some of the states haven't finished 2016 investigations yet, but compliments to the agency and the registrants and the grower community for having come together to create a label change landscape for 2018 that I think will help put more incentives in place for applicators, whether private or custom applicators, to pay attention, because more recordkeeping is going to be in evidence and we'll know more about, you know, what happened in 2018 than we'll ever know about 2016 and '17.

So we're quite supportive of the progress that's been made. Obviously there will be more to be learned, and thank EPA for, you know, being a proactive participant in all of this.

MR. KEIGWIN: Okay, Liza, then Andy, then Sharon.

MS. TROSSBACH: I'd like to just provide some information. There were some questions about the education pesticide applicators, whether they're commercial applicators, private applicators or agricultural producers, in ensuring that they're aware of the changes to the label. As a state lead agency for, you know, for pesticide regulation, I can speak for the entire association and indicate that we believe an educated community is a compliant community, and we stress education all the time.

In addition to applicators having to be certified through examination, there's also continuing education or recertification, and one of the things we want to make sure is that applicators understand and know how to use the tools that are in their hands. And so certainly when there's any huge type of change like this, when something is going from being a general use pesticide to restricted use pesticide, and all of the different requirements, and the fact that this is such high-profile, and it is significant, you have growers that have this technology in the field, they need a tool to use to be able to, you know, to make those treatments. We want it to be available, but we want to

be able to use it properly.

We're certainly -- I know the states that are impacted by this have done a lot of training. It may have been required, it may have not. They're certainly doing that now. And as these changes have just been announced, I think states are working to get that information out to their grower communities to certify those applicators that didn't previously have to be certified.

Some is done by the state lead agency directly, some is done through cooperative extension, and Andrew can certainly speak more to that effort. Right now is applicators are going through their continuing education units or recertification courses, so the timing of this is good in that we have these folks that are coming to the table and working with extension. It's very easy for me to work with people who are certified, because I regulate those individuals, but those applicators who didn't have to previously be certified to use dicamba, that's where that relationship with extension is so important, because that grower, the first call they make is to their extension agent.

And so I can speak, you know, very emphatically that the state regulatory authorities are working through extension and those frameworks and mechanics

that are already out there to disseminate that information. And so it's certainly -- we're certainly, you know, making every effort to do that starting now, part of the growing season, and then working on how will the training be implemented. You know, is it going to be registrant training? Is it going to be state training? You know, how is it going to be -- how are we going to reach those individuals? And we do this all the time. Dicamba is not the first issue that's come up with pesticides, it won't be the last, certainly, and we do this all the time.

And so, you know, I like to think that we do a good job at that. So just to address any of those concerns about the grower group, the applicators not having the information that they need.

MR. KEIGWIN: Okay, Andy, then Sharon, then Richard.

MR. WHITTINGTON: Fair to say that we all know that we can't have a year this year next year -- like we had this year next year. We are in Mississippi making significant changes. We were RUP last year, and so the changes that are here are not that significant to the changes that we will have to make. We are going to -- I mean, we require training prior to purchase, rather than prior to application.

I believe our plant board this year is going to recommend that we go restricted use on the generic dicamba products, to try and take that piece of the puzzle out, but as someone who works with people who were both affected and unaffected and the affecter, the conversations that we are having is that we have to be -- we have to do a better job of being stewards of these products if we expect to keep them. And everybody I have talked to is committed to that, and making sure that they're good neighbors.

So we appreciate the label changes, we are incorporating them into what we already have, and we look forward to whatever success looks like next year.

Oh, and I do want to say that damage -- I'm not sure that's the word I would use, because as harvest has come up, some of it appears to be cosmetic, and I don't know -- are you -- has the agency started getting information on whether it's yield reduction or if it was just cosmetic foliage damage? And is there a difference?

MR. BARIS: We're asking for that type of information, we're still continuing to try to wrap our heads around it.

MR. KEIGWIN: Okay, Sharon, then Richard, then Damon.

MS. SELVAGGIO: I was wondering about when you have the slide about impacted crops, at the very end you say trees and shrubs, and so I'm not sure if that means crop trees or if that means native vegetation of non-crop vegetation, or are those any other kind of non-crop vegetation. So my question is has there been any reports of ecological damage, you know, to non-crops, and if so, do you have any quantification of that?

MR. BARIS: As Jay was indicating, the investigations are still ongoing, specifically to quantify those acres that are not soybean. So we still don't have an entire picture, but what we were trying to do in this effort was to provide as much information as we could and take appropriate action with the information that we had available to us to inform growers for the 2018 season. So as that information becomes available, we'll certainly use that to inform any future decisions.

MR. KEIGWIN: Okay, Richard, then Damon, then Amy.

MR. GRAGG: I was curious as to whether or not is EPA doing -- other than the information they're receiving from the users or people who were impacted, is EPA doing any of its own monitoring?

MR. BARIS: So the state lead agencies are the -- they have primacy when it comes to pesticide enforcement and investigations, so we work cooperatively with the state lead agencies to investigate all cases of incidents and working with them cooperatively to develop those metrics to better evaluate what 2018 will look like.

MR. GRAGG: Okay, thanks. And on slide 7, you labeled it Investigations, but I guess my question is, how are you -- what's your criteria for damage and are you looking -- how are you identifying that in other crops or plants?

MR. BARIS: We're looking at all of it. I mean, we're trying to gather all that information together and use the best available information to make the most informed decision.

MR. KEIGWIN: So, Richard, let me just add on to that. So, some of the initial reports that we got, for example, in non-dicamba-tolerant soybeans, there was a cupping within the plant, and so it was -- it was before the seeds -- the pods started to form. I think that in part was why we got the question we did about how did this impact yield. So when Reuben is talking about investigations, it's starting when the off-target movement began to show some impact on a non-target

plant. That was kind of the premise. And so we're including that, and the numbers that Reuben is citing are coming from that -- those initial reports of potentially some impact.

MR. GRAGG: So on -- so you cited the three million acres of soybeans, however that's going to end up actually, like the gentleman raised, what that actually means, but what are your numbers? Do you have numbers on your other crops, other impacted crops?

MR. BARIS: That's actually one of the things that we're trying to -- or that we're actually requesting from state lead agencies and those conducting the cases of incidents is to measure what occurred in 2017 so that we can better evaluate 2018.

MR. GRAGG: And my last question is that if it gets on other crops, is it always going to be some type of physical or visible damage or do we know that or could it get on a crop and not have any visible signs and then it could get into the consumption -- into the people purchasing or utilizing it for food?

MR. BARIS: I mean, dicamba has been registered for a number of years and has a number of different uses on it. Namely, it does have residential uses. So different crops show different symptomology, depending on its sensitivity. So I mean, I can -- we can go into

that, but I don't necessarily -- soybeans are the most sensitive plant to our knowledge.

MR. GRAGG: All right, thank you.

MR. KEIGWIN: Okay, Amy, and then Andrew, are you coming in for round two? And Nichelle.

MS. LIEBMAN: Thank you. This is a really --

MR. KEIGWIN: I'm sorry, I skipped Damon. So, Amy then Damon.

MS. LIEBMAN: This is a really interesting update on something that's been a little bit out of a John Grisham novel with murder and all sorts of intrigue with this. And I think this has been really helpful. But I wanted to point out that this is a really interesting case study when we get into our discussion tomorrow about how important the label is and how critical it is for people who are applying pesticides to understand the label, and to use it accordingly. And I want to echo what has been said about the importance of education and training, and that we are not going to have safe use, if there is a safe use, of pesticides if people don't understand the label, can't read the label, don't know the label, and are not educated about it.

So -- and it's interesting about the -- the impact it's had, because it's affected a crop. And so I'm also curious, you know, in terms of response when it

affects people. So I think the reaction has been great in terms of looking into it, trying to investigate it, understanding what's happening, changing the label, all of these things are really good actions, but I find it intriguing all of this is happening because of crop damage and not -- changes don't happen when we have human -- I'd like to see similar responses and action.

And then the other thing I wanted to point out, I think the numbers on that map, on slide 5, are super interesting. And I find it hard to believe about the zeros in Florida and Georgia, and I think it would be helpful for the agency as you move forward to look into what has happened in some of those states in terms of the education, because my guess is, is now that they've done a great job educating -- I mean, I have no idea, but I have a feeling that the states where there has been a lot of outreach and a lot of education, you're probably getting some higher numbers because people are aware of what's going on. So I think the higher number, they're almost an interesting -- could be an interesting impact of the educational efforts.

So essentially like if you look at pesticide incident reporting for people in California, versus Texas or Florida, it's always higher in California because they have a better system there. It's not

because there's more incidents happening in California, there's more reported incidents happening in California.

So I just think that's something for you guys to investigate and see what's happening and what's at the root of such enormous differences between Georgia and some of the other states.

MR. BARIS: Thank you for your comment. I mean, I think the -- there are a lot of factors that go into these numbers, and these are just numbers on a slide. Just because Georgia has a zero and Arkansas has 986, it may be a factor, like you said, of reported incidents or outreach or awareness or anything. There's -- topography, geography, proximity, there's so many -- there's so many factors that go into whether or not an incident is reported or not. And that's -- those are exactly the things that we're looking into and examining as we move forward.

MR. KEIGWIN: I think that -- and point taken, Amy, I think one of the things I would say, I know the Georgia program particularly well, they started training their applicators three years ago, well in advance of the technology being available, so it wasn't just a one-time training, there was some repetition involved, too, and I think at least for myself, as I was going through my academic training, repetition certainly

helped a lot.

MS. LEIBMAN: Great, and let's remember that tomorrow when we talk about WPS and the certified applicator training.

MR. KEIGWIN: Right. So, with that, Damon, then Andrew, then Nichelle.

MR. REABE: Thanks. I also noticed something really interesting on that map that I'd like to bring to the attention. Obviously we're all aware of the fact that aerial application is not an approved method for any of these active ingredients. And when you look at the map and you think back to the time at which these products were to be applied, where those numbers are the highest are correlating with some very, very wet spring. And these growers did not have the tool of aerial application to use to apply this product.

And so with that being said, that probably put a lot of ground applicators in a very, very difficult position where the timing of this application needed to be made under less-than-ideal conditions. Aerial application can help with that in that we can make these applications regardless of soil conditions, so when we have these really wet periods, access to this tool to fight weed resistance is available to our producers.

And I think had there been access to this tool

by the aerial applicators in Arkansas and the Bootheel of Missouri, these products would have been applied by professionals who are paid very, very well for what they do, clearly understand how to use herbicides properly and under what conditions they have to use them in, and as professionals, really have a -- they have their career to lose if it's done incorrectly.

And so the understanding of the training is there because we're dealing with people that are truly professionals with -- that are making a career out of aerial application. So that was one observation that I noticed, and I think that we would clearly see a correlation not only in the number of acres treated, but also under what -- what was the story of the spring regarding soil conditions.

In regards to the 3.6 million acres affected, that's approximately 4 percent of all of the soybeans planted in the United States, so had -- if they're truly affected or particularly if they are destroyed, we would see a very significant change in commodity prices associated with that. So that number, I know the intention isn't to inflate the number, but it is -- it is probably a serious overestimation.

The other thing that I was really interesting in this presentation was the fact that 22 million acres

were treated with this tool. That's nearly 30 percent of the entire soybean crop. These are not good numbers. This is a very serious problem, but what is not quantified in this presentation is how many applications were done. Thanks.

MR. KEIGWIN: Okay, Andrew, then Nichelle, then Liza.

MR. THOSTENSON: Well, as a pesticide trainer, and that's what I've been doing for the past 21 years, I can tell you that I have observed both the Arkansas training and the Georgia training, and they're both very good trainings. You'll notice that Arkansas has 986, even though they had a very good training program, and Georgia had a very good training program, and they had zero.

So I tend to believe that good training is good training. But that means that there's something else going on there besides just training in Arkansas.

The other question that I have is because I am a trainer, what are the criteria for this mandated training? Do we have a curriculum? Do we have a standard like what we've done in soil fumigation of certain topic areas that need to be covered? I'm just curious what that may or may not be, for the dicamba-specific training.

MR. BARIS: Thank you, Andrew. The intent of the label language on the -- in regards to the mandatory training statement, training is required, and then it's a two-part statement after that, giving an acknowledgment to the states that either implemented a training requirement in 2017 season through a 24(c) label requirement that developed that state requirement and developed a state training, say Georgia or Alabama, North Carolina, Arkansas, Mississippi, Louisiana, I could go on.

It was an acknowledgment that those requirements could be in place for 2018 as well. But by no means was that to say that a state must develop that training. They have a -- they have the decision to implement a requirement and develop a training, should they choose to; however, that could also open up an opportunity for the state to decide whether or not they take a registrant-provided training.

And I think Liza may actually be able to speak a little bit more articulately about the effort that AAPCO is actually going through right now to make that determination across the 34 states that are affected for these registrations of dicamba-tolerant soybean and cotton.

So again, that's just the intent of the label

language, and I think we're actively working on that. There is no specific curriculum, but there is work being done to address the requirement.

MR. KEIGWIN: Okay, Nichelle, then Liza, then Lori Ann.

MS. HARRIOTT: So pesticide drift is not a new Phenomenon that farmers have had to be facing and that EPA by extension has had to address. And given that risk, we see more genetically modified crops being paired with specific products that are to be used on those genetically modified crops. I just want to urge EPA, in conjunction with collaboration with USDA, to work together to proactively -- and this is me thinking ahead -- to proactively develop a new strategy where we do not in the future see any more of these dicamba-like incidents when it comes to spray drift, given that we know that there are new pesticide products in the pipeline to be used on these type crops.

And just going back to an earlier question of what does success look like, EPA in conjunction with USDA need to sit down and evaluate that question. I think it's a very valid question. What does success look like? Are we just trying to reduce incidents from the 986 that we see in Arkansas to, say, 500 incidents? Is that what success is? Is it 200 incidents? Or are

we trying to move away from having farmers face these types of incidents year after year and are we trying to eliminate spray drift?

MR. KEIGWIN: Okay, Liza, then Lori Ann, then Richard.

MS. TROSSBACH: Thank you. I will mention briefly this survey, I had planned to do that initially when the question was asked about the crop damage that's not to soybeans or to cotton, and in that -- in the map that you see, that was done by weed scientists asking specifically about soybeans and cotton. And so one of the things that AAPCO, the association has done, is put together a survey to the states, and one of the questions in that survey is, are you able to quantify the non-soybean, non-cotton crop damage and what specifically it is, to try to gather that information.

So that survey actually just went out this week to state lead agencies and we're gathering that information to help provide that information to EPA, you know, just so that they know, you know, for their consideration.

Also in that survey, we're also asking the states questions about the training requirement. As you heard, there are some states that mandated training already, so they already have training in place. You

have some states, like Virginia, that didn't mandate training, but conducted a lot of training over the last year. And we're one of the states that there were no reports of potential pesticide misuse or damage to the state lead agency, which is my office.

And so I like to think there is some correlation, but again, there are so many factors, if you look at Arkansas, it's a cropping system, the amount of acreage, how they're applied. There are so many factors, you know, in that. But to the training, one of the things that we are asking states is just that question, Andrew, is what would it require, you know, what would you want, or what would you require before you would accept registrant training? You know, are there certain components. Does it have to be -- you know, do you want it approved by EPA? Does it have to be certain factors?

So there's a lot of that work that's being asked of state lead agencies right now, you know, to get their opinion on and to gather that information. Also are you going to do state training, will you allow registrant training. There's a lot of flexibility for states. For those states that already have training, who have a mandated training program, they may already have training in place. Not that they might change it a

little or amend it, but they already have that in place. Then you have some states who will have to start over, or may have to work from scratch.

So I think that information that will be gathered through this survey will kind of be helped, whether it's something that comes out officially from EPA or whether it's a guidance document to state lead agencies to help each other, say this is what we think is important for this type of training, certainly working with extension, our pesticide safety educators, who are those individuals who are experts in that area, we'll be able to pull all that information together so we're ready for the 2018 use season.

And there is an urgency, because now, as I mentioned before, is when certification courses and -- excuse me, recertification and continuing education happens, and we need to get individuals trained and certified so they're ready to use for 2018, which can be early in some states, you know, in some areas.

Just one other thing about the differences in the numbers. I think the statement was made about Florida being zero. Well Florida has very limited use of dicamba. So just as an -- a total amount that's supplied to total amount of acreage is much smaller than, say, Arkansas or some of the other states. So

once again, it's hard to make those comparisons between states because we are so different.

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

MS. BURD: Hello. Reuben, thank you for your excellent presentation. My question arises in the context of resistance management. We've heard reports that many growers are adopting this technology because they are concerned about drift, and so they're just kind of prophylactically adopting it which, of course, goes against some of the excellent resistance management guidelines that this office has issued, and some of the approach to resistance management that we've all discussed, which, you know, would not involve a lot of prophylactic adoption of these kinds of technologies.

And then, of course, subsequent increase in dicamba use that would come from that. I'm wondering if you guys were thinking about this at all from a resistance management perspective.

MR. BARIS: There is a five-year check-in point on the registration for resistance management and the registrants are required per the terms on the registration to report cases of resistance that they know of to the agency, and there's mechanisms for that. So we are acutely aware of resistance management, and are keen to take action appropriately as needed.

MR. KEIGWIN: Okay, Richard?

MR. GRAGG: Okay, my questions have to do with the -- I guess around success in your maps, but it was just communicated that Florida may be low because they don't use a lot of dicamba, so is that true for the other half of the U.S. as well? The same type of thing, there's not a lot of dicamba used where it's all white?

MR. KEIGWIN: So I believe the white states are the states where this technology has not been registered. So this only reflects the use in the states where the over-the-top technology is registered, right?

MR. BARIS: The yellow states are the states that actually were reported and polled as part of Dr. Kevin Bradley's survey that have been affected by the issue that we're talking about today.

MR. GRAGG: Okay.

MR. BARIS: The 25 states are highlighted; 34 states actually have registrations that this product is actually registered on.

MR. GRAGG: Understood, thank you.

MR. BARIS: Some maybe just didn't report, this is the information that we have available to us.

MR. GRAGG: So again, on the metric of success, what -- is there a standard of what is an incident or an impact? Because if there is -- you have these various

numbers, is everybody using the same metric to determine that there's an impact? You know, how is the data -- how can you rely on the data if it's not uniform?

MR. BARIS: I think that -- thank you for the comment. I mean, we're still gathering information, like Andy was mentioning earlier about what the actual impact on yields are. I think harvests are still wrapping up, and so we're still gathering that type of information.

So I mean, that's really what -- the yield weights are really what's going to tell us the true story about the measurable impact of dicamba damage, whether it's cosmetic, whether it's growth and reproduction, yield rates will tell the story.

MR. GRAGG: Okay. Thank you.

MR. BARIS: And we are trying to collect -- and you reminded me that we are trying to collect information on non-soybean impacts, so that's an important point.

MR. GRAGG: Thank you.

MR. KEIGWIN: Okay, round three? Andrew, are you back up? Oh, I didn't see Amy. He's gone a couple times. Go ahead, Amy.

MS. ASMUS: What are you doing when you're looking at the effects of the drift that's different?

When we talk about education of applicators, I think that's very important, but I've got applicators in our area that have been applying dicamba for many, many, many years, and we have never seen this high of incidents of off-target movement. So is there any study? Are you looking at the differences between dicamba use in the past and dicamba use on crops like cotton and soybean where, you know, what's the difference in an application? Because if you tell my applicators they have to be trained in dicamba application, they've been doing that for many years successfully. What is going to be different in this training to actually address the off-target movement on these crops that's different than the crops that we've been using it for many years?

MR. BARIS: I mean, you are correct, dicamba has been around for a number of years, and it has a number of different uses. The difference is these uses over-the-top on tolerant soybean and cotton.

And so the training will be involved in following explicit label directions to prevent noncompliance and follow the directions that are intended to prevent off-field movement, and the consequences that an applicator could face if they aren't compliant with the label directions.

MS. ASMUS: Can I follow up real quick? So we did extensive training with our applicators before it was applied, and we believe that for the most part, it was very consciously applied, made every effort to apply it according to the label direction, and we still had many off-target movements. So to believe that the applicators are in error for all of this I think is maybe a misunderstanding, and we need to address why it worked and why it didn't work when all applicators followed the label -- not all, the majority of the applicators that I work with, I will quantify that, followed the directions and were as methodical as they could be in the applications, and we still had off-target issues.

MR. BARIS: We're not insinuating that by any means that growers did not follow the label. That's not the case. One of the efforts that we tried to undertake in this process has been to tighten the label, make it clearer, integrate the supplemental labels into the main label so that the label is easier to follow in and of itself could provide a Cliff's Note version for itself, because the label then is more integrated and is less contradictory.

And these products are more similar than they were in the past, so that training efforts can be done

to teach to the technology as opposed to individual products, and I think that's really an important point that -- as pesticide educators are -- application educators are up in front of a classroom or on farm teaching about the technologies. It's the risks, the benefits, and how to follow the label and specific elements of the label to ensure that these products are used appropriately.

MR. KEIGWIN: Okay, I want to do a time check so we don't go over. So Lori Ann, are you back in?

MS. BURD: No.

MR. KEIGWIN: Okay, so let's just do the last four that are up. So Andrew, Richard, Amy, and Sharon.

MR. THOSTENSON: Well, in an effort to, you know, get a better grasp on the number of acres and the types of damage that our growers were impacted with, we implemented a survey, self-reporting web survey tool that applicators and farmers could go into and report the sorts of problems that they had. Minnesota did the same thing, South Dakota did the same thing.

I'm fairly confident that we will probably set that up again for 2018 so that we can, you know, quickly in real time assess what's happening out there. You know, I'd be willing to share that survey tool with you all and the results of the survey that we had this last

year, and it was interesting in that we only had 40 formal complaints, but we had over 207 registered issues out there.

And interestingly enough, the farmers indicated to us that 50 percent of their fields showed typical physical drift with a gradation of damage across the field. And so we were like, okay, that's good. But the other 50 percent said it was field-wide, with no discernible pattern.

And the numbers that we reported in that survey that Dr. Bradley put together incorporated the numbers we received directly from the farmers. So at least for purposes of North Dakota, I think those numbers are pretty reasonable, but certainly as we go into 2018, anything that we could do in real time to monitor what's happening so that if an intervention is necessary, perhaps we would have some ability to do that.

MR. KEIGWIN: Richard?

MR. GRAGG: She said that she had well-trained people and this drift was still happening, and we said earlier that well-trained people were great applicators and less error. So my question is -- I've got a couple of questions. Is this pesticide used differently for different crops, and is it applied differently for different crops?

MR. BARIS: Yes, there's -- there are -- whether it's a tolerant crop or nontolerant crop, there are specific restrictions in place for the over-the-top uses on tolerant soybean and cotton compared to a non-tolerant cotton or soybean that is, for example, pre-emerging application, or asparagus, or there's specific wind speed restrictions, boom height restrictions, things -- other restrictions for --

MR. GRAGG: So then if it's used -- so the labels will tell you for this crop, this is how you do it and for this crop this is how you do it?

MR. BARIS: And one of the major changes into this season will be or has been the growers will see on the label that those restrictions apply across the board for all uses on the label. They've been -- the supplemental labels have been integrated into the master -- the main label. So there are no supplemental labels in 2018.

MR. GRAGG: Okay, so in terms of monitoring for what we don't want, there's not the ability to put out any type of physical or biosensor to detect the movement of the chemical off the field or where on the field you don't want it to be in terms of realtime monitoring to try to understand why and on what basis the stuff is drifting?

MR. BARIS: So a marker or a tracer or a bioelement would require a formulation change, and that wasn't exactly something that we could address this year. What we did do, with the registrants' cooperation, was to involve a restricted use classification for all three pesticides so that the use of the products could accurately be tracked and records are required to be kept by the applicator so that state lead agencies have the tools that they need to investigate potential incident investigations.

In 2017 that was actually one of the pieces of information in cooperation with our regulatory partners that they reported back to us we don't have the tools necessary to enforce or distinguish between labeled use and nonlabel use.

And so one of the cases, as I mentioned, for root causes of off-target movement was misuse, that could be using generic products, as Mr. Whittington highlighted, that, you know, they're pursuing applying a restricted use for all dicamba products in Mississippi. But for restricted use of these three products, that at least give the states the tools that they need to distinguish between an approved use and a nonlabeled use. Or misuse.

MR. GRAGG: And why would the formula have to be

changed in order for it to be detected with a bio or some type of physical sensor? Why would that require a change in the formulation of the product?

MR. BARIS: It's a different ingredient in the formulation, so we have to evaluate -- we evaluate all formulations for all pesticides as part of the registration process. And that would be a change in the formulation by adding an ingredient.

MR. GRAGG: Why would you need to add an ingredient in order to detect it?

MR. BARIS: I'm not sure I understand the question.

MR. KEIGWIN: So I think there might be ways, Richard, to get at your point. One suggestion that had come forward was that some type of an indicator dye be added to the formulation, so I think that's what Reuben was referring to. If what you're talking about is putting some type of a sensor in adjacent areas so that -- you know, at the time that wasn't something that we had really looked at in --

MR. GRAGG: But you could do it other than by adding a dye or something to the formula.

MR. KEIGWIN: And I think that's the point that you were trying to make, right?

MR. GRAGG: Yeah, um-hmm.

MR. KEIGWIN: Is that you could put some type of receptor off-target and see if you got something. You know, there are issues with analytical sensitivity, what would be the best type of receptor being used to do that, is there laboratory capacity available in the states and at EPA to do it. I think these are very good suggestions that as we think about and as we see what happens in '18, do we put some additional things in place if we renew the registration after the 2018 use season. Thank you for that.

Amy, and then Sharon.

MS. LIEBMAN: I think you've addressed some of what I was asking, because Amy's question was two-part and her point was that in some cases you have a very well-trained, you know, properly used, properly applied pesticide, and what is being done to sort of figure that out. And then it sounds like Richard offered some suggestions, you threw back some suggestions, but I guess could you just clarify what is your plan in terms of trying to figure out this component of the well-trained, well-educated applicator, and there's still this drift happening and crop damage.

MR. BARIS: So this effort has really tightened up the label in all aspects that we could possibly tackle in this short amount of time that we had

available to us. Our goal was really to present a decision in a timely manner so that growers had the most -- the best available information so that they could make informed choices for 2018.

So the label has been tightened up as much as we possibly could for the 2018 season. And I think we're hearing a lot of really good suggestions this afternoon about how to measure and I think we all need to continue to think about those aspects and as we -- the conversation continues to evolve and throughout the off season or winter seasons, winter months, and into 2018.

MR. KEIGWIN: The other thing, Amy, you know, would be to say that we know that there's a lot of really interesting work going on within the Weed Science Society, and a lot of weed scientists across, you know, these states are looking -- are doing some additional work to see what other factors might be involved, what other things might be affecting movement, what other adjacent crops might be more sensitive than had been previously known to be.

So I think through the work that the land grant universities are doing in tandem with the Weed Science Society, I think we're going to have a lot more information in 2018 that will help to inform the decision that we would have to make if we were to renew

the registration for the 2019 use season.

Sharon?

MS. SELVAGGIO: I might be missing something here, but I'm just kind of confused about the volatilization issue. I'm not clear on which of the label changes are meant to address the volatilization issue. And so I'm just wondering, are you confident that your label changes have adequately addressed volatilization as opposed to spray drift?

MR. BARIS: The time-of-day restriction was one, the sunrise to sunset was one type of restriction that would -- was aiming at focusing applications when times of day when temperature versions are least likely to occur. There are -- states may have the requirement to further restrict that, depending on their specific variability -- the specific variability or their specific conditions in the state or region.

We tightened up the label in almost every other way possible, and 2018 will be a marker for how this technology is working. And I think, as I was just reminded, one additional point is that we added some -- with the registrants -- added some additional labeling on all three products about how to identify temperature inversions, how best to identify temperature inversions, and bringing some awareness to growers and applicators

about the risk of applying during a temperature inversion, because a temperature inversion still may occur between sunrise and sunset and how do you identify that to prevent suspension of spray material in the air during those climactic conditions.

MR. KEIGWIN: I feel like I have to let you go since I skipped you before, Damon, so go ahead. No, go ahead.

MR. REABE: Thanks a lot. I'll make it really brief. Something just occurred to me as we're having this discussion, if there's some way to identify how many of these incidents were associated with the applicator being misinformed as to whether or not the downwind soybeans were, in fact -- had the GMO technology, I believe that when RoundUp first came out, this was a very big problem, growers weren't used to communicating with their neighbors, so that when they hired a commercial applicator to do an application, that applicator didn't -- wasn't aware that it wasn't RoundUp-ready corn downwind.

And so I think that would be a pretty critical piece to all of this is almost like a pollinator protection plan, if we're not communicating that, this type of thing is going to continue to happen.

MR. BARIS: I'm sorry, I had to turn my mic' on.

There's two important elements to that and I think it gets right at the point that you're trying to make is that the buffer descriptions and how the applicator must actually follow those buffer restrictions and identification of sensitive or susceptible crops has been added to the label. And then further to that point, there's two elements on the recordkeeping requirement side that the grower applicator must survey the neighboring sites around the application site and document that they've checked, say, the sensitive crop registry for their state and their situation.

So those were intended to increase the awareness element that you're highlighting, and improve the communication between neighbors.

MR. REABE: And just going off of, you know, previous experiences with RoundUp, there would be fields that would be originally when that work was done, the idea was to plant RoundUp ready, things changed, and in between time, a different product -- a different product got planted. So more outreach like that I think is good.

MR. KEIGWIN: Last comment.

MR. THOSTENSONL: My question goes back to the volatility issue. We know that in our Arkansas and Tennessee and Missouri and Purdue is all doing work in

this area evaluating the volatility aspect of these new formulations. What are you looking at from those programs to be able to make assessments moving forward? Are we looking at needing published data in the Weed Science Society of America? What sort of criteria do you need to be able to make decisions about whether or not these products are sufficiently non -- or low volatility moving forward?

MR. BARIS: The intent is to use the best available information, and that's the standard we use to evaluate the registrations that are in front of us, the registration applications that are in front of us. We are continuing to cooperate with our partners and university weed scientists like yourself, and others, to ensure that we have the best available information. And they are invited to share with us any information that they have that would inform our decisions. I would be happy to discuss that further.

MR. KEIGWIN: Okay. That was a very good discussion and lots of good feedback, thank you. As Reuben was mentioning, he and his staff probably spent the majority of the summer working on this, and it was a very extensive collaboration with the states in a very productive way, not only with the state agencies, but with the land grant universities and the registrants as

well. And I think our ability to move as quickly in making label changes I think in part was due to the partnership with the states and the land grants, so we do appreciate that.

So thank you, Reuben and Dan.

Let's move on to the next topic, which is synergy, and I think Marietta is going to come back up, along with Kimberly Nesci.

MS. ECHEVERRIA: Good afternoon. I'm Marietta Echeverria, again, I'm the Director of the Environmental Fate and Effects Division. So for this session, we wanted to provide an update on our evaluation process around claims of synergy, so by just way of very brief background, in 2015, we became aware that pesticide manufacturers were applying for and being granted patent claims that products in combination were having synergistic effects or enhancing efficacy in the field. So this caused us to call into question our approach of evaluating single active ingredients as part of our ecological risk assessment process.

So back in May, we gave a brief update on where we were in that learning process, and today we have a more detailed presentation to describe what we're thinking and we will welcome dialogue at the end.

So with that, I'm going to introduce Kimberly

Nesci, the Deputy Director of the Environmental Fate and Effects Division, to give the presentation.

MS. NESCI: Thank you. So in the time I have today, what I'm planning to cover is a little bit of background, a little bit more than what Marietta just gave on why we're doing what we're doing, why we're choosing at this time to focus on patent data specifically, the proposed process that we're following itself, and our next steps. And, of course, we have 30 minutes I think at the end for questions.

So background. Before we get into the details, I think it's important to ensure that we have a common understanding of the terminology. Synergy, from what I understand, can have multiple definitions and can mean different things to different people, or different groups. So despite the title of this session, we are moving away from the word "synergy," and instead defining the issue that we're proposing to -- the issue that we're proposing to address as greater than additive effects, or GTA effects, or an observed combined effect greater than the sum of the effects of individual chemicals.

So historically, EPA has based our ecological risk assessments on the toxicological evaluation of single active ingredients, and we have understood that

toxicological actions between active ingredients that produce significantly greater toxicity than expected is a rare occurrence. The available monitoring data that we have indicates that in a predominant number of cases across the country. The potential toxic risk of contaminants is dominated by one to a few chemicals. And the thresholds that we use to make our risk-based decisions are extremely low probability events, or no probability events, and this suggests that the combined effect of exposure to two pesticides both at no effect levels or at very low probability effect levels can reasonably be considered to be extremely low.

In addition, the National Research Council in its 2013 review of OPP's methods for endangered species effects determinations supported the general opinion that synergistic interactions between pesticides are rare, and the council suggested that the agency consider pesticide active ingredient interactions when the best available scientific data evidence supports the quantitative evaluation.

So as Marietta mentioned, in 2015, we've discovered a number of cases where pesticide producers have been granted patents for claims that selected mixtures of pesticides produce toxicological effects in excess of expected additive effects, that is claims of

synergistic interactions, or GTA interactions, for effects in specific to pest species, this is enhanced herbicidal, fungicidal or insecticidal effects.

Because of this discovery, we have developed a process to, one, obtain and analyze the patent effects of these GTAs -- the claim of GTA effects of these mixtures and determine whether or not these claims and data need to be accounted for in our risk assessments, which I'll be describing in more detail over the next few slides. And it's important to note that the process that we've come up with follows the suggestion by the National Research Council that pesticide interactions be considered to be extensively supported by scientific evidence.

So why have we decided to focus on patent data specifically? Again, there are a large number of these patents making GTA claims for pesticide mixtures; the patent data are readily available to the public; the PTO, U.S. Patent & Trademark Office's process is well understood; and the data typically contain information on the mixtures being considered, the conditions of testing, the effects observed and the organisms being evaluated, all of which was needed to determine whether the data warrant changes to our risk assessments. And these data likely represent the most compelling evidence

to support these GTA claims, otherwise they wouldn't be submitted to the Patent & Trademark Office in the first place to support the patent applications.

However, there are differences between the standard to receive a patent and standard for use of data to quantitatively evaluate risk. While the U.S. PTO focuses on a determination if a claim is unexpected given existing background information, publications in prior patents, and the Patent & Trademark Office personnel are to give claims their broadest reasonable consideration and interpretation in light of the supporting information. To use this GTA evidence quantitatively to evaluate risk, it must be subject to the standards for the use of other -- of our standards for the use of other toxicological data, that is they must be relevant, supported by empirical data, and that empirical data must meet the agency's standard for data quality.

So, does the granting of a patent automatically mean the data are appropriate for ecological risk assessment? I think as I just described, no, the patent review is not equivalent to EPA's data quality criteria. Does that mean patents are never pertinent to ecological risk assessment? And the answer to that is also no. Our experience to date has shown that some patents do

have sufficient information to inform our risk assessments.

So with that, I'll get to the process itself. The goals of our proposed process are to document these GTA patent claims and that we've taken these claims into consideration in our decisions and in our assessments; second, to establish a data search and reporting approach so efforts are consistent in scope and that there's a level playing field to establish criteria to narrow these GTA patents to those relevant to agency ecological risk assessments; and to provide a data analysis framework for evaluating the statistical significance of any GTA findings.

Ultimately what we're looking to do is to determine whether these patent claims indicate a need to quantitatively or qualitatively change our assessments or decisions. So we're proposing a five-step process. The first is the -- the first step is the identification of granted U.S. patents that make claims of GTA effects; the second is a review of patent relevance to ecological risk assessment, and we've established relevancy criteria that are in the slides here above that I'll go through that will be considered as part of this step.

The first criteria is the patent must contain actual data, must contain comparisons of empirical

effects. The second, the patents -- the effects -- sorry, the effects are relevant to direct effects on tested taxa. So, for example, a direct measure of death or growth would be applicable to us would be relevant, but a reduction in yield loss or reduction in plant damage as a result of pest control -- a better control of pest populations would not.

The tested taxa must be relevant -- the taxa themselves must be relevant to ecological risk assessment; for example, fungi -- for fungicides, of course, we may be seeing synergistic or GTA claims because of enhanced efficacy, but we don't assess effects to fungi, so we -- that would not be -- those types of claims would not be relevant to us. Instead, claims of enhanced insecticidal activity or herbicidal activity would be relevant.

The test must be on the chemical considered for regulation, so the actual chemical that we're looking at. And the mixture components tested must be registered in the United States. So some patents consider active ingredients registered in other countries. These aren't relevant to us until such time as they're submitted to us for registration.

So, steps 3 and 4 are really obtaining and analyzing the data supporting these relevant patents to

determine -- to see if the effects are statistically significant, and then step 5 is to evaluate that analysis to determine whether the statistically significant observations impact the conclusions of ecological risk assessments, whether the observations can be used to inform quantitative adjustments to the ecological risk assessment or risk mitigation, and whether additional mixture toxicity data may be needed as part of our evaluation process.

So this slide doesn't show up all that well, but it is in your packets, and it really just shows a schematic of all the steps I've just described with a little bit more detail. And I'm not going to go through this in a lot of detail here, but we wanted to provide it to you. And it's a useful tool, I think, for more visual learners to see to walk through the process.

So what do we do with what we learn? It's important to note that we do not -- we are not evaluating the U.S. Patent & Trademark Office's decision, we are evaluating the data to determine if qualitative or quantitative changes are needed to the ecological risk assessment or if additional studies are needed. If those data -- if additional data are needed, we will obtain that and evaluate it accordingly.

In some of the actual cases we have looked at so

far, this additional data has come in the form of guideline studies on formulated products. For data where EPA feels the observations are appropriate technical rigor to support quantitative application, we're going to consider a number of different things. The magnitude of the GTA effects, so whether the quantification of the excess toxicity is large enough to alter our risk conclusions. We will consider any transient observation across treatment levels. We will be considering other lines of evidence associated with the mechanism of action that could inform the interaction assumptions.

We'll consider background information on the frequency of observations of effects, interactions and data sets extending beyond the patent reporting data. So companies may have sets of data beyond what is specifically submitted to the Patent & Trademark Office.

We will evaluate existing ecological risk assessment findings, and we will look at the tested concentration level and compare that to our expected field exposures, so can the information that we have reliably be extrapolated to field-level exposures.

So, and again, it's important to note for the cases while -- that we've evaluated so far, while some have warranted the need for a closer look, or additional

guideline studies, none have ultimately resulted in changes to our risk conclusions.

So our next steps. At this time, we're planning to continue to follow this process and collect information on the cases that come before us. We are considering whether to publicly release a memorandum describing this process for formal public comment. And ultimately, we intend to develop a final position on GTA effects of pesticides that would consider public input either through a formal public comment process or through any other public comment process. And, of course, your input here as well, and what we've learned, what we're continuing to learn on the cases that we've evaluated so far.

So with that, I would really like to acknowledge the EFED synergy team. They've looked at all the cases we have done so far and they have certainly spent a lot of time using those cases to develop this process. And Ed Odenkirchen, who I think is here today in the back, Rochelle Bohaty, Frank Farruggia, Christine Hartless, and their managers, because they've spent a lot of time to help develop this and to look at the information we're getting. And with that, we'll take questions.

MR. KEIGWIN: So I want to keep us on time, so we'll do about maybe ten minutes of questions to get to

the break. So any quick reactions? Noting that we're likely going to take public comment on this and, you know, sharing a fuller memorandum, so what Kimberly has provided is a very high-level overview of our process to date. So, I see Pat, Jay and Preston.

MS. BISHOP: Hi, Kimberly. I'm a little confused in that I'm assuming these mixtures have already been registered and gone through toxicological evaluation for human health? Or -- I mean, so there's a patent that says there's a synergistic effect, and that's a claim that's separate from the product already going to EPA and being evaluated, is it not? So then how does it -- I mean, have you looked at these already as far as ecological risk and now you're looking at them again because there's this claim that's been made? I'm not quite understanding that.

MS. NESCI: So what we're looking at specifically is the data supporting the patent claim. So the data supporting the patent claim may be for a combination that's in a combination product or it may be for something that's not in a combination product that would be -- that could potentially be applied as a tank mixture.

So what we're looking at is unique, is not something that we've seen before, because we typically

don't -- don't -- we haven't historically gotten these data as part of our registration packages.

MS. BISHOP: So then it's just the data that are new, not necessarily that the product is something you haven't -- it hasn't come across your desk yet as a formulation of some sort?

MS. ECHEVERRIA: That's correct. So we would have evaluated the formulation and the registration process, but the patent claims are for unique combinations like in-tank mixes.

MS. BISHOP: Okay.

MS. ECHEVERRIA: So we don't evaluate a tank mix, which is a way that growers combat resistance management and also make efficient applications of pesticides. So that is where we're seeing a lot of the claims.

MS. BISHOP: So you said that additional studies might be needed, would that entail any kind of new animal studies do you think, or more like efficacy type testing?

MS. ECHEVERRIA: So in the cases we've evaluated so far, where we have gone to guideline testing, it has been for plants, so guideline plant testing of base in a formulated product which informed the decision.

MS. BISHOP: Okay, great, thanks.

MR. KEIGWIN: Jay and then Preston.

MR. VROOM: So I wanted to compliment all the staff and in particular you called out Ed for leading in this area, I remember like it was yesterday, it was the day before Thanksgiving two years ago that I learned of this, and what you've assimilated and the interaction you've had with our industry to result in this much progress is nothing short of amazing.

I think it's important to also note that quite a number of these synergy patents have been filed prospectively and granted but maybe not used in the marketplace. And some of them are marketing defensive strategies that have no implication with regard to the use of pesticide combinations. In fact, they may prevent pesticide combinations.

And then lastly, some of them actually do result in reduction of total pesticide uses because of the synergistic effects that may be already noted in the marketplace. So there are a lot of permutations of this that have nothing to do with increased risk, and some of them actually result in reduced risk.

MR. KEIGWIN: Preston?

MR. PECK: Thank you. I have -- well I just wanted to say thank you for the flow chart, that was the slide that was very helpful as far as trying to lay that

out and processing a lot of it, and I don't really have any comments on it, but it is much -- I'm a visual person, so it's very helpful.

But I wanted to ask one quick question about -- it was on slide -- I want to say maybe 4 or 5, depending on if you count the title one. It said there are a large number of U.S. patents making GTA effect claims. Do you have an idea of what large -- just kind of a definition of large? Like what -- about how many? I'm just curious.

MS. ECHEVERRIA: Well, we have received a petition from the Center for Biological Diversity, and I believe that the number claimed in that petition was 186 or so. Does that sound -- okay. So the number that was reported in the petition I believe was 186 claims, but maybe that's not extensive, but it's not the complete universe, perhaps, but that's the information that we have.

MR. PECK: Okay, and then did I hear you right, and I may have misheard, but something like the ones that may claim GTA but only a small amount actually do? Is that what you said? Or did I mishear that?

MS. NESCI: So I think of the ones that claim GTA, I think that there are a small amount that we've discovered to be relevant to ecological -- to our

ecological risk assessment.

MR. PECK: Okay. Thank you.

MR. KEIGWIN: Sharon?

MS. SELVAGGIO: I have a couple of comments and questions. One of them is, with your characterization of GTA effects being rare, after our last meeting in May, I think that was in the last summary that we -- when we went over this, and I went and I looked for that, and I did not find that anywhere in that document. So I'm really curious about maybe it happened, you know, in a meeting, I'm not sure, but I just don't see that kind of conclusion in that document. I know the organophosphates have definitely been found in the literature to be synergistic greater than additive, and so anyway, I'm just really curious about that, that use of the term "rare."

My second question is about the process, and I guess I'm thinking about this like Venn diagram, but -- so what happens if somebody has submitted, say, a formulation that combines two herbicides, and in their patent application, they have tested that on plants, certain plants, but there's no data for insects and fish, say. If you find that for plants, in fact, the data looks legitimate, it meets all your data quality criteria and all of that kind of stuff, would you then

go out to the registrants and say, we want more data because it looks like there is a potential synergy on some taxa, therefore we want to see if this is also synergistic to potential non-target insects and fish and mammals?

And what about if you don't find evidence of synergy, but, in fact, it may happen in the field for these things that no data was presented to the Patent Office? I don't know if that makes sense, but it's sort of like outside the Venn diagram circles in my mind. Okay.

MS. NESCI: So on your first one, I do have the citation, so I can get that to you and we can send you a highlighted link that shows where our conclusions are coming from, so we'll take care of that.

On the second one, we are not intending to extend beyond the species for the -- that -- the species on which the data are based that we get in front of us for the GTA claims.

MS. ECHEVERRIA: Yeah, I would just add, we would not make the assumption that any interaction was conserved across taxa, that would not be an appropriate scientific assumption. And so we were really focusing on where we do have evidence that -- and what that evidence tells us and how that impacts the risk

assessment.

So to assume that greater interaction for plants would also come up with insects is not supported, understanding the mode of action and how these interactions work from the biology and the toxicology.

MS. SELVAGGIO: So you wouldn't ask for additional data, then, in order to fill in the gaps?

MS. ECHEVERRIA: Unless we had compelling evidence to make us concerned. So we do evaluate the open literature as part of our routine process, so if there's any information in the open literature or if there's anything that we know about the potential mechanism of interaction that's occurring that would lead us to have a concern, then we would have broad authority to request an additional study, but not as a routine matter.

So unless we have that evidence or we have the other scientific rationale to make that determination, we would not be doing it across the board.

MR. KEIGWIN: Okay. And Damon will be our last comment.

MR. REABE: Thanks. Question, is there going to be any modifications to the risk assessment process to account for the multiple passes that would be required if the product as a combined mixture doesn't meet risk

assessment, what the risk would be then from making, say, two or three applications to control the same pests when you separate out those products? Is the risk assessment methodology, is that going to get factored in then?

MS. NESCI: So, no, we aren't intending at this point to make any changes to our risk assessment methodology. We're instead adding the process that I've described to date on top of that to look at the patent data to see if there's any need to get additional data or to change our risk assessment conclusions.

MR. REABE: Would the EPA consider changing it because it might create additional risk by having to make these separate applications? Right? I mean, we can imagine how now that we have --

MS. NESCI: So I think I understand what you're getting at. So in terms of tank mixes, there are some benefits to tank mixes and related to the ecological impact of passes across the field and, of course, resistance development and those sorts of things.

So we are not -- I don't think there's any plan to quantitatively consider that, but certainly as part of the FIFRA evaluation process, we do consider risks and benefits, so --

MR. REABE: That might be -- because there may

be some unintended consequences that may come from this. Thank you.

MS. NESCI: Yeah. Thank you.

MR. KEIGWIN: Okay. Thank you for that. So we are now back on time. So let's reconvene at 3:15 and we'll -- I guess we'll pick up with glyphosate. So, thanks.

(Whereupon, there was a recess in the proceedings.)

MR. KEIGWIN: Okay, so we're going to pick up where we left off from this morning, and so I believe we were -- so Yu-Ting is back, and she has reinforcements. So I guess we'll first address glyphosate. Thank you. So, there's a one-page update in your folders regarding where we are the glyphosate re-evaluation.

Oh, sorry, but before we get to glyphosate, so we just got a notice from our building management that there are some cars illegally parked in the spaces reserved for hybrid cars that need charging. So if you inadvertently parked your car in a charging station spot, your car is about to be towed.

All right, Yu-Ting is pulling it up. They usually provide us license plate numbers. You know, if you drag it out. All right, so the first one looks like a black Honda with a Maryland tag 9DJJ22. No, but it's

parked -- it's actually not only that, it's actually parked in an illegal spot. So how do I advance it? Oh, right here?

Yeah, but it's parked illegally, too. Virginia tags -- it's not plugged in -- BMW, ZTZ8207. Apparently that's an OPP car, never mind. Oh, and then there's another BMW, a black BMW with no front tag. So that's probably a Virginia car. All right, well, good luck. I can't stall you out anymore.

So any questions on the glyphosate update that we provided in the folders? Jay?

MR. VROOM: So I just wanted to observe that of the three categories of active ingredients that were listed under 5C, this one probably is the one that has the most global reach. The other two are more confined to U.S. regulatory focus, and we are supportive and complimentary of the agency's work in this space, both domestically and internationally, and I think that the work that you began in 2009 with regard to the re-evaluation of the product is moving forward and we look forward to the next risk assessment.

MR. KEIGWIN: Other questions/comments on glyphosate?

(No response.)

MR. KEIGWIN: So the next one we have is the

neonicotinoids and the status update there.

(No response.)

MR. KEIGWIN: No comment? Cynthia?

MS. PALMER: Is there something missing where it says -- the bullet right in the middle, "Potential on-field risk from some use patterns, includes foliar uses," it doesn't say if it's low or high, I assume that's a high. I'm using the website version. Is there -- the sentence is just dropped off.

MR. ANDERSON: I'm Neil Anderson from the Pesticide Re-evaluation Division. And no, there isn't missing words there. That's simply how we meant to present it.

MS. PALMER: Okay. And then for later on it mentions "draft benefits assessments." Is -- can we look forward to the benefit assessment for treated corn seeds? Is that part of it?

MR. ANDERSON: Those -- that will not be one of the assessments that's being -- benefits assessments that's being released for public review here in the very near future. It's possible that some benefits work on corn and perhaps the treated seed element for corn will be done at some time in the future, as we move closer to the planned activity in mid-2018, when we expect to release the proposed interim decision. So there will

probably be a fair amount of benefits documents at that time.

MR. KEIGWIN: Okay. If there's nothing else on the neonics? Thanks, Neil and Dana and Eugene.

The next one we have in your package is an update on where we are with acute animal testing alternatives. Dr. Anna Lowit is here if there are questions on that effort. And I thought I saw Garland [phonetic] around at one point, too.

Sorry, Pat.

MS. BISHOP: I have two things. I have a comment that this is some really great work that's going on that OPP as well as NICEATM exam, you know, I think you're making some really excellent progress here on this issue. And my only question, and I think I forgot to ask you yesterday, Anna, is the fact that the final dermal tox waiver came out. There was also a draft, I think, about a year or a year and a half ago. Have you received any requests for waivers on this yet?

DR. LOWIT: So, yes, that document did go final just November of last year, so it is final, and we have received a relatively small number. You have to remember, there's a lag time that's sort of built in here, and generally companies will have done the studies that they would submit to us one, two, three, even four

years in advance of them submitting to us.

So there's a time by which the policy will have been finalized, and companies will already have in existence their in vivo studies. So although the number that we're seeing is relatively small, over the next year to two years it should incrementally start to increase.

MR. KEIGWIN: Okay. Anyone else for that one?

(No response.)

MR. KEIGWIN: Okay, thanks. So the next one we have is resistance management. Wynne -- so Wynne Miller and Bill Chism and Nikal Mallampalli and maybe Skee Jones, too, are coming up. So we just finalized two pesticide registration notices after taking public comment. And the paper outlines our path forward for implementing those two notices. Comments? Questions?

Cynthia.

MS. PALMER: Thank you. I just had two questions. One, I may show my ignorance, it says no new herbicide mechanism of action has been developed in the last 30 years. I'm curious why not.

And, second, in the very last line of the memo, it says that herbicide products labeled for use by the general consumer, such as residential products, are not included in this development of herbicide resistance

measures for end-use products. So I'm wondering why are the consumer uses not part of that.

MR. CHISM: Thank you. I'm Bill Chism from the Biological and Economic Analysis Division. We presented the PRN before, we've gotten some really great feedback from some of the groups here, and I wanted to thank everybody.

The first question, why no new mode of action in the last 30 years, I'm totally not competent to answer that. Finding and discovering a new mode of action is kind of an art, kind of luck, kind of a whole bunch of mergers and different things, and if it doesn't happen, it just doesn't happen. So I think possibly the registrants could help you with that. I don't know.

But your second question is why didn't we include homeowner products. When we look at -- and there's a really nice website that looks at all the herbicide-resistant weeds worldwide -- when we look at use sites, homeowner sites don't come up very often, and we thought the things we were asking were pretty technical, would be very difficult, and we thought the risk of resistance was very low.

MR. KEIGWIN: Okay, Andrew.

MR. THOSTENSON: I notice most of the work that's been done more recently in the herbicide arena.

Unfortunately this year in North Dakota and Minnesota we are suffering some very significant reverses in both fungicide and insecticide resistance. One of them will result in a dramatic increase in the amount of chlorpyrifos we use to control soybean aphids in our state because our conventional pyrethroids have demonstrated significant failure to control these soybean aphids.

So I'm wondering what sorts of plans you all have to really start grappling with that on the same level that you have been with the herbicides.

MS. MALLAMPALLI: My name is Mikal Mallampalli. I work with Bill in the same division. And the labeling PRN right now, the labeling PR notice addresses the insecticides. Then it -- our intention is to develop internal policy documents to help make sure that staff include that guidance in registration review and new registration actions.

We aren't at this time proposing to ask for the additional detail, product stewardship of the type that the herbicide PRN talks about at this point, but going forward, we might explore incorporating that into the insecticides and fungicides.

Now, as far as giving you other tools to -- of new modes of action to combat resistance that’s already

going on, I mean, that faces the same situation as herbicide modes of action as new discoveries go. We -- the registrants do that, so I don't know if that helps answer it.

MR. KEIGWIN: Okay, Jay.

MR. VROOM: Yeah, so, I would guess that maybe with respect to the kind of insecticide resistance that you're describing in a market like yours for soybeans there are other modes of action, newer chemistries that haven't been labeled for soybeans because it's a fairly unusual event for most or a lot of the soybean crop that needed insecticide treatments at all.

And, so, as you discover those kinds of challenges, if you're in communication with the industry, particularly those that have other modes of action registered for other crops, I'm sure they'll be a receptive audience to talk about those kinds of opportunities.

With respect to the fact that there's been nothing discovered and brought to market in terms of a clearly new mode of action, it's because all the easy-to-discover things have been discovered, but that doesn't mean that companies aren't continuing to invest in discovery research, looking for that next new broad-acre application mode of action. There have been

a few that have been discovered and brought in the '90s, all the way up through potential registration, and denied because of risk effects that were determined to be unacceptable based on the standard in the law.

And, lastly, there have been analogs of original modes of action that do change the performance and environmental and effectiveness benefits. So I think you need to look a little closer at some of the rediscoveries and slight changes in molecules that have been accomplished for things like I know metolachor went through a process like that and actually qualified for a new patent on a new analog of an original molecule.

So I think there is continuous innovation. It may not look like the blockbusters of the past, but continuous improvement is certainly a commitment for the members of CropLife, and I'm sure that we look forward to working with a lot of other stakeholders in that regard.

MR. KEIGWIN: Any other comments on the resistance management work? Charlotte.

MS. SANSON: Yeah, so, I know a lot of comments were submitted on this, and I guess one of the concerns that I have has to do with what you might call false reporting and how you're going to manage through that. For example, if, you know, a 682 is submitted

because of suspected resistance but then the testing is done to indicate, oh, it really actually is not resistant, how do you go back and correct the record, if that makes sense.

MR. CHISM: No, that's a great question. For the herbicide/pesticide registration notice, we ask for reporting of suspected resistance and also reporting of confirmed. And our intention is that -- excuse me -- in a couple instances, it took five years to confirm resistance. And, so, we would like to be able to get that information out to the user community that we're not sure yet, but we potentially have resistance here. And the intent is always to get the confirmation. But in some cases, it takes a number of years. And we look at that as a golden opportunity. That's when it's only a few acres impacted. We can maybe have a real chance to control these pests.

MR. KEIGWIN: All right. Thank you.

So the next update we had was dealing with some labeling issues. So Michelle Arling and Patricia Parrott are going to come up to answer any questions you have about web-distributed label or the SmartLabel efforts.

All right, so Preston, then Jim.

Charlotte, I don't know if you're up for this

one. Is your tent up for...okay. So Preston, then Jim.

MR. PECK: Thank you. So this project is also -- it's not only for registrants but also for applicators as well to access information regarding a label; is that correct? The Smart Label project?

MS. PARROTT: For the Smart Label project, ultimately it will be made available to the public as a, you know, structured data information. At this time, we're just finishing up the builder. We have the label information coming in in a structured format. The actual label as they're printed, all that flexibility will remain there.

Eventually, it will be made in a searchable database to the public. That's going to be a little while down the road. I think preliminarily the early adopters were -- didn't want the information made public until everyone was there, thinking that it would give some kind of advantage or disadvantage to them, market-wise, to be able to search their labels to find (inaudible) or something. So to make it an even playing field eventually it will be level.

But, ultimately, it could supplement what -- for the applicators and things what is envisioned with the web-distributed labeling where you would go for specific application on a crop and get that information,

but for now, web-distributed labeling will do that.

MR. PECK: Okay. Is there -- a followup question. Is there anything being done to proactively think about various languages, access from various languages?

MS. PARROTT: At this time, we have -- we have it in English, and then we do have our sections that we have our Spanish labeling pilot that has been going on for certain phrases that are in Spanish as far -- that's as far as we've gotten right now.

MR. PECK: Okay. Well, I just -- upon reading it, but just at first glance, I don't know too much about it. It looks like a fantastic opportunity to address that issue that I know is of great concern of many people that not only work with Spanish-speaking but indigenous-speaking communities, Haitian-Creole as well, just seems like if that's the future, then that's a great opportunity to do it right.

MS. PARROTT: Good point. Thank you.

MR. KEIGWIN: Okay, Jim, then Cynthia.

MR. FREDERICKS: Thanks, and I just first of all just want to commend the agency on their efforts to try to make labels more clear, simpler, modernize labels, because from an applicator's point of view, labels can be a real bear sometimes. And ensuring that

folks are reading the label and following the label is critical. And, so, you know, we appreciate that and we obviously believe that, you know, smart labeling and web-distributed labeling can -- you know, is a means to that end. And we look forward to it.

One of the things that stood out in the note was that I guess the PRNs from 2014 and as of October of this year, there's still no -- there's no approved product labels for web-distributed labeling. So my question is is that because of a lack of applicants or applications for that, or is that due to some sort of, you know, a hangup in the system.

MS. ARLING: Thanks, Jim. I'm Michelle Arling from the Office of Pesticide Programs, and I worked on the web-distributed labeling, basically since its inception. We've had a lot of conversations with registrants that have expressed an interest in web-distributed labeling, but for various reasons, no one has jumped at the gun to rush in to be the first applicant.

So I think part of it is waiting for smart labeling to get fully implemented so that registrants do have those structured, searchable databases that then they could use to develop web-distributed labeling and make it available to users. And then there's the

hesitance to be the first one to try anything new. So it's not a lack of EPA's approving applications. We just haven't gotten any in.

MR. FREDERICKS: For the record, I wasn't accusing you of that.

MS. ARLING: No, no, that's okay.

MR. FREDERICKS: I was -- I was really just curious.

MS. ARLING: Yes.

MR. KEIGWIN: Okay, Cynthia, then Aaron, then Charlotte.

MS. PALMER: So I'm pleased that one of the expected benefits would be quicker implementation of public health and environmental protective measures, and that makes me think about incident reporting. And I'm just wondering whether if this new electronic system might be combined with the electronic portal and database on incident reporting and the great work started by Rich Dumas and Melissa Panger.

MS. PARROTT: The way that this is being smart labeled and ultimately web-distributed labeling is the first step in a fully integrated digital system for the agency. So the SmartLabel and the e-CSF -- electronic composition statement of formulation -- are going to be launched through the portal, needless to say at the same

time, sometime in 2018. And the back-end database is being built to accommodate both of those in the hopes to integrate all of our reporting systems. And I think the vision right now is to use the CDX portal as the way to get information exchange into the agency from registrants and others. So ultimately I think that is the vision.

MR. KEIGWIN: Okay, Aaron, then Charlotte.

MR. HOBBS: Great. Thank you. So, first, I know a lot of good work has gone into the SmartLabel pilot, work by the agency, as well as work by members of the registrant community. And while that work has been diligent, I am aware that there's a lot of work that remains for that to really be show-ready, and that as I understand it that program is far from complete. And with it being far from complete, that probably puts a little damper on the ability to do web-distributed labeling.

So could you speak a little bit to -- a little more details about how we get from a very well executed pilot and then bridge that with what can be a significant gap between a successful pilot and a ready-to-use program.

MS. PARROTT: So right now we are finishing up -- or we got the contract and we're finishing up with

the input that we got from the third phase of the pilot. We are going to engage our pilot participants one more time before we roll out the builder. All of the information so far has been made publicly available through the website. We also have a mailbox for comments. So we will still anticipate having it out for voluntary use in the next year.

There will be a learning curve, and I think some people -- you know, those that have been participating and asking questions along have an idea of what it will look like. We have built out the builder to greater extent than originally I think we thought we were. It has taken some extra time, but I think that the effort that's gone into it has been well worth it to give a product that we'll be pleased with.

Now, as far as, like, the full implementation and vision, yes, it's going to be a work in progress, and this will be a first phase to getting it perfected, but we do hope to have it launched for voluntary use in the next year. Does that answer your question?

MR. KEIGWIN: Charlotte.

MS. SANSON: So following up on the SmartLabel pilot, and then just a suggestion that perhaps looking at a pilot that would -- that would -- that would focus on the different types of labels, like, you know,

conventionals verus antimicrobials and, you know, biological consumer labels, because all those type of labels are fairly different from one another. So maybe segregating the pilot in those areas, and maybe you can speak to that if you've already considered that. I have other questions, too, but I'll let you answer that one first.

MS. PARROTT: Yes, we did. So when we initiated it in the summer of 2014, we solicited partners from the different registrants to represent kind of a cross-section of the industry, so conventionals for ag products, also lawn and garden, microbial and biochemical in the agriculture and in the mosquito and larvicide products, antimicrobial pesticides for hospital disinfectants, wood preservatives, and pool products. And so all those are represented.

MS. SANSON: Do we look at a separate pilot for each of those types or --

MS. PARROTT: No, we're doing it together, so the idea was that we would have one -- one builder and one set of requirements, but then you could go to the areas that pertain to your specific products, and you could hide the rest. So rather than have separate areas for separate registrants, have it all in one place.

MS. SANSON: Okay. And I'd like to respond to the question on implementation with the web-distributed labeling. And I think maybe there are still some implementation concerns with that, and I think we'd like to know the status of where the states are in terms of acceptance of web-distributed labeling because I've heard enforcement -- concerns with enforcement and having one -- you know, be easier if there was one website for the states to go to rather than, you know, several individual ones. So I'm -- if Liza or, I don't know who can answer that, but it would be helpful to know.

MR. KEIGWIN: Liza, if you've got an answer.

MS. TROSSBACH: Sure, sure. State lead agencies have been aware of this effort, you know, since the getgo. And some of our concerns from the very beginning, one was the availability of the information to users, so our concern was that while I think we all certainly support the availability of information via the website, we were concerned that it still needed to be provided to the user on the container. You know, there are many areas where there's not ready access to the internet or to something like that. So that was one concern or one thing that we wanted addressed.

Another was with web-distributed labeling and

having certain versions that would be good for a certain period of time and with that back-door access for state lead agencies if there were enforcement situations, if we had to do an inspection or investigation to be able to determine what label was enforced or, you know, in place at that particular time. So that was another.

I think that states certainly support this idea of making labels more easy to read. I mean, some of your labels are huge, and there is some -- I think there is some validity in an applicator only having to read what they need to read, so if you're applying to -- I'll just use corn as an example, you get the information for corn. But from a state lead agency perspective, are you getting all the information including corn versus just corn. So are you still getting all the use directions, you're still getting all of the environmental hazards and those types of things.

So I think states will -- are willing to accept web-distributed labeling, as long as that information is available to any user, whether it's on the container or via the web, as long as it's available to them.

MS. ARLING: And just from EPA's perspective, we have engaged the states throughout the process, and we do plan to work really closely with states once we do

get applications in to make sure that everyone's comfortable with the way that we're proposing to issue a web-distributed labeling.

MS. SANSON: Okay, great. I appreciate all the feedback. And then just one more, and that has to do with supplemental labels and if you can clarify the process for supplemental labels via web-distributed labeling if you've thought about that.

MS. ARLING: So I think right now they're separate processes, and because web-distributed labeling is right now a fully voluntary process, they'll stay separate. The hope is that we can move away from supplemental labels and have updated labeling provided via web updates that are linked to the container of the product.

MR. KEIGWIN: Anything else on the labeling efforts?

(No response.)

MR. KEIGWIN: Okay. Thanks.

And then there was cannabis. Nicole Zinn. You don't want in on that one, Aaron?

Nina does.

MS. WILSON: I have a question for a friend of mine.

(Laughter.)

MS. WILSON: Actually since you know that biological products are often exempt, but not always, from tolerances, and I understand the distinction between a 25(b) and it's 24(c) for an exempt product, but I'd be interested in a little bit of that discussion about how that -- those statements came about.

MS. ZINN: So EPA does not register 25(b) products, so 25(b) products are not prohibited from having -- we don't evaluate them, we don't register them -- so they're not prohibited from having cannabis on the label or being used for cannabis. However, we do register products that are tolerance-exempt in the Biological and Pesticide Pollution Prevention Division or other divisions, and so that is where, you know, it will become a federal action to register that product and approve it. And because cannabis is a federally illegal crop, that is where we start to have some difficulty.

MR. KEIGWIN: Okay.

MS. PALMER: So maybe this is the obvious question, but since no one else is asking it, so since EPA disapproves of the special local needs registration, so where does this leave cannabis production? Does it all go organic, or do they now use the product illegally? Or I'm not sure where this leads us.

MS. ZINN: Okay, so there -- the states have legalized cannabis within their states. And there are a variety of things that are being done within the states. First of all, 25(b)s, as I mentioned, are not prohibited. So I think some growers are using 25(b) products. We are aware that some states have developed lists of products that are not -- they do not consider to be illegal to use. And each state has different criteria for those lists, and they would be on like a state website.

We know that some of these lists exist, but we have not reviewed those lists. And I think those are the two primary ways that people are using pesticides. And then I think you're probably right, there are other cases where growers are probably using things that are not legal.

MR. KEIGWIN: All right, Preston.

MR. PECK: You kind of touched on my question, and I just want clarity. So if someone were to use a product on, like, starting industrial hemp projects in North Carolina and they use a product that isn't 25(b), would that be an off-label use of that product?

MS. ZINN: In most cases, yes.

MR. PECK: And, so, therefore, would the state lead agency have to step in or would that be EPA? I'm

trying to wrap my head around this --

MS. ZINN: I'm sorry, I'm trying to understand what you're asking.

MR. PECK: So I'm asking if someone were to use a product in an industrial hemp operation or somehow this product that's not for cannabis was to be used, that would be an off-label use, and would the state department of ag, or in North Carolina's case, the North Carolina State Department of Agriculture, step in and say you've committed a label violation?

MS. ZINN: Yes. Usually yes.

MR. KEIGWIN: So the states have primacy for use violations.

MS. ZINN: Yes.

MR. PECK: Right, so that would be the state, okay.

MS. ZINN: Yes.

MR. PECK: Thank you.

MR. KEIGWIN: Anyone else?

(No response.)

MR. KEIGWIN: Do you want to run before...

That's the easiest Nicole has ever had to do on this topic. So, all right, thanks.

Okay, so, our last topic for the day is an update on PRIA. So Steve Schaible, who is our newly

appointed PRIA coordinator for the Office of Pesticide Programs will come up and give us an update.

MR. SCHAIBLE: Good afternoon, everyone. So I'm going to talk a little about PRIA, and currently we are under PRIA 3 still. The PRIA 3 expiration date was September 30th, but the continuing resolution extended it through December 8th. And, so, we'll talk about sort of PRIA as it currently exists, as well as the effort to reauthorize PRIA that is ongoing. And then after that I'll just be talking about some of the metrics, performance metrics for the last fiscal year for PRIA.

Okay, so PRIA 4 is the reauthorization legislation that is currently gone through Congress. As I said before, PRIA 3 had an expiration date of September; that passed. It was extended by the continuing resolution. So as far as PRIA 4 goes, the bill that was -- the EPA assisted in the development of with the PRIA coalition was for a seven-year reauthorization, and that version was passed by the House of Representatives by unanimous consent back in March.

It then went on to the Senate, and the Senate amended that bill to be a three-year extension of the PRIA authority. And that passed out of committee in June. That bill is awaiting vote by the full Senate at

this point in time.

If that bill was passed by the Senate, that amended bill would need to go back to the House to reconcile the differences between those two bills. And at that point in time it would proceed to the President for signature.

So we can talk about, then, what are the provisions of that bill. I just want to go through quickly on this because I want to spend more time focusing on PRIA 3 and our accomplishments. But very quickly, if that bill were to go through and be passed into law, there are -- the maintenance fee authority would be extended, and there are some wrinkles to that. Currently, it's at $27.8 million per year for collections for maintenance fees. The proposal is to raise that to $31 million per year.

Likewise, currently EPA is not able to average across years, so if we undercollect or overcollect within a given year, we can't offset that in the years advancing. You just sort of take what you got that year. We have a formula where we attempt to estimate what the fee for registrants should be, and it's taking into account, you know, the number of products that are currently registered, you know, how many small business waivers we anticipate might be submitted, and sometimes

that formula doesn't end up with the outcomes that we project.

So PRIA 4 would allow averaging across years to account for that over or undercollection within the authorization period. Likewise, PRIA 4 has some language which eliminates a longstanding provision from FIFRA that requires for every maintenance dollar which is spent, an appropriated dollar must first be spent. And over time under PRIA 3, we've seen our appropriated dollars get smaller and smaller, and that has had an impact on our ability to spend maintenance fee dollars. And, so, there’s a provision in PRIA 4 which removes that constraint.

Continuing with maintenance fees, in PRIA 3, currently there is an IT set-aside that allows for activities -- specified activities for EPA to use maintenance fee dollars towards. I think one of the big ones is developing a tracking system where applicants can be looking at their applications as they move through the agency, but there’s others as well.

There’s endangered species database development; there’s conditional registration; the ability to look at sort of how EPA is receiving and reviewing data that were required under conditional registration.

That IT set-aside is going to be replaced with a new set-aside, at $500,000 per year. And, so, again, there's a seven-year version and a three-year version. And, so, depending on what version you end up with, that protects your overall dollars that are collected and put towards that.

But that set-aside is developed and finalized rulemaking and guidance for product performance data requirements for certain invertebrate pests of significant public importance. So these are public health pests. And, likewise, it establishes a mandatory schedule for the EPA to develop the guidance and then the rulemaking on that guidance as needed for those pests.

It also creates a separate set-aside of $500,000 per year for good laboratory practices inspections. And these funds would be collected under PRIA and would be then shared with our Office of Enforcement and Compliance Assurance, hire additional inspectors -- inspectors to conduct those inspections.

Okay, and now I'm going to move on to the PRIA registration service piece side of PRIA 4. PRIA 4 extends the existing set-asides for worker protection, partnership grants, and pesticide safety education programs and further emphasizes that those activities

shall focus on fieldworker populations in the United States. It also directs EPA to look for opportunities to streamline review processes for new chemicals and new use applications and to provide feedback to applicants during that process.

And, so, this is overall when new uses and new chemicals, in particular, tend to -- our decisions tend to occur in time frames that are longer than the mandated time frames under PRIA. And there's a lot of reasons for that, and we will be looking at ways in which we can expedite our review for those types of applications.

As with PRIA 3, PRIA 4 has reporting requirements and it extends the existing requirements and expands upon them. So reg review reporting requirements currently have a lot more to do with your preliminary work plans and sort of the beginning stages of reg review. PRIA 4 has language that starts reporting out on some of the later stages of reg review and what is our performance for those cases further down the road.

It talks about we have to report on meeting mandatory schedules and developing those efficacy guidelines I spoke of earlier. There's time frames that are specified, and those time frames differ between the

two different versions, but EPA is to complete those activities in certain time frames, and we'll be reporting out on that and our progress in doing that.

The progress and the review and approval of the new pesticides to control vector-borne public health use -- to control the pests that vector public health diseases in the United States. And this includes territories and military bases globally.

There's another requirement for, again, the number of GLP inspections which are conducted. There is a new category for design for the environment amendments to labels, and we will be reporting out on how many of those we approve, and then the existing requirement for worker protection partnership grants and pesticide safety education, how those funds are being used.

But additionally to that, there's also language on reporting out on the effectiveness of those activities and EPA's engagement with stakeholders around those activities.

Okay, so, PRIA 3 has currently 189 fee categories. There was an effort going into PRIA 4 to look at where we could consolidate categories, eliminate categories, and then, of course, we also added categories because that's what usually happens. So we went from 189 up to 212, and I just want to hit on some

of the highlights around these.

In general, there is an effort to better align fees and time frames with increasing increments of activities received and work done. And, so, for the inert ingredients, we lowered time frames, raised time frames, increased and decreased fees. The inert ingredient categories were new to PRIA 3. I think having five years under our belt we have a much better understanding of what are the time frames and resources that go into those types of reviews. And I think that the proposed changes to those fees and time frames reflect that, that knowledge that we've gained.

For the efficacy data and public health efficacy data and review, these are disinfectants, these are antimicrobials where there's organisms involved. These are public health pests and bio-pesticide in the conventional realm. We've created new categories where if you're asking for additional organisms and additional target public health pests that there are differing categories. Increase in categories are incremental increases in categories and/or fees as your number of pests or organisms get higher.

There was a desire expressed for a category to provide incentive for U.S. harmonization of existing tolerances with international MRLs, CODEX MRLs. And,

so, amended an existing category, the R292 category, to allow for a one-time -- you know, any tolerances -- U.S. tolerances that existed that were not in align with MRLs, you can come in under that category and harmonize all of your tolerances for your chemical.

There was an OIG audit of the conventional reduced risk program a while ago and found that there needed to be additional incentive provided for participation in that program. And one of the recommendations from our OIG was to provide a fee differential in addition to the time frame differential for reduced risk actions. And, so, the new -- the pending legislation provides an incentive by increasing the fee amounts for new chemical and new use categories where there's an analogous reduced risk category. And that would be a 20 percent increase.

There are new categories to better align antimicrobial categories to be consistent with the Part 158W revisions that happened a few years ago, and in that realm, there are much fewer categories under PRIA 4 than there were under PRIA 3. There was consolidation there. There's new PIP categories being added, and PIP is a plant-incorporated pesticide, I believe. So there's new PIP categories.

On the inert front, there were no categories

for safeners, and safeners are inert ingredients, but the data set required for safeners resembles much more so a new active ingredient. And we were finding that we were not able to complete those applications in near the time frame specified under the existing categories, nor were we getting money that any -- in any way aligned with the work that we were putting into this. There's a whole slew of safener categories that are being proposed.

And, then, finally, in Table 19, which is the miscellaneous table, there are a number of new proposed categories requested by stakeholders. One is for non-FIFRA determinations. These are device determinations, treated article exemptions, minimum risk determinations. These are activities that currently exist outside of PRIA but for which I don't -- my understanding there isn't a set time frame. And I think there was a desire that for a fee there could be a time frame for that type of product being produced by the EPA.

Again, I mentioned before, there's design for the environment amendments where for a pesticide product you can amend your label for the design -- for the environments for pesticide product logo. And, finally, this last one, there's a conditional ruling on

pre-application substantial similarity findings. And, so, right now, if you have a new product that you're claiming to be me-too or substantially similar to another product, you submit your application, it goes to the similarity clinic, at the front end of the process, as part of our preliminary technical screen review, and if it's found to not be substantially similar, you get another bite at that apple. And if you don't come up with another product, then it gets kicked out under the screen.

And, so, I think in the registrant community, there was a desire of some to be able to know up-front whether or not the agency was inclined to think that there was a favorable argument to be made around similarity. That gives you greater certain when you submit the application itself of a time frame for an EPA decision.

In terms of fees collected in Fiscal Year '17, on the PRIA side, we collected $18.265 million. This is higher than we have in the previous few years. And on the maintenance fee side, we collected $27.99 million, and so $27.8 is our target, that's what we were shooting for. So as you can see, sometimes you collect slightly over and under, and, again, there's not a way that we can know until we actually receive all the small

business waivers, weigh in on them, and receive the fees.

Okay, moving on to some of the summary statistics. So I apologize if these are a little small, but so light blue bars are for the number of submitted primary applications, so this is what came in in the last fiscal year. The yellow bars are the number of completed decisions. And these would be primary and secondary decisions. And, so, primary/secondary, just to quickly summarize that, you can submit an application, for instance, for a new chemical or a new use, and there might be a technical product, there might be multiple amendments to end-use products, there might be new products.

As long as they're related to each other and share data, they're -- the primary is -- one of them is assigned the primary decision, and the others are the tag-alongs or the secondary. And, so, if you're looking at more accurately what are the number of packages that we receive for a certain request in the use of a new chemical, new product, or otherwise, primary decisions are a more accurate way to count that.

And then, finally, the dark blue bar is the number of completed decisions that involved a negotiated due date for the decision. And, so, starting with the

antimicrobials division, we received 300 primary applications in the past year. We completed 338 decisions; 282 of those were the primary decisions; and there were 26 of those 338 decisions that involved a negotiation of the due date.

For biopesticides, there were 148 decisions received; 163 primary/secondary were completed; 145 of those were primary decisions; and 22 of those 163 involved a negotiation of the due date -- one or more negotiations, actually.

For conventionals, there were 880 decisions received; 937 decisions were completed, of which 746 were primary decisions; and 197 of those 937 were negotiated.

For inerts, 55 were received; 42 were completed; and those 42 were all primary decisions; and 16 of the 42 involved a negotiation. And just going back to PRIA 4 and adjusting the time frames, I think this is an example of how under PRIA 3 we set some time frames and in some cases they didn't end up being the right amount of time for the work that we were doing.

Finally, for the miscellaneous categories, and the bulk of these are going to be gold seal letter requests, there were 562 miscellaneous applications received; 544 were completed; and those 544 were all

primary decisions as well, there were no secondary decisions; and there were no negotiations of the due date for any of those miscellaneous categories.

In addition to gold seals, those can also include actions that had to go to HSRB or SAP, new product applications that span the regulatory divisions that had a BPPD element and an RD element. Extension of exclusive use requests were also included in the miscellaneous category.

Okay, this next slide speaks about -- it's sort of the different way of presenting information from the previous slide about a negotiated due date. And it gives you a historical perspective. So you can see back -- and it goes back to 2010, and at that point, for antimicrobials we had 35 percent of our completions involved negotiations. For biopesticides, it was 62 percent. For conventionals, it was 26 percent.

And as you go down through here, this year, you can see we have done exceptionally well on all of our divisions. For antimicrobials, there were 26 of the 338 that involved a negotiation. That's 7.7 percent of the completions. For biopesticides, the number was 13.5 percent. For conventionals, it was 21 percent; miscellaneous, again, had no negotiations. And for inert, it was 38.1 percent. So this was in terms of

performance around a negotiated due dates, this was a good year for OPP staff in terms of completing these actions.

The next slide has to do with late completions or inversely on-time completion rate. For antimicrobials, there was one late completion of all of their actions this last year. For biopesticides, there were two late completions. Conventionals had 12; inerts had two; and there was one late completion on the miscellaneous front. So the range there, I think, were all, you know, above 95 percent, and most of them were at 99 percent or above. So, again, this was a good year compared to our previous years. And I think the last two or three years we've been showing improvement. So this is a good news story for the staff at OPP as well.

In the PRIA quarterly stakeholder meetings, a couple of years ago, the request was made to start reporting out on some activities that are non-PRIA but are also of great importance to the community that's submitting applications. And, so, I want to talk a little bit about the non-PRIA fast-track amendments and notifications. For the office, OPP completed 2,302 fast-track amendments this last year. At fiscal year's end, there were 1,048 amendments pending. And 521 of those were in backlog status, and for fast-tracks,

that's greater than 90 days.

For notifications, OPP completed 2,787 notifications in FY17. At the year's end, there were 622 notifications pending, and 463 of those were in backlog status, which is greater than 30 days for notifications.

Okay, this next slide has to do with our effort to transition to receiving applications electronically. So a while back, we just received things in paper, and then we moved to the point where we were getting things on CD or DVD. And then in 2015, the pesticide submission portal was put out there and made live, and there's been -- there was an update to that, a Phase 2 of the portal that expanded the capability, and then there's going to be a Phase 3 as well. I think some elements in it are already live. It's in stages right now.

But I just wanted to talk about sort of the number of submissions we received and what the breakout of those submissions is, paper or CD versus portal. And I think I -- for time's sake, I don't think I'll go through individually. I'll just go through the total, but we received over 12,000 total submissions for the year. 6,500 of those were in paper. 115 of those were on CD or DVD. And 5,705 of those were through the

portal. And, so, the percentages are 53 percent, 1 percent, and 46 percent.

If you look within the divisions, I think you can see that, you know, antimicrobial applicants are leading the way in terms of submitting electronically and through the portal, but I think everybody is showing progress when we look at sort of the -- when the portal first went live and how the progress we've been making, there has been incremental progress over time, definitely moving away from the CDs and DVDs and moving towards the portal, and the paper submissions have been going down as well.

In September, the ability to submit gold seal letters through the portal was implemented, and I think that given the number of gold seals that we get, I think that will -- the next time we report out on this, I think there will be a significant change in these numbers reflecting that the gold seals are coming in through the portal -- or can come in through the portal now. And we encourage you as the registrant community to be submitting those through the portal as well.

As I mentioned earlier in this slide, there is a set-aside under PRIA 3 for worker protection activities, and I just wanted to give a quick summary for FY17 and 18 how those grants were awarded. So for

the first grant for worker protection activities is to the Association of Farmworker Opportunity, or AFOP. That's the national farmworker training program, and it's a cooperative agreement for $500,000.

AFOP is responsible for developing and administering a pesticide safety training program to support the national network of pesticide safety trainers, providing pesticide worker safety training to migrant and seasonal farmworkers and to their families.

And the second grant under the general worker protection is to the Pesticide Educational Resources Collaborative, or PERC. And this is through UC-Davis and the Oregon State Cooperative Agreement. That's, again, for $500,000. This cooperative agreement will develop or coordinate the development of pesticide educational material. An advisory board and EPA will help in setting national priorities.

The PERC will use subject matter experts and production professionals. And it focuses on WPS materials -- or will focus on WPS materials in its first year because of the urgent need for training materials with the newly updated regulation. PERC will focus on the certification and training materials in its second year in response to the anticipated changes in categories and needs nationwide.

And the next slide talks about some of the current projects for which that grant money is being applied. And I think for the sake of time I won't go through them individually.

Okay, there is also a $500,000 set-aside of PRIA Funds for pesticide safety education program activities, and that went to NPIC, the National Pesticide Information Center. This cooperative agreement facilitates informed decision-making about pesticides and supports the protection of human health and the environment by serving as a bilingual factual source of information for professionals and public audiences on public-related issues.

And, lastly, there is a pesticide education program set-aside that went to the eXtension Foundation. This was previously granted, but the grantee did not accept the award. And, so, there was a two-year lag time for that to be re-competed and a new grantee to be awarded. So this is $1,500,000 of money.

This establishes a pesticide safety education funds management program to help support state cooperative extension programs, conduct their certified pesticide applicator training activities. And, again, this is the current-year PRIA funds of $500,000 and then the two previous years of unexpended funds.

These are the PRIA points of contact within the Office of Pesticide Programs. So if you have any questions, do feel free to contact the divisional representative, and that's Andrew Bryceland in BPPD; Diane Isbell in AD; RD, Ashwasi Balan [phonetic] is serving in that capacity informally, so you can contact her or you can contact me as well. And at the office level, you're free to contact me.

That's it. Are there any questions around PRIA?

MR. KEIGWIN: Jay.

MR. VROOM: So early in the presentation you referred to the GLP program. Separate from this, there's reports that GLP is being moved out of OECA. Any reports on where it is? Is the truck lost coming across the river?

MR. KEIGWIN: So the GLP program currently remains in the Office of Enforcement and Compliance Assurance. In the last administration, there had been plans to transfer those functions to another office within the Office of Chemical Safety and Pollution Prevention. That move has been put on hold for now while we onboard the new team and they can make some choices on things like that. So for now, all the good laboratory practice program activities are continuing to

be run out of OECA.

MR. VROOM: Some years ago, we experienced a government shutdown, and PRIA fees got put into a purgatory account. I think it was $800,000. Is that money still in purgatory?

MR. SCHAIBLE: It is.

MR. VROOM: And it will require the appropriations committees to free it?

MR. KEIGWIN: We would need to check with our appropriations law attorneys to get you an answer to that one.

MR. VROOM: Thanks.

MR. KEIGWIN: Iris?

MS. FIGUEROA: Thank you. Just a quick question on the worker protection activities. If you could just give a little bit more detail on sort of the worker voice in that and to what extent workers will be involved, especially in the development of these materials that are listed.

MR. KEANEY: The program we have has an advisory board, and it's available for worker advocates to be participating in that and then guide the particular products that are developed over the course of the -- of the cooperative agreement.

MR. KEIGWIN: Andrew.

MR. THOSTENSON: Yeah, I would just add that they've created a number of rather high-quality materials that are already available, including a how-to-comply manual, a variety of different posters and websites, videos for training workers and handlers, how-to-train-the-trainer manual. They've been very productive, at least in the agriculture arena that I work in.

MR. KEANEY: The AFOP grant, as well, has produced new training flip charts with upgraded graphics and responding to comments we've gotten from folks that have been trained and the trainers as to the effectiveness of the graphics. So we've made adjustments -- or AFOP's made adjustments there and it's very, very -- a very graphically intense presentation, along with the scripting of the training.

MR. KEIGWIN: Any other questions? Jay.

MR. VROOM: So with PRIA only extended and not reauthorized, what does that do to the money flow to AFOP and PERC?

MR. KEANEY: It obviously presents a problem.

MR. VROOM: Thank you.

MR. KEIGWIN: Amy?

MS. LEIBMAN: I just want to encourage the EPA in terms of the cooperative agreements. I think that,

you know, PERC has done a lot of work, and they have tried to -- they have an advisory board, but there's still a feeling among the farmworker advocate community that involvement of workers in the testing of these products and how they're used and their effectiveness still needs some work, and how they, you know, use their funds to gather that information and evaluate it. We would like to see a stronger voice from EPA in the guidance that it gives to its grantees about the worker involvement.

MR. KEANEY: All the grants and cooperative agreements, not -- but there's a distinction between a straight-out grant and a cooperative agreement. And, so, there are -- there is interaction from EPA with the -- with the grantees, but obviously we aren't in a position to strongly dictate all that they will do. It's a cooperative agreement, as I said.

MS. LEIBMAN: I understand that, but you can design requests for proposals and how you design the cooperative agreement proposals to encourage that and score on that.

MR. KEIGWIN: Other comments, questions?

(No response.)

MR. KEIGWIN: Seeing no tent cards going up, thanks, Steve. Thanks, Kevin.

So we had one person sign up for public comment, so Cindy Smith from Gowan.

MS. SMITH: Thank you, Rick. And I just want to share, after listening to the comments this morning on chlorpyrifos I really feel compelled to share maybe the other opinion. So as strongly as I think people feel that the administrator made the wrong decision in denying the petition, I think there are a significant number of people who think the administrator made the right decision for the science side of it.

And, so, the frustration, I think, that many of you expressed today is the same frustration that many of us in the registrant and user community felt back in December of 2014 when the human health risk assessment was released and the epi-data, which have been available since 2007, but for legitimate reasons was rejected by EPA for use in the way that it was used in the 2014 human health risk assessment was suddenly being used.

And, so, I think it isn't a simple issue. It is a complex issue. And I would like to pose that it isn't just about chlorpyrifos. I think it’s really about epi-data and use of epi-data. And, so, I think to Nichelle’s question about what science needs to be looked at, I believe the answer is that it is -- what’s the appropriate use of these specific epi-data.

So not all epi-data is the same, right? Some of it is conducted for certain reasons, some for others. In some cases, the data are available and in some cases they aren't. In some cases, they're good exposure metrics. In other cases, there's not. There's epi-data that has been done with exposure to OPs that doesn't show these neurodevelopmental effects. So how do you weigh that in? So I think that's one question that probably deserves some legitimate continued conversation.

And then I think the second area is that once you determine that that epidemiology data may be appropriate for use, how do you integrate that with the animal and toxicity -- the animal and human toxicity data that exists for many of these chemicals. So I think it was said that, you know, chlorpyrifos has been used for over 30 years. Many OPs have been used for over 30 years. I would agree. I think, Amy, it was your statement that there's a lot of data that has been generated on these products.

And I would say that the available animal and human toxicological data supports that regulating under cholinesterase inhibition is protective. And, so, I think those to me are the two areas that really do warrant some further science review. What are the right

criteria to say that epidemiology data should be used, and once you determine it's usable, how do you integrate it with all that available animal toxicology data that is required to be generated under specific conditions that looks at those exposure metrics and other things that are important?

And I guess that the last thing I would say is, you know, I've been in the registrant community for over 20 years. I've dealt with EPA staff on the registration of products through I don't know how many administrations. And I've had products approved; I've had products denied. But I will say that every single staff person that I've dealt with has put first and foremost the protection of human health, and I think particularly the protection of infants and children, and I would say concern about workers.

So I'm troubled at the implication that that may not be what's driving their decisions because when I agree with their decisions and when I disagree with their decisions, I have always found them to be based in what they believe the data says is protective of humans and the environment.

MR. KEIGWIN: That concludes our day. So thank you all for the very productive discussions today. I think we made some good progress, and we really

appreciate your input. Just a reminder that tomorrow we are starting at 8:30, and I expect an even more lively and robust discussion on the two rules.

So have a good evening, and we'll see you tomorrow. Thanks.

(Whereupon, the committee meeting was adjourned.)

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