UNITED STATES

ENVIRONMENTAL PROTECTION AGENCY

PESTICIDE PROGRAM DIALOGUE

COMMITTEE MEETING

OCTOBER 31, 2018

Conference Center - Lobby Level

2777 Crystal Drive

One Potomac Yard South

Arlington, VA 22202

P R O C E E D I N G S

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MR. KEIGWIN: All right. Good morning. Welcome. I think everybody is through security. It took a little bit longer today. So sorry about that. Pleased to welcome you here for today's meeting of the Pesticides Program Dialogue Committee. We are fortunate to have Nancy Beck, the deputy assistant administrator for the Office of Chemical Safety and Pollution Prevention, here with us this morning to give us some initial opening remarks. So, Nancy?

MS. BECK: Great. Happy Halloween, everyone. I'm surprised there isn't more orange in the room. Thank you all for coming, and to our PPDC members, I really want to thank you again for your invaluable contribution and your time and effort that you've put into making this committee so helpful to us. I recognize your time is valuable so I want to be short today.

First of all, I want to thank Shannon Jewell, who is our new DFO who helped organize everything today. Thank you, Shannon. She'll be working with us in the years to come. And, of course, the remainder of the day,

you all know very well Rick Keigwin will be your sheriff shepherding you through the discussions.

As you know, the PPDC has been meeting for over 23 years now, which is quite impressive, and gaining new perspective and improving our discussions has always been important to us.

I think today for the first time we have some outside presentations. And maybe it's not the first time we have outside presentations, but it's the first time we've had to figure out can we put these presentations on our webpage? So that's a little bit of a new approach to have more speakers from the PPDC and outsiders presenting to the group. So I welcome your feedback on how that goes; if you find it useful; if you want to hear from more outside speakers; if you're interested only in getting updates from the EPA. We really -- our goal is to facilitate more and better dialogue.

And along the lines of changing perspective, we also recognize that sometimes changing the setting can help facilitate new dialogue and engage new stakeholders. So I've asked the program to think about shaking up the location of the PPDC in the next year to see if that's a

possibility. And I guess I wanted to also get your thoughts on, you know, should we partner with states or should we partner with other regions; should we consider having the meeting somewhere else throughout the U.S.?

So this past summer I think I went to three different regions and it was all agricultural-related, and it was incredibly useful for me to hear those perspectives and see what's going on throughout the country. So that's one thing we'll also be thinking about, and any thoughts and suggestions you have for who we can partner with; locations where we might reach our diverse stakeholders; where you might enjoy hearing from regional and state agricultural representatives, would be helpful to us. And if you have feedback, I would suggest you give it to Shannon or Rick. So thank you for that.

Looking at the agenda for today, there's an ambitious schedule. I don't want to steal too much of Steve Schaible's time. But I'm continually impressed with OPP's ability to meet their target goals. So in 2018 OPP completed 99.7 percent of over 2,000 -- I think it was 2,199 PRIA actions on time. And they improved -- they reviewed active ingredients on average 199 days

faster than previously. So there is a lot of excellent, hard and good work going on.

Also, recognizing that our 2022 registration deadline is quickly approaching, I'll point out that OPP also made great progress in this area and completed 113 draft risk assessments and 65 proposed and final interim decisions in 2018. So it's really quite impressive. You'll hear more details about that later today.

You'll also be hearing about another tool that we hope will make us even more efficient. And this is the much-awaited electronic pesticide label. This is a key element of the feature of our program and we're excited to share that update with you today.

So just touching a bit more on future programs because I think this is what today's agenda really focuses on. You'll hear about two more important topics, unmanned aerial vehicles for pesticide applications. So this is, I think, a burgeoning, important new topic that is really going to help us bring precision technology to our farmers and growers. And then tomorrow we'll be talking about biological products, which is an area we've seen significant uptick and we expect that to continue.

So I hope you'll stay through tomorrow morning where they'll be providing an overview of emerging technologies, including EPA's role in oversight within the national strategy for biotechnology, future products that we expect to see coming down the pipeline.

The knowledge base in the biotechnology area and OPP is incredibly strong. And if you stay tomorrow, you'll be able to hear from at least a strong portion of the team about the work that's underway and what our current thinking is. That seminar will be in the same room here, and it will be from, I think, 8:30 to 12:00. The public is also invited to attend, and I believe it will also be webcast.

So with that I just want to welcome everyone again. Thank you for your time. And I'll turn it over to Rick to walk us through the day's events. Thank you.

MR. KEIGWIN: Thanks, Nancy. And I, too, just want to thank all of you for joining us today. I know everyone's schedules are incredibly busy and that you can break away from all the other things on your plates to spend some time with us, share your perspectives; it's incredibly important to us. And perhaps more

importantly, it's incredibly vital to us in helping to move the program forward.

I wanted to walk you through a number of changes that we've had in the OPP senior leadership team since our last meeting of the PPDC. I'll kind of just start in the immediate office itself. Arnold Lane, who had been serving as the deputy office director for management, is on a developmental rotation to the Office of Chemical Safety and Pollution Prevention as the acting associate assistant administrator overseeing our Office of Program Management Operations for the entire AAship.

Wynne Miller, who I think will be joining us later today, has graciously agreed to step in on an acting basis to backfill Arnold while he's on his detail.

Neil Anderson, who many of you may know from the Pesticide Reevaluation Division, recently started a detail as the acting deputy director in our Anti-microbials Division.

Kevin Costello, who many of you may also know from the Pesticide Reevaluation Division, is now on a developmental assignment as the acting deputy director of our Biological and Economic Analysis Division.

Frank Ellis is on a developmental assignment as the acting deputy director of our Biopesticides and Pollution Prevention Division.

And there's more. Brian Anderson is now permanent as the associate director of the Environmental Fate and Effects Division.

Jeff Herndon and Patty Parrott are now permanent as the deputy and associate directors, respectively, in our Field and External Affairs Division.

Jeff Dawson, who many of you may know, had been the deputy director in our Health Effects Division, is on a developmental assignment to the Office of Pollution Prevention and Toxics as the acting director of the Risk Assessment Division, helping them with standing up the Lautenberg Act.

And so Alyssa Reeves has moved into his position on a temporary basis, and then Don Wilbur has come into help Dana as the acting associate division director in the Health Effects Division.

And I think our last one is Donna Davis is now permanent as the associate director of the Registration Division. So a lot of movement in a relatively short

period of time. But we think it helps us to have movement around the office and gives people some opportunities to see the program from a different perspective, but also to bring in the learning and the experiences that they've had in one part of the program to benefit another.

Nancy also mentioned that Shannon Jewell is now serving as our designated federal official for this meeting. This is her first meeting as the DFO. But she'll be our right-hand person. And Dea is here, so we'll save some remarks about Dea for the end of the day, even though she told me I didn't have to do that. But Dea has been invaluable to the program in this role and many roles for the agency over a number of years. But thank you to Dea, and thank you again to Shannon for everything that she's done to help get ready for this meeting.

I wanted to acknowledge that we've had a departure from our committee. Nichelle Harriot, who had been with Beyond Pesticides, has changed jobs at the end of September. And so she has stepped down from the committee. So we are a bit smaller of a group this time

than we were in the spring. We have -- we do, however, remain in balance, which enables us to continue to move forward under our current charter.

There are a couple of people, and some of you have a little bit more room around the table today, who weren't able to join us in person. Lori Ann Burd and Gina Schultz and Leyla are joining us, I believe, via phone. And then Tim Tucker informed us late yesterday/early today that he was not going to be able to join us today.

Today our PPDC meeting is going to be one day today. That's in part in response to some feedback that we had when we were soliciting topics and what we heard from the last meeting. So as Nancy mentioned, tomorrow, while it's not a PPDC meeting, we do invite all of the members of the PPDC as well as the public to come back tomorrow morning for a seminar on OPP's Biotechnology Program.

A couple other logistical things. You will see in your packets one-page summaries of topics that we're not going to be covering today. But we did -- some of you had asked for updates on a couple of chemical or

rule-making activities. And so that information is in your packets for your information.

So I think Nancy pretty much walked through our agenda today. So I won't do that again. But I would note that some of the topics that are on the agenda are there in part because we envision in the future we will be coming to the PPDC for input, and so we thought it was important to use this opportunity while you were here to provide some background information to help inform future discussions within the PPDC.

All right. So now on to some housekeeping. Hopefully you all have signed in at the registration desk outside here in the lobby. If you have not been able to do so, please do so at the break so that we have that. Tent cards, if you have a question or a comment, please put them up. We have the same audio system as we've had in the past. So if the red light is on, that means your mic is activated, and when you're finished speaking, if you could turn that off.

The teleconference line is open and we do have a global mute in place. So we will be controlling the muting and unmuting. So please do not -- for those of

you participating over the phone, please do not unmute your lines unless we ask you to. And because we do have a number of PPDC members who are participating over the phone, during each session when we open it up for questioning, we'll go around the table here and then we'll go to the PPDC members on the phone.

Members of the public, I just want to remind you that when we do have the go-arounds, those go-arounds are for the PPDC members. There is a public session at the end of the day. If you're here in person and want to make a comment during the public session at the end of the day, please do sign up out at the registration desk. If you have a comment -- if a member of the public has a comment and you're participating over the phone, if you could email Shannon Jewell and then we'll get you signed up for the public comment session.

And then finally for safety, in the event of an emergency, there is an emergency exit door up here at the front of the table, and then there are a couple of exits out behind you.

So with that, why don't we start with introductions, and maybe, Ed, I'll start with you.

MR. MESSINA: Ed Messina, I'm the acting deputy office director for programs within OPP, and I work for Rick.

MS. KUNICKIS: I'm Sheryl Kunickis. I'm representing the United States Department of Agriculture.

MS. VAL: Hi. I'm Charlotte Val. I'm from U.S. Food and Drug Administration, Office of Food Safety.

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

MR. GORMAN: John Gorman, EPA Region II.

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

MS. LIEBMAN: Good morning. My name is Amy Liebman from the Migrant Clinicians Network.

MR. THOSTENSON: My name is Andrew Thostenson. I'm from North Dakota State University in Fargo, North Dakota. I represent the American Association of Pesticide Safety Educators.

MR. VROOM: My name is Jay Vroom, retired CEO of CropLife America in late this summer, but remain in a consulting role with them and representing some other ag technology companies.

MS. JAIN: Good morning. Komal Jain with the Center for Biocide Chemistries of the American Chemistry Council.

MR. GJEVRE: Eric Gjevre, Coeur d' Alane Tribe, representing Tribal Pesticide Program Council.

MR. KUNKEL: Good morning. Dan Kunkel with the IR-4 Program. We register products for specialty crops.

MS. ASMUS: Amy Asmus from Asmus Farm Supply. I'm a grower, a consultant, a retailer, and I represent the Weed Science Society.

MS. SANSON: Charlotte Sanson with ADAMA Crop Protection, representing --

(Break in recording.)

Ms. Figueroa: Iris Figueroa. Farmworker Justice.

MR. WAKEM: Edward Wakem, American Veterinary Medical Association.

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

MS. BISHOP: Pat Bishop with Humane Society International.

MR. HOBBS: Aaron Hobbs, RISE.

MS. WILSON: Thank you. Nina Wilson with Gowan

Company representing the biological products industry.

MS. PALMER: Good morning. I'm Sylvia Palmer. I'm representing the Council of Producers and Distributors of Agrotechnology.

MR. LAJOIE: Good morning. I'm Dominic LaJoie. I'm a grower from Maine and I'm representing the National Potato Council.

MR. WHITTINGTON: Andy Whittington, Farm Bureau Federation.

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

MR. REABE: My name is Damon Reabe. I'm an aerial applicator from Wisconsin representing the National Agricultural Aviation Association.

MS. TROSSBACH: Good morning. I'm Liza Fleeson Trossbach with the Virginia Department of Agriculture and Consumer Services, and I'm representing the Association of American Pesticide Control Officials, or AAPCO.

MR. ALARCON: Good morning. Walter Alarcon with SENSOR-Pesticides Program in CDC.

MR. KEIGWIN: And then I believe we do have some PPDC members participating on the phone. So if you're a

member of the PPDC participating via teleconference, if you could introduce yourself, please.

All right. So Lori Ann or Leyla --

MS. MCCURDY: Oh, good morning. This is Leyla McCurdy with the Children's Environmental Health Network.

MR. KEIGWIN: Great. Welcome, Leyla.

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

MR. KEIGWIN: Lori Ann.

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

MR. KEIGWIN: Thanks, Gina. Is there -- are there any other PPDC members participating over the phone?

(No response.)

MR. KEIGWIN: All right. Thanks again to all of you for participating today. So why don't we turn to our first topic, an update on our performance under PRIA, as well as provide you all with an update on some of the activities that we've been able to accomplish using some of the set-aside funds to support our worker safety program activities. So, Steve?

MR. SCHAIBLE: Thank you, everyone. Good, we don't have a squeaky mic here. My name is Steve Schaible. I am the OPP PRIA coordinator, and I'm going to go through some of the PRIA performance metrics for FY-18. Next slide, actually.

MR. KEIGWIN: For people on the phone, we're just having a brief technical issue as we try to bring up Steve's slides, so bear with us. Thanks.

(Brief pause.)

MR. KEIGWIN: All right. So I think everyone who's here in the room has paper copies of the slides, and I believe this slide deck is also available on the PPDC website. So in the interest of time, while our technical folks get things going, Steve, why don't we just keep going.

MR. SCHAIBLE: So what I'm going to hit on in this brief update, I'm going to be talking about updates for PRIA legislation, PRIA 3, PRIA 4. We'll be talking about some of our performance metrics; how many submissions and completions occurred this last fiscal year; our negotiation rates; on-time completions; fees collected. And I'll be talking about the PRIA set-asides

for worker protection activities. I'll be hitting on some process improvements, and then finally just talking about the PRIA annual report.

So as far as PRIA updates, the good news is we still are operating under a fee-for-service system. PRIA 3 was extended by the continuing resolution through December 7th of 2018. That was signed on September 28th. So we do continue to have the authority to collect registration service fees as well as maintenance fees for this duration of time.

There is pending legislation on re-authorizing PRIA beyond PRIA 3. The PRIA 4 bill in the House reauthorized PRIA through fiscal year 2023. That passed unanimously in March of '17. A Senate version of that bill, which amended that bill, passed in the summer of '18, and that -- that bill had limits on pesticide worker protection rules.

So those two versions of the bill would need to be reconciled between the House and the Senate, and that's where that sits right now. The House Farm Bill, the House version of the Farm Bill, HR-2, does include a provision which would enact the House version of PRIA 4.

The Senate version does not have that provision. And so in order for PRIA 4 to occur through that means, you would have to have a reconciliation again. So that's sort of where we are on the pending legislation landscape.

Moving to the next slide, this is a bar chart of a PRIA -- oh, good, we're up. There we go. Thanks, Shannon. This goes through basically our receipts in '18 as well as our completions in '18, and finally our negotiations. The light blue bars are the receipts. The yellow bars are the completions of both primary and secondary PRIA decisions. The grays are primary only. And then the blues -- the dark blues are our negotiations.

Just very quickly to go through primary, secondary, what that means, if you have a number of PRIA applications that are all associated with each other; for instance, a new chemical comes in and you have a technical product and two end use products and tolerance petition, the primary would be counting those decisions one time whereas the secondaries would be the associated applications with that overall submission. And so the

primary really sort of gets more into the chemical level work that we do.

So that being said, start off at the left of the chart with antimicrobials. In FY-18, they received 273 primary applications. They completed 328 primary and secondary, of which 267 of those were primary decisions. Six of the 328 were negotiated one or more times.

For biopesticides, they received 144 primary applications; they completed 214, of which 120 were primary decisions. And 40 of those 214 were negotiated.

For the conventionals, 858 primary decisions were received; 1,044 primary or secondary decisions were completed in '18, of which 817 were primaries. And 310 of the 1,044 were negotiated one or more times.

For the inerts, they received 46 applications; they completed 35, all of which were primary, and 16 of those 35 involved a negotiation of the PRIA due date.

For the miscellaneous category -- and the great majority of these are gold seal letter requests, so requests from the registrant for a letter demonstrating that the product is currently registered in the U.S. We received 579; we completed 578, of which 577 were primary

decisions. And two of those 578 were negotiated.

So total for the office, we received 1,900 primary applications in '17, and we completed 2,199.

Okay. This slide has to do with our negotiation rate. It's basically presenting the same information from the previous slide slightly differently. We go back to 2010 and give some historical perspective. I'm not going to get into that too deeply. I'll just report on the 2018 results.

For antimicrobials, six of the 328 decisions involved negotiations. That's a 1.8 percent negotiation rate, which is a pretty phenomenal performance compared to sort of the last few years.

For biopesticides, 40 of the 214 were negotiated. That's an 18.7 percent negotiation rate.

For the conventionals, 310 of the 1,044 were negotiated, or just under 30 percent.

For miscellaneous, 2 of the 578 were negotiated, or .3 percent, less than 1 percent.

For the inerts, 16 of the 35 were negotiated, and that's just under 46 percent.

For the office, we ended up at around 17 percent

negotiation rate for the year, which is up somewhat from previous years. In FY-17, we were around 13 percent for the office.

Okay. And so this next slide has to do with the on-time completion rates. We only had six late completions in FY-18 for the office. This, I think, is largely due to the fact that we were negotiating instead of -- we were working with the registrants. A negotiation is mutually agreed to between the applicant and the EPA. But we tended to negotiate instead of ending up in a situation where the application was late.

For antimicrobials, we had -- there was one late completion. And this actually was a late completion on a response from an applicant within 30 days on a label dispute. So it wasn't even necessarily a metric for the agency performance.

For conventionals, there were three late completions. For miscellaneous actions, there were two late completions. Those were gold seals. And there were no lates for biopesticides or inert ingredients in '18. So the on-time completion rates range from 99.7 percent up to 100 percent. And for the office, we ended up

overall at a 99.7 percent completion rate, which is better actually than we have done in previous years.

So moving to the next slide. In terms of fees collected in '18, $16.8 million in PRIA fees were collected and this reflects the overall collections minus refunds that were provided back to applicants. And so this was sort of what was ended up on our end.

For maintenance fees, $28.4 million in fees were collected. The target is $27.8. And so our algorithm ended up not hitting it exactly in the past year.

Moving on to the next slide, this is a summary of PRIA supported worker protection activities. There are three different set-asides under FIFRA Section 33 for these activities. And so $1 million in PRIA money was set-aside in '18 for worker protection activities. And those went to three different -- there are three different vehicles for that. And this is the PRIA money. I also want to point out there's also appropriated money that goes as well towards these activities. And so this is just talking about the PRIA set-aside.

The first cooperative agreement was the National Farmworker Training Program with the Association of

Farmworker Opportunity, or AFOP. This program develops and administers a pesticide training program to support a national network of pesticide safety trainers. They provide pesticide worker safety training to migrants, seasonal workers and their families.

And moving to the next slide, some of the accomplishments for this program in FY-18. 150 pesticide safety trainers in 30 states delivered WPS pesticide safety training to 7,649 farm workers; over 2,000 women were trained on pesticide exposure in pregnancy; there were 28 Train-the-Trainer courses delivered for 230 new WPS pesticide safety trainers; over 16,000 materials were distributed to farm workers and their families on preventing take home exposure; over 13,000 long-sleeve shirts were distributed to farm workers on the National Long Sleeve Shirt Drive during the National Farm Worker's Awareness Week in March. And, finally, a new WPS pesticide safety training flipchart was developed for farm workers to align with the revised regulations.

Okay. The second cooperative agreement was for PERC, the Pesticide Education Resources Collaborative, run out of UC-Davis, Oregon State -- that's a UC-

Davis/Oregon State cooperative agreement which develops and coordinates pesticide education materials, the development of those materials. An advisory board helps set national priorities and PERC uses subject matter experts and production professionals.

As far as the accomplishments for PERC, next slide.

UNIDENTIFIED MALE: Hey, Steve, you just clicked --

MR. SCHAIBLE: Am I one off here?

UNIDENTIFIED MALE: My OCD was kicking in.

MR. SCHAIBLE: Bingo. Where is that? Yeah, there we go. Thank you. The safety training videos, there was a new safety training video for farm workers and pesticide handlers both in English and in Spanish; a respiratory protection guide was developed for WPS. There's a WPS compliance assistance library, and that is information for the regulated community filtered by responses to questions. There's a new WPS pesticide safety poster, and finally, a seed treatment study manual for pesticide applicators and exam questions for use by certifying authorities.

Under worker protection activities, the last -- the third activity was pesticide education for medical professionals; also a cooperative agreement with UC-Davis and Oregon State. In this program, through outreach, technical assistance and training, the program seeks to achieve improved health for farm workers and agricultural communities by increasing knowledge and awareness of environmental and occupational health risks.

The program expands on previous programs by including health care practice sites, improving existing educational materials, and targeting larger audiences of providers. And this would include doctors, nurses, emergency response personnel and other clinical staff. In terms of accomplishments, I think this was newly established in FY-18 and so it's getting up and running.

Next slide? Okay. There was also a PRIA set-aside for partnership grants. And $500,000 was awarded through a cooperative agreement with Oregon State University for the National Pesticide Information Center, or NPIC. NPIC facilitates informed decision-making about pesticides. It supports the protection of human health and the environment by serving as a bilingual factual

source of information for professional and public audiences on pesticide-related issues.

In terms of NPIC accomplishments in FY-18, NPIC responded to over 10,000 inquiries. The website had 6.4 million views, and 195 original posts were developed on the webpage.

And then moving to the next slide, the final set-aside under PRIA is for pesticide safety education programs, or PSEPs, and this was a cooperative agreement with the extension foundation. And that involved $500,000 of PRIA set-aside money. So the Extension Foundation distributes funds to PSEPs to provide pesticide applicator training on the safe use of restricted use pesticides in agricultural, commercial, residential and public settings.

In ‘18, $1.1 million was awarded for 46 PSEPs that applied for funding. And in terms of those applications, 46 out of the 57 applications received funding. PSEPs committed to developing pesticide applicator materials for state, regional and national use on topics such as respirator use and care, pollinator protection and spray-drift awareness. So that is a

summary of the PRIA set-asides.

And now I'm moving on to process improvements. And for this talk, I'm going to highlight the pesticide submission portal and some of the improvements that occurred in '18, as well as some work that we're doing developing additional functionality within the portal.

And just very briefly, the portal is the web-based secure means by which applicants can now submit applications to the agency electronically. In '18, some of the improvements that have been implemented, there is functionality for a consortium application. So if you have multiple companies that are working together to develop data either for registration or for reg review, like a DCI, for instance, you can now apply as a consortium and just submit data associated with multiple entities that have a shared data requirement.

There's also passphrase enhancement. For those of you that have used the portal, your company -- up to now your company received a password that you had to write down because if you forget it there was no way to get into the portal. So recognizing that was causing problems, especially for infrequent users of the portal,

you can now create separate passphrases for data submissions in addition to your overall company password. So you can have a password at the data submission level, and there's also a box -- popup box for passphrase hints. So if you don't remember your password, you can set up a hint to yourself so that you're able to possibly and hopefully remember it.

There's also a file size and file limit validation. So you are prompted when you're submitting your application, if your files are too large or you have too many files, then that's going to cause a problem on the agency's end with processing the applications. There's -- you're now prompted saying this is going to be large; this prevents you from -- it's too large; this prevents you from submitting that application; getting it hung up on our end and losing some time on that application. So you're prompted now if that situation occurs.

The two final bullets actually shouldn't be sub-bullets. But we now have functionality for a registration review label application. Users can submit labels associated with specific reg review cases along

with the supporting administrative materials.

And, finally, functionality for Gold Seal letter requests was created in the portal. So now when you submit a Gold Seal letter request, there's a specific pull-down menu on the -- for application type that you can select Gold Seal letter. It makes it much more obvious. Before you sort of had to -- you had to make an amendment. It wasn't very intuitive, and I think registrants were submitting those in paper rather than through the portal since there are so many Gold Seals in terms of our overall PRIA actions that we receive each year. We did want to make sure that those -- it was obvious and apparent how to submit those through the portal.

As far as improvements that are in progress, and these specific improvements have a target delivery date for early 2019. This goes along with what's going to be talked about in the next talk. The first is the OPP e-label builder. Formerly, I think this would be known as the SmartLabel. This allows applicants to develop and submit label and corresponding use index information in a structured, standardized format. It's my understanding

that the portal will be the means by which you can submit e-labels to the office; the only means.

Secondly, there is the eCSF builder functionality being developed. This would allow applicants to develop and submit an electronic confidential statement of formula. And so both of these efforts overall are helping us to receive information electronically so that we can work towards developing our internal electronic work flow, which will result in efficiencies on our end certainly.

Finally, there is a functionality for pet spot-on enhancement. This will allow applications to submit corresponding sales and incident data as they relate to pet spot-on products.

Further out on the horizon, we are looking to develop within the portal environment a company number generator. So if you're trying to get your company number, you no longer are calling us up or sending something in. You can do that through the portal. And then finally people will be able to submit Section 24(c) special local need applications as well as Section 18 emergency exemption submissions through the portal.

Finally, I just want to remind everybody, under PRIA, EPA is required to publish an annual report. There's specific PRIA/non-PRIA related actions we're required to report on that are described in Section 33(k)(2). EPA posts that report on our PRIA webpage. That occurs no later than March 1st of the year following the fiscal year we're reporting on. And the weblink is included on the slides. In addition to the current PRIA report, you can also look at previous years PRIA annual reports as well on that webpage.

As far as who to contact if you have any questions relating to PRIA, you can contact me at the office level. And at the division level, in RD, you can also contact me as well. Aswathy Balan is another resource, and I can -- certainly if you contact me, I'll be able to give you her information as well.

In AD, the APP -- the AD PRIA Ombudsperson is Diane Isbell, and you can reach her through the AD -- the OPP AD Ombudsman mailbox. And in BPPD, it's Andrew Bryceland. So that is the conclusion of what I needed to -- wanted to present. We can take any questions.

MR. KEIGWIN: All right. Thanks, Steve.

Questions?

MS. ASMUS: Thanks, Steve, for your update. I have a couple of questions. The first one is it seems on your PRIA updates on where PRIA-3 and PRIA-4 is and getting it reauthorized, I think that there's -- you mentioned that there's a limit on the pesticide -- the Senate passed PRIA-4 with some limits on the pesticide worker protection rules. I wonder if you can explain that a little bit more, and also let us know what the status of the worker protection standard is right now because it seems like that might be an issue with PRIA.

MR. KEIGWIN: I'll take it. So the version -- it's been a while since I've looked at the bill that passed the Senate. The bill that -- my recollection is that the bill that passed the Senate has a shorter reauthorization period for PRIA than the house bill. As it relates to the worker safety provisions, that would be both worker protection standard and the certification of pesticide applicator rule, for all intents and purposes, it puts a moratorium on the agency's ability to make changes but for some designated pieces. I think it allows for some modification of the application exclusion zone and some

other kind of technical adjustments. And that would be for a two to three-year period of time, is my recollection. That's the version that the Senate passed. That's not law. So that's where that stands.

And then in terms of where the rules are. So the worker protection standard is now fully in effect as promulgated in 2015. Earlier this year, we did publish the last notice that the 2015 rule had called for, which was to announce that the training materials were available. So that kicked off a six-month process. I think that goes, Jackie, into December. So beginning in December those materials are the materials that need to be used.

And then certification rule, states have until early March of 2020 to submit their revised certification plans for EPA review.

MS. ASMUS: And did the EPA submit proposed changes that's going through the Office of Management and Budget and --

MR. KEIGWIN: So there -- I think there is -- I think there's an update in your packet. So there is -- you know, we did announce in December of last year

that we, in response to the regulatory enforcement initiatives, moving forward with seeking public input on some possible changes to the worker protection standard and the certification rule; that those proposals are in interagency review. And that's where they remain right now.

MS. ASMUS: And do those changes -- are they in, like, what the Senate moratorium bill is passing? Are those changes that you're proposing? Do they go -- are they in line with what the Senate is asking you to do, or no?

MR. KEIGWIN: I can't really talk about what's subject to the interagency discussions. What I can say is we did issue an OPP update in December of last year that outlines what areas that we were considering. But because we're still in the interagency process, I can't really go further than that.

MS. ASMUS: Well, it's not the interagency process, per se, but it's sort of like what did the Senate say and what did you do?

MR. KEIGWIN: I can't talk about what's in a proposed rule that hasn't been issued for public comment

yet.

MS. ASMUS: Okay.

MR. KEIGWIN: So -- and I don't have the Senate bill in front of me. But, you know, thematically it covers the areas that I was talking about.

MR. KEIGWIN: Okay. Iris?

MS. FIGUEROA: Yes. I had raised -- I actually had the same question that Amy had about the Senate -- the worker protection rules. I just think that since there are set-asides in PRIA for worker protection, it was the right time to ask. So thank you for the handout. I'll take a look at it.

MR. KEIGWIN: Sylvia?

MS. PALMER: Yeah. I have an easier question. It just has to do with the numbers on slide 5 with the renegotiated due date. There's a disparity between the antimicrobials all the way down to the inerts. You're looking at 1.8 percent, then 18 percent, 29 percent, and then 45 percent for the inerts. I was just curious as to what accounts for that disparity in numbers and why the percentage of inerts is so high compared to the others.

MR. SCHAIBLE: Right. So I can say that the

inert categories were new to PRIA-3, the last reauthorization. And so I think when those time frames were set in PRIA-3, I think having more experience with how long it takes us to do those reviews, I think we found that some of them are consistently needing to be negotiated; that the time frames have not been adequate for us to complete the action in the PRIA time frame.

In PRIA-4, some of those time frames are adjusted both to be less time where we have experience suggesting we're doing them more quickly, as well as longer time. I think -- and there's going to be a PRIA stakeholder meeting in mid-November, and we're doing an internal analysis that will be presented there looking at sort of what are some of the reasons for the negotiations.

I can say that sort of at a very high level, it has to do with, you know, additional data submissions occurring, instead of with the initial package being submitted later, that's one of the issues. And then there's also issues internally around sort of our getting through our review and getting the tolerance exemption published in a timely manner. So that's going to be a

report out that occurs for the PRIA stakeholder meeting.

MR. KEIGWIN: Komal?

MS. JAIN: So I actually just want to make note of the process improvements. They're really welcomed and I think it's really responsive to a great number of issues and feedback that was provided by the registrant. So just a thank you.

MR. KEIGWIN: Iris, you still have your light on. I didn't know.

MS. FIGUEROA: Oh.

MR. KEIGWIN: Okay, just checking. All right. Anybody else around the table? Go ahead. Amy?

MS. ASMUS: Just another question. I think it is really helpful on your updates to know -- particularly for, you know, where I'm coming from for the worker protection activities. But we've been funded by the EPA in the past and we get a lot of grant funding. And we have to spend a lot of time in addition to sort of the number crunching, like how many people did you reach; how many trainings did you do? We spend a lot of time showing what our impact is. And on all of these numbers that we've been given today, both from the registration

process to what you're doing with the worker protection part, we're just getting numbers. And, you know, we're not seeing how well workers are protected; we're not seeing how well the public's protected with the registration process.

I mean, I'm happy everything goes so fast if that's what you want. But, like, you know, going fast isn't always -- always a great thing when it comes to protecting the public. So I kind of would like to know a little bit more about what our impact is in protecting human health and the environment with this. And then on the worker protection part, it's great that, you know, resources are produced, but what's the impact? What's the bang for your buck here?

MR. KEIGWIN: So I think that can probably be a topic at a future meeting. We'll take that under advisement. Let me see if Lori Ann or Leyla or Gina have any questions for Steve.

MS. BURD: I just want to echo the points raised by Iris and Amy. You know, the numbers are fine, but what we're interested in is the impacts and beyond just on time, on target figures. How are farm

workers being protected?

And, also, I'm not clear why the interagency discussions need to be held confidential. Is there a legal reason for that, or why can you not share with us where EPA is coming from on this?

MR. KEIGWIN: I think I heard your question, Lori Ann, but you're kind of faint. There are interagency discussions that happen that they are deliberative in nature prior to the release of a rule. This is consistent across the government as far as my experience has been. And so it is still at a deliberative process, and so it has been my experience that that information is not public until the rule itself goes public for public comment.

MS. MCCURDY: This is Leyla McCurdy. May I make a comment?

MR. KEIGWIN: Please, Leyla.

MS. MCCURDY: Thank you very much. I just wanted to say quickly that I'm not going to repeat it, but I do agree with Amy's comments, and Lori Ann also supported that. These numbers look great. However, how do we know that they are really making the impact in

terms of protecting the public, including vulnerable populations, including children and others, as well as the workers, of course. Thank you.

MR. KEIGWIN: Thanks, Leyla. Any other questions on this topic?

(No response.)

MR. KEIGWIN: If not, Steve, thank you. And then I would ask Patricia Parrott from our Field and External Affairs Division to help us with our next session.

MS. PARROTT: Leading the SmartLabel project -- one of the leaders, anyway. So this is to give you an update on the process. So we've been working on this SmartLabel for a number of years, and for anyone -- just to give you a refresher, what is a SmartLabel? So it's a master pesticide label structured data, and it's part of our vision for instantaneous access to quality information. And that means that it's part of a comprehensive plan of getting us into an electronic environment and doing away with a lot of the paper.

And so specifically the label, it's not just a structured label, but it's the use pattern as defined by

the registrant submitted to us as data. So what this does is it eliminates the need for us to interpret a label that comes in on paper into a database with the parameters that you've cited from that information, and thereby we reduce errors. It's also quicker. It's less labor-intensive.

So we're also standardizing the vocabularies, and this is -- by putting out a list of what we mean by a term and its synonyms and definition, and we have that all coded so there's structure around it. We can also share it with other partners. We're using the HL7 model that FDA uses and other federal agencies.

And so this way we'll have a common understanding of the terms and we'll be able to share that data. It's also a process to improve our review and our risk assessment work flow. So by having the information from the label, which is what drives the risk assessment, we'll be able to more quickly move that information, and it will be available as data for modeling. And it's also scalable for managing the information.

So when this -- we worked on a data model for

all of the information within OPP. So the label has a big portion of the information that can be used across the program, and what we did was -- it was designed to be built out in a modular fashion. So we're starting with the label, the eCSF, the tolerances, and then it will move onto the other information that we produce.

So some of the benefits of this structured, electronic content is that it will be in a consistent format. We're going to have the use index as data. We'll have the standard vocabulary, and that means less ambiguity. I won't say no, but less. And it's going to give us a faster review process. So if we have the label in electronically, we can compare it and use the computer to do some of the validation for us. And then it will be easy to see where those changes were made, to review them, and that will add to efficiencies in the review process, saving time on both the registrant's side and ours.

It will give us the improved access to the information. So we'll be able to more quickly search across products and it will give us the ability to respond to public health inquiries. What do you have

registered to -- you know, that's effective against X product? A black mold or something like that.

It will also give us the ability to directly upload this information into PPLS so there's no delay. As soon as something is approved, it can go immediately out there.

It's going to save us paper. And as I said before, the electronic validation, having the computer and the validation rules do those checks for us, we're going to reduce the manual labor that's involved in reviewing these labels.

So terminology development and management. So in developing our vocabularies, we built them. So we took our lists and we defined and we developed what we could from OPP from our knowledge. But we also borrowed. So external stakeholders, rather than reinvent the wheel or where we needed additional expertise, we reached out to societies. We've been working with the entomological society, for instance, on our bugs list.

We've also merged lists. So what we're doing is we partnered with FDA in the beginning to model the whole SmartLabel project off of their pharmaceutical labels and

then use that as a basis to build out pesticide labels. And we've merged our lists where possible to draw those connections so that the data can be exchanged.

So our vocabularies are managed by the EPA terminology service, which is a Synaptica program. And so there is governance and there's standardization in these terms. And we also have a central repository to maintain that terminology.

So this is to demonstrate some of the advantages to having the terminology and the structure around it. So we have dropdown lists in our databases. Like for use sites, there are 1,100 topics -- 1,100 things to select from. So that's impossible. That's unmanageable.

So we restructured it starting with the use site. And this is our example of the use site. And then a location. And then in doing that we've been able to reduce those -- the number of items in that list. So the example of a site could be a residential lawn; it could be a grass around an oil well or a sod farm. And those are very different label sites. But the use site is grass turf in all of those, and the location that we would use for risk assessment would be residential,

recreational, school, institutional, occupational, manufacturing or processing, industrial or ag. And you can see, you wouldn't expect, for instance, a child to be playing around an oil well; you would around a residential lawn.

And so by providing this structure, it's going to facilitate doing a risk assessment correctly the first time around with less interpretation. So with 140 sites and 10 locations, we're able to capture what our universe is right now in the database.

So the benefits of the structured label is going to be increased consistency in review. We're going to be able to more easily check the label to a previous version, or to other labels to make sure that we've got that label -- that level playing field.

We're also going to be able to compare to the supporting documentation, which will also be in electronic format. And as I've said before, they'll reduce the need for interpretation.

So it's going to reduce our review time because we can identify what's changed from the previous version, and then we'll be using the computer and the validation

rules to help us do some of the review.

So the benefits of the Use Index is also -- I'm just making sure I'm on the right slide here. The increased consistency in review. So we're not interpreting whether that grass or turf -- whether a child is going to be exposed to it with the definitions that we have. We're going to be more easily able to identify a data gap. So if there are data that we need to support a use because previously we had interpreted incorrectly, we'll be able to identify that up front and work with the registrant to get those data in. And we're going to compare use pattern data to the label during the registration.

So all of this is going to help us, again, reduce the time for review and improve our accuracy. So in developing our SmartLabel, our electronic label, we've been working with nine pilot participants since 2014, and these are the companies.

So over the years we've gone through different phases, and so this year we finished up Phase 4. So we made the builders more user-friendly and we continue to work with FDA to harmonize the terms, and we've updated

the vocabularies.

Phase 5, earlier this month we initiated the soft launch, and that's for the submission of the pilot participants to test the entire system. So we're testing the builder, the submission portal, the database loader, the new database, the OPP electronic review tool, and the label approval process for processing this into PPLS.

So the registrants have had experience with the pilot participants in building labels through the label builder and taking that .xml file, submitting it through the portal, and it's going to test our whole pipeline. And then OPP is going to learn how to review these electronically. We've built a tool and we're not really going to know until we start using it how effective it would be; any tweaks that we need to be. So there's a learning curve on our end, too.

But right now we're still in the pilot phase, and we want to make sure that we have this down before we release it for anyone to use. So that's our next step, is after we have sufficient testing and we're satisfied that we have a good product that we can put out and that we're ready for this, it's going to be put into a

production ready environment for registrants.

So the integration of the SmartLabel into our workflows will happen, and we'll begin to build up that database of SmartLabels. And when the time comes, then we will be ready to encourage voluntary adoption. This won't be required until we initiate rule-making. We're not going to start rule-making, like we said, until we're sure that we have a workable product.

So the other things we're going to do is leverage SmartLabel to work on our future OPP IT modernization. So we're going to establish a governance to maintain this vocabulary. We want to make sure that we don't lose the control over the structured vocabularies that we've put so much time into. So if someone comes up with something that they think is a new term, we're going to get our experts and reach out to our experts groups as needed depending on the topic to find out is this truly a new term, a new thing, or is it a synonym of something that already exists?

We're going to expand to put additional information in the structured content. There have been

talks about, you know, a toxin point database and other things that we can do. Because, as I said before, we built the model to be built out at a modular fashion and we've thought about these things. So we will incrementally increase our ability to move what are now documents and flat files as data.

And we're going to develop new tools for access. And some of this would be internal for us and some of it would be for the registrants. One of the -- bit of feedback that we've gotten, it would be useful to have the portal go two ways. So not just the registrant submitting information to us, but we submit it back out through the portal; things like that that would facilitate. Because right now you submit a label in, we are going to review it and then we will email with you back and forth because the portal isn't two ways. The advantage, though, is that we will have the data -- the information as data. So we're doing this in a step-wise fashion, but there are plans in the future to improve this and make it even more useful for all of us as we work forward.

And then to continue work on the MRL database or the exchange of information with FDA. As you know -- or

as you'll find out, EPA sets the tolerances and FDA enforces them. And having accurate information is important. And so one of the agreements we made with FDA was to exchange this information with them into the .xml format to facilitate that process instead of more of the manual exchanges we do now.

So we've developed this chart to show some of the benefits to us all. So the curated vocabularies, having the structured labels, having the smart database, and having the ability to query and having that information electronically could benefit all of us.

One of the caveats I want to put on this is that one of the agreements that we made with the registrants initially was that early adopters wouldn't be penalized by having their information exposed as data in a way that others wouldn't. There was concern that some of the information -- it would be too easy for a competitor to find a data gap or something to jump in to fill that. So we do have some constraints about that.

Right now what we're planning on doing is putting the information, the structured labels, up as data in PPLS as we have now. But any additional

information that would be available to the entire public, that would -- there would be a process to talk with everyone about what's acceptable and are we going to do it. It wouldn't be until it's mandatory for everyone to have their label in.

So on the last slide, here's some information. So the information about the pilot webpage, all the processes that we've done up through the current pilot is not up there, the information. That's an ongoing thing. We haven't had our results. We're planning on running the pilot preliminarily until the end of December. And that's probably going to be extended. We want to make sure that we get sufficient labels in to ensure that we've fully tested this before we release it.

We do have a mailbox, though, where we can take comments if you have comments or concerns. You can let them go. We do monitor that. And you can contact me directly; my information is up there. So, thank you.

MR. KEIGWIN: All right. Thanks, Patty. Questions? Aaron, then Liza, then Iris.

MR. HOBBS: Thank you. Good morning again. Two questions: Do I understand correctly that the voluntary

submissions under the soft launch, that has begun?

MS. PARROTT: Yes. But that's with pilot participants only.

MR. HOBBS: Okay, thank you. And then my Follow-up is, what is the plan for engaging and taking feedback from registrants beyond those that are participating in the current pilot?

MS. PARROTT: So we've had the mailbox and we've had webinars after the previous stages of the pilot, and we've taken feedback through our mailbox. We can't engage everyone in the pilot because of ICR. And so we took a cross-section of the industry. But the general public or anyone, registrants, are able to submit the comments into the mailbox.

MR. HOBBS: And will there be a clear process after this moves from the pilot phase for continuous improvement and feedback from those people that are actively using it?

MS. PARROTT: Yes. This is our first attempt at doing this, and so we want to get it right and thoroughly test it. But we realize that there will be additional hiccups. And, also, we anticipate that this will be part

of a continuous process of improving and adding refinements and things. So, yes, we'll be looking for that feedback.

MR. HOBBS: Okay, great. And then there have been some comments that we feel some of our members and some of the industry feel have not been properly assessed. So is there any guidance you have for any outstanding concerns that we may feel haven't been properly addressed at this time?

MS. PARROTT: You can speak with me directly and we can talk about that. I think one of the -- what we're trying to do with this is make it as broad as possible so that it fits all sectors. And so we've tried to address because initially, I mean, there's quite a difference between an agricultural crop for a conventional and an antimicrobial; for instance, a homeowner product.

So we've tried to address those without having separate systems. And so we hid fields and things. So part of this is trying to hit most of the segment of our stakeholders without getting it too customized for one industry. But certainly if you feel that what we've done doesn't address your concerns, then we can talk about it.

MR. KEIGWIN: Okay. Liza, then Iris, then Charlotte.

MS. TROSSBACH: Thank you. I just have a clarification.

MS. PARROTT: Sure.

MS. TROSSBACH: So on slide 11, you talked about the testing of the entire system, the builder, the submission, the portal.

MS. PARROTT: Mm-hmm.

MS. TROSSBACH: So those all things together make up SmartLabel, and then the e-label builder that was mentioned under PRIA and the targets for 2019, that's just one component of the total SmartLabel system. Am I thinking about that correctly?

MS. PARROTT: Right. So the e-label builder is the tool that we've developed to assist registrants in getting the information into the data package, the .xml, with all the structure. Think of it as a Turbo Tax. You don't have to use it, but it's there. And so we anticipate that with FDA, the third party vendors will step in and maybe develop the tool for your industry or something that works better for you.

Because what we're interested in is that .xml file. What we have available and what we'll be updating and posting is all of the code, the information you need, the instruction guide, the vocabulary lists, are all there so that you can build your own if you'd like.

Then once you havean .xml file, yes, the system that it goes through, getting it through the portal, through our -- what we call our pipeline into our thing and you're electronically reviewing it, that whole thing is our SmartLabel system. We hope to have it rolled out in the next year.

MR. KEIGWIN: Okay. Iris, then Charlotte, then Amy Asmus.

MS. FIGUEROA: Thank you. Could you speak to any plans or opportunities for developing the labels in languages other than English?

MS. PARROTT: Right now we do have the ability to submit portions of the label in Spanish, and there is a Spanish labeling initiative ongoing within the agency. That's an option in there, and we can -- anything that you can do with a paper label right now, you'll have that option in SmartLabel. We don't have the tools available

to translate it for you. But those chunks of the label can be put in.

There's much more content in the label -- well, label content portion. There's more text and fewer data fields. The use index would be the underlying data. And that's really independent of language because it's a lot of the data.

MS. FIGUEROA: So just one follow-up question because you mentioned vocabulary development.

MS. PARROTT: Mm-hmm.

MS. FIGUEROA: So the language, is that something that you're addressing sort of terms in Spanish as well, or no?

MS. PARROTT: No, not at this time. But that can be a future improvement as the need arises.

MR. KEIGWIN: Okay. Charlotte, then Amy Asmus, then Sharon.

MS. SANSON: Thank you. And thank you for the update, Pat. So I have a couple questions.

MS. PARROTT: Okay.

MS. SANSON: So my first one has to do with existing product labels. Is there -- what's the plan for

moving existing product labels into the -- into the SmartLabel process, or is it going to become mandatory at some point?

MS. PARROTT: To become mandatory, we have to go through rulemaking. And as you know, that's a long process and there will be many opportunities for comments and a big process -- public process around that. In the meantime, the agency is not going to be putting any labels into the SmartLabel format. We want to do away with our interpretation or introduced errors. This would be something for the registrants to submit.

There are advantages. The first time there's a learning curve in getting the information in there. Subsequently -- and I think a lot of our pilot participants have told us this -- that they definitely see the value in doing this, and that although it is upfront effort, in the long run for version control, for easily finding things, it's helped them get their arms around what they have on their labels, too.

So what we see happening is when it's voluntary, as registrants need labels coming in with an amendment, a new product, anything, that they would start using that.

We're also opening up for reg review and we're trying to pilot this for reg review. We do have the RRL system, which is to submit reg review labels as Adobe Acrobat through -- just for the reg review portion. We're also making that available to build out a reg review label through the builder. And we're doing that with the pilot participants. That would be an opportunity to get a lot of labels and get it done one time, up front with the mitigation in.

And, like I said, there's a learning curve. But ultimately it will be faster for the reviews and to make changes on the registrant side, also.

CHARLOTTE: Okay, great. Thanks. And then for the companies who haven't had an opportunity to be part of the pilot, will there -- will it be open to them at some point to explore the possibilities, you know, with -- as, you know, with the portal without having been part of the pilot?

MS. PARROTT: Yeah. So we put the materials out for testing or for people to -- for transparency for registrants to look at, at various times. Once we release it, we would be looking for additional input. We hope to

have it sufficient for most people to be able to use. Like I said, we're expecting some hiccups. We've been talking about it with industry groups. Your industry is also represented, I hope, on -- by the pilot participants. You could speak with them about it if you have some questions. And then we will be doing some rollout and presentations and training before we release it.

CHARLOTTE: Okay.

MR. KEIGWIN: Okay. Amy, then Sharon, then Amy Liebman.

MS. ASMUS: I commend you for your work that you're doing for the EPA and the registrants. But my first question is what will access be to the field outside of the EPA to use this information? Because the frustrations you go through are the same frustrations that me and my counterparts go through as we advise growers on how to find information in a label, how to interpret that information in a label, and how to use the label. And I think once you get that structured data, can we look at standardizing where to find information in the label?

I thought it was excellent, the quote that's on our folders today, that people are inherently capable of making proper judgments when they are properly informed. And the labels I look at are not consistent from Bayer to BSF to Syngenta. Sometimes they're long like you had pointed out. And it's really an onerous process to find some of the basic information that we are looking for so that we can help our growers do what we all tell them, read and follow label directions.

So is there a movement to go through -- once you get the structured data to go through a standardization across the companies of the label? And I don't think it can be just electronically because when my guy is in a sprayer in the field and they don't have access to electronic data, they're going to call me and say, how do I do this? Or they're going to pull the paper label that's distributed with the product and they're not going to know where to look to find the information that they need in a timely fashion.

So is there any next steps to address that?

MS. PARROTT: So right now the -- what we've done in making this transition was we're not making any

changes to the paper label that appears on the product. This is to get the information provided in a structured format electronically so that you can quickly find what's allowable, what's been registered.

As far as the next steps and how useful it's going to be, I think that we'll all determine that as we start using it, as we get the database built up and the next steps to see how we could facilitate that. There are some advantages and we're hoping that this would -- having the SmartLabel, the .xml information, that this would help other initiatives such as the label -- web-distributed labeling. And we can discuss other means of providing and serving up that information. I hope that's helpful.

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

MS. SELVAGGIO: Well, I'd like to echo what Amy just said. I think that there's a lot of potential here. I think it can be useful to lots and lots of different stakeholders. I've looked at a lot of different labels and had many, many frustrations trying to find information; trying to compare labels. So I really like a lot of what you're doing here.

Right now I looked at PICOL, which is managed by -- I can't remember if it's Washington State or the Washington State Department of Ag, but I think it's through the Department of Ag. And so I'm kind of wondering -- and I also look at CBMS a lot. And I'm wondering are you coordinating with those entities and other entities that already compile label information and make it available to you so that users who are searching for, you know, through this universe of potential pesticides are able to find? Because those of us who are already looking for this kind of information use those kind of sites.

My second sort of comment is that I don't really understand why rulemaking and the burden that that poses on the agency would be considered overly burdensome. Because I think ultimately having this standardized across the board and mandatory will provide all the benefits that you show on that one chart, especially, you know, to the users and the public.

Right now this really identifies the benefits. But if access is not available, if it's not comprehensive, if it's not mandatory, these benefits will

not be available.

So my final question, I guess, is about examples so that those of us who currently search labels can actually see what it looks like and can understand when accessibility will be available for the general public or for people in the public who need this information. Thanks.

MS. PARROTT: Okay.

MS. SELVAGGIO: Thanks.

MS. PARROTT: All right. First of all, we have been working with other stakeholders who have this information. We've been working with California, Canada, other -- NPIRS, which is a group that does a lot of the state registrations. I think Washington we have. We have discussed this with our regional and state partners. So we've been doing a lot of outreach over a number of years. So we have been -- we're trying to build a tool that's useful for everyone and trying to take some of the best practices that are out there rather than start completely from scratch.

As for rulemaking, I didn't mean to imply that it's extremely burdensome. Like I said, we wanted to

have a product that we know works before we release it. Once we release it, to make it mandatory we do have to go through rulemaking, and we intend to do that. But there is -- there will be the opportunity for public comments. So it's not as though that will happen without people being heard.

As far as providing examples, we can look into that about providing some. Okay?

MS. SELVAGGIO: Sure.

MR. KEIGWIN: Thanks, Sharon. Amy and then Jay.

MS. LIEBMAN: Thank you for your presentation. It was really helpful. And I commend the agency for moving forward with this.

Since we have a balanced committee with plenty of farmworker representatives -- and I'm not a farmworker representative -- on the committee, I feel that somebody needs to say something in addition to Iris. But I really do think that it's important to consider the need to put forth the label information in different languages. And I know that the agency has had some -- you know, has toyed with it as far as we know. But we really haven't seen results. And it doesn't make any sense when you

look at the diversity of the population that's involved with pesticide use.

And so it's not only an issue for workers who are applying it, but it's an issue if it's applied incorrectly for the public. So thinking about communicating about the language that people understand and a vocabulary that people understand, I think needs to be right up here with all the work that you're doing in this electronic label phase.

MS. PARROTT: Okay, thanks.

MR. KEIGWIN: Jay?

MR. VROOM: Patricia, this is a very concise and cohesive presentation. It's something that's obviously been underway for a long time, and so I want to congratulate you for the progress. This shows that, you know, you have your arms around this and it's really making progress.

One thing that I don't think has been mentioned is ending up with lots of different label versions. There already are lots of versions, as have been alluded to. But going back to the notion that the label is the law and how to manage what liabilities exist after use

and disposition, et cetera, is a topic that I know has been discussed about this with OGC and outside legal counsel over time. I'd be curious to know where the arc of that conversation is at.

I'm pleased that you mentioned talking with other regulators like California or PMRA in Canada. OECD would be another place that, you know, this kind of work, the more it can be harmonized, the more beneficial it is globally to users as well as registrants.

So thank you for all that progress. And then lastly you mentioned web-distributed labeling. So can you say a couple words about how the work that you described here is married up against what is ongoing with regard to web-distributed labeling, which touches all of this?

MS. PARROTT: Okay. I'm trying to remember everything you said. So as far as -- you mentioned OECD internationally and stuff. So I will say that HL7 is an international standard that we're using. So our vocabularies will definitely be. There are other hurdles with OECD labels, but at least we have that foothold there.

You were talking about web-distributed labeling. And that -- we haven't had any yet. What we're hoping is that once the registrant has their label electronically that it would facilitate them putting it into the web-distributed labeling format or finding a way to use that information and have it automated and posted.

I'm not the expert on the web-distributed labeling website information. But we can -- we can get some information on that.

MR. VROOM: So I presume that there's still somebody assigned to that task at OGC. Right?

MS. PARROTT: Yes. They're not here right now.

MR. KEIGWIN: She's just not here today.

MR. VROOM: Yeah. But are you planning some kind of coordination there at that interface?

MS. PARROTT: Yes.

MR. VROOM: Great. And the last question was around, you know, managing the legal liability of how electronic labels are regarded when it comes to those kinds of issues.

MS. PARROTT: Right, yeah. So we are -- they will be stamped as they're approved with the date and

time so that you -- and the versions will be available so that you'll know which version. So that's all being coordinated and it has been looked at with legal counsel and the registrant's input.

MR. KEIGWIN: Okay. Andy, then Donnie.

MR. WHITTINGTON: Okay. So I just want to go back to Amy because I'm like Amy. I'm the one that gets the calls from the field. But I understand the great benefits to the EPA and to the registrants, and I think it's a wonderful opportunity to have great benefits to the producer as well. If the end goal of this is a QR code on a container where he can scan it, he's looking for the return entry intervals on a product and he can just put in REI and it pops up so he doesn't have to go through a hundred-page label, I think if that's the end goal of this, this is a wonderful project. Thank you.

MS. PARROTT: That's -- you know, best, better, wonderful, whatever. We have to walk before we can run. Yeah, I know, I know. So, yeah, yeah. But, you know, this -- like I said, it's an integrative process, and so it's just our first attempt. And I think the first is the hardest. And so once we do this, we'll find out

ultimately -- and hopefully at a quicker speed we'll be able to adopt some of this and really make it useful for all of us.

MR. KEIGWIN: Okay. Donnie?

DONNIE: So thanks for the update. My question, are you also working with OSHA (inaudible)? (Microphone off.)

MS. PARROTT: So we've put our information out there. What we're doing right now is our label review manual is what we started with and we're doing that. I know that with OSHA and the respirator language that we're doing some, some changes there. The system is built to manage any changes that come up. It has that flexibility. So to the extent we can. But right now, as I said, what we've done is we're not -- we didn't start out by making any wholesale changes to the label and we're using the label review manual. Okay?

MR. KEIGWIN: Okay. Let's turn to our colleague members from the PPDC on the phone. So Emily is going to open the line real quick. And so Lori Ann or Leyla or

Gina, I wanted to see if you had any questions or comments for Patty?

MS. SHULTZ: I do not. This is Gina.

MS. MCCURDY: I don't either. This is Leyla. Thank you.

MR. KEIGWIN: Thanks, Leyla. Okay. Any other questions from people around the -- Nina?

MS. WILSON: (inaudible) -- of the pilot program. So I'm going to speak without talking to those specifically. But I do -- I think the last meeting that we had about this, there was a little bit of concern about -- so usually biological products are pretty ubiquitous about how they're labeled because they're without exemptions for tolerance. I think there's some discussion about how you would handle that and not have a really defined use. I just wanted to comment on that.

MS. PARROTT: I'm not aware of that specific issue. But we do have the -- all of the divisions represented. So I'm pretty sure that they're speaking with their -- the appropriate technical contact. But if you have additional information for me, we can speak.

MS. WILSON: Yeah. We'll go back to our

membership and specifically ask the members that are on the pilot program about that.

MS. PARROTT: Sure, thanks.

MR. KEIGWIN: Okay. Any other questions or comments for Patty?

(No response.)

MR. KEIGWIN: All right. So we are about 15 minutes ahead of schedule. But we're going to use that additional time to try to fix the microphones at the end of the table. For our session that begins at 10:45, part of the reason for giving you some extra time -- and I know you're so worried about having extra time -- is that one of the members of the next panel is actually participating remotely and so will be joining us at 10:45. So we can't start Session 3 until that point. So let's regather at 10:45. And thanks to Patty.

(Brief recess, some background noise and mic checks.)

MR. KEIGWIN: Okay. So welcome back. For this next session, I'm going to turn things over to Ed Messina.

MR. MESSINA: Thanks, Rick, and thanks, everybody. This is what I hope to be a really

interesting session. I was asked to facilitate a discussion amongst our panel regarding emerging technologies, specifically UAVs, unmanned aerial vehicles; or unmanned aerial systems, UASs, or drones; goes by many names and each have distinct terms.

The panel is going to include Liza Fleeson Trossbach. As you know, Liza is the program manager for pesticides for the Virginia Department of Ag. She's also the current chair of SFIREG and the PPDC representative for AAPCO, and the past president of ASPCRO.

Damon Reabe is the president of Reabe Spring Services, the largest aerial application company in Wisconsin. He is here representing the National Agricultural Aviation Association and is currently the chair of the NAAA government relations committee.

And then we have Grant Canary on the phone. He is the CEO of DroneSeed, a company that helps manage and grow forests with swarms of unmanned aerial aircraft for governments, non-profits and private land owners. And they use UAVs to apply pesticides in these operations.

I just want to check before I sort of begin my introductory remarks and then turn it over to the panel.

Grant, are you on the line and able to hear us?

MR. CANARY: Yes, I am. And I am joined by Jennifer Flonacher, our VP of operations.

MR. MESSINA: Great. Can we get a test, Grant? You're coming in a little faintly. Can we maybe boost his volume? Or we'll kind of work on that.

Yeah, just speak up into your phone if you don't mind. You're coming in a little faint.

MR. CANARY: Sure, happy to.

MR. MESSINA: Okay. So from my perspective, you know, the increased use of UAVs in agriculture really represents an example of some of the transformative technologies that are currently shaping the world that we live in. You know, some of these larger societal technological breakthroughs include advances in microchip; computational capabilities and miniaturization; the connectivity of devices and the internet of things; artificial intelligence; 3D printing; robotics; voice recognition; and the ability to rapidly process large amounts of information and data and data analytics.

So technology is really changing the world

around us. And if you think about today how many of us checked into our flights; how we hail rides today; how we drive semi-autonomous vehicles; you know, vacuum our house. There's robots that will vacuum your house. You can turn on your lights with your voice; control the temperature of our homes. How we buy products, including groceries sort of at any time of the day from any place in the world. I mean, technology is really changing the world that we live in.

And you think about what these processes will look like in the future, the rapid changes is really incredible. And similarly the world of farming is changing through these technological developments and advancements, and will continue to change. You know, how we grow our food today may look very different tomorrow. And examples in this space include precision farming; the increased use of robotics; indoor growing; increasing use of data analytics; spectral imaging; the connectivity of devices; biotechnology and UAVs as an example.

So some businesses are predicting that UAVs will be a large sector in the coming years, and agriculture could be that large sector that UAVs space are going in.

And including the application of pesticides.

I have some pictures here, just pictures as a brief introduction. You know, this is sort of your -- you know, we think of these UAVs, this is like the toy. But they come in many shapes and sizes for many different niche applications. So early on you had your small hobbyist; you have now your professional film companies using these with greater and greater load capacities; you have -- you know, this is really a picture of somebody using more of a remote control. But this is, you know, spraying pesticides. This is from an article in Asia where a lot of these applications in Japan and China are happening.

And this is the Yamaha device, which is registered -- regulated by the FAA and approved for pesticide applications. Almost sort of a miniaturized helicopter. You can see sort of scale. And then we have, you know, other applications that you'll see some pictures in Grant's presentation.

So these are not an endorsement of any of these, but these are sort of the references of some of the technologies that you can see are sort of out there and

they're -- they vary and they have really interesting particular types of applications.

And they've been in this space since the 1980s. They're used to scout soil, water, crop conditions and now potentially spraying pesticides. The FAA, as we know, has regulatory authority over the safety in the United States air space of these devices, and then EPA has the regulatory authority over the pesticide chemical and the application equipment on the device, i.e. the nozzles and the application directions, height above crop and the like, as we know, on the labels. So when the FAA certifies a UAV operator or aircraft, they're still liable to abide by any state or EPA regulations such as the pesticide applicator license.

So the question here, and the reason for this topic is, how as regulators do we do our best to understand and adapt to these new technological transformations? One of the challenges for government regulators is in finding the balance between encouraging innovation in the space that they regulate while also protecting public health and the environment and ensuring a level playing field for our existing and our new

stakeholders.

Now, how does this technology fit into the framework that was created at a time where the technology didn't even exist? Right? So you've got the regulations that come about; they're designed to address certain problems. And new technology comes along and the technology may or may not have even been contemplated in the language.

So, you know, to the terms that were used at the time of that, do they apply today? So, you know, the example is aerial application. Does that apply to these devices? Those are sort of questions. And there's lots of other questions. And I think UAVs are a great case study for how advances in technology reflect the challenges and opportunities for regulations. And many questions instantly come to mind. Are there greater or less potential health and environmental impacts from their use? What data do we have or need to create to make sound policy decisions? What are the benefits? What are the potential next steps for EPA, industry and growers in this space? What policy documents, if any, are needed? Which ones should we work on first? What

lessons can we glean from other areas where disruptive technologies were adopted?

So these are just a few that sort of instantly come to mind. And I think our presenters will touch on some of these in their presentations.

So through PPD discussions like this one, the hope is that EPA can be more proactive and strategic in our thinking regarding the adoption of these technologies and their intersection with our regulatory scheme rather than just merely being reactive.

And the panel includes some great speakers who you know, and I'm really looking forward to that. And with that brief introduction, I will start with Liza; then we'll kick it over to Damon; and then we'll kick it over to Grant; and then we'll have time for questions later. So, thank you, panel.

MS. TROSSBACH: Thank you, Ed. So I was asked to provide comments on behalf of pesticide regulatory programs. So as I go through my presentation, you'll be hearing me say the word "states." But what I really mean are states and territories, and as appropriate tribes who are responsible for pesticide regulation in their

respective jurisdictions.

So the other thing I want to mention is all pesticide regulatory programs I feel confident saying have overarching goals of protecting human health, the environment, and ensuring the availability of pesticides to be used as appropriate. Of course, again, all of those states, we're all different. So while we're all operating under FIFRA and that general federal rule and our co-regulators of the EPA, our programs can vary. So I'm going to talk in great generalities. But what I may say is true for one state may not be true for another. So just to keep that in mind as we go through.

I would say in general that states welcome, you know, emerging technologies and chemistries. Pesticides is very dynamic. And I think that's part of the excitement and challenge working in this area. But one of the things is when these new technologies come into our portfolios, I'm going to call them, does it require consideration by the regulatory authority to look at their current programs, including laws, regulations, policies and procedures to see where they fit and how they fit. Because even if a new technology or new

chemistry comes in, if a particular state's laws and regulations do not allow that use as they're written now, then states have to consider that and have to determine how best to approach that.

Also, with government, we have a public process. Any type of lawmaking or regulations, there's a public process which may end up delaying the implementation or adoption of that technology in the particular state. It's not purposeful. It's not because we are not wanting that to be there. But we have a public process.

I know people say, you know, it takes government so long. Well, it does because we have to listen to everybody. If we could make a decision based on what we thought was best, you know, it might move a little bit faster. So those things have to be taken into consideration when we're looking at this new technology again.

And, of course, states will proceed at different paces. So you may have a state that has a very nimble public process or is a little farther along and has the ability to quickly adopt a technology or put in place a policy or procedure to address something that's new,

and then you may have another that has a much longer process. That can depend on how often their General Assemblies meet; how long the session is; there are other priorities, as well as human and financial resources. Because it is possible that a new technology isn't just simply adoption. There's a whole lot of other things that go along with that. And I'll talk about some of those challenges here in a minute.

When speaking about other priorities, a great example, I think, is Dicamba. As you know, there have been a number of years at Dicamba for over-the-top applications. There have been some issues with misuse, et cetera, and so a lot of states have had investigations and cases and complaints. For many states, that has been their entire program for the last year because that is a priority. And new technology, while still important, may not be the priority just based on the resources of that particular state.

So when we're talking about regulating unmanned aerial vehicles, or UAVs, it's relatively new to states. And certainly some states have had more experiences than

others. The technology was first introduced on the west coast of the United States, which tends to be where technology comes in, and then it slowly migrates to the east coast. So the west coast, Washington, Oregon, probably saw it first and are probably a little farther along in considering this technology or actually having it implemented in their states. And then as it migrates eastward, you have states like North Carolina, and my state, Virginia, that are just now starting to get those inquires about UAVs and kind of where they fit in our programs.

And it's a learning curve. It's a learning curve not only for regulators, because they're new, so we have to learn about the technology; how they work their limitations, all of those things. It's also for the regulated industry who is saying, you know, oh, now this technology is available, how does that fit into either my business model where I want to -- I want to be the applicator, you know, I'm going to do a commercial application, or for a private applicator that maybe wants to use it themselves. So there's a huge learning curve, and as technology advances, of course, we're trying to,

you know, keep up with that.

And there are a number of implications to pesticide regulatory programs that I'm going to just talk briefly about five of them just to kind of get the thought process going. One of the things that has to be considered or implications is there's implications for the certification of pesticide applicators. As you know, all states certify commercial applicators and private applicators that use restricted use products, and then they may have other individuals depending on their state. This has implications for certification. I'll talk about that.

Pesticide labels; the label is the law in all states, and then some states have additional standards above the label. So there are implications for the -- for the use of the products.

Risk assessments. This is a different use pattern potentially. So how will that impact, you know, risk assessments, and then again by default to labels. We talk a lot about UAVs in terms of ag uses. There's also a non-ag component. So that's something else that has to be considered.

And then finally amending laws and regulations and the time that it takes. And then there are a whole bunch of other legacy issues that follow programs. Again, while all states have some basic things they follow, every state is unique. And so consistency across states in their regulation will also be something that has to be considered.

So to talk about applicator certification, again, all states require certification of commercial applicators and private applicators to be certified. And when you're certified, there are core competencies and then also category-specific requirements or competencies.

So in talking about UAVs, one of the questions is who is the applicator? Another is what is the appropriate category for certification? Is it an existing category, for example, aerial application? Is that the appropriate category? Depending upon a state, the definition of "aerial" could be a little bit different and there could be implications there.

So is it -- you have a category and it's existing and you can just make changes to it, or is it a state feels like it needs to be a whole new category

because unmanned aerial vehicles are completely different.

And then also related to that are your training manuals for applicators and your exams; do they include UAVs or the information, those competencies. Are applicators being tested on that as part of that. And, if not, then you have to make revisions to those manuals and to those exams.

And I got this example of applicator questions, and this came out of actually the State of Oregon. So in this particular situation, there are five people involved in the application of pesticide using UAV. So person one does the mixing and the loading of the pesticide; person two is operating the UAV controls; person three is serving as a remote pilot in command and they have final authority over all the decisions; person four is the second controller who manipulates only the application equipment; the other person controls the aircraft; and person five is an observer who radios in advisory information.

So that's five people involved in this. Now, granted, this is maybe more complex than some, but this

is the kind of thing that has to be considered. You know, who is the applicator or applicators and how do they have to be certified is something that each state will have to figure out.

When it comes to pesticide labels, as everybody knows, the label is the law. We look at labels as a legal agreement between the registrant, the EPA, the end user and the regulatory authority in the state; meaning if you use this product according to the label, it's a legal use. There's an agreement. We know the labels mitigate the risk to an acceptable level. And, of course, failure to follow the label is a violation of state and federal law. And, of course, violations, because states have primacy, could end up in an enforcement action by a state. But also EPA also has -- still has the ability to take enforcement actions.

So some of the questions about current labels, for example, assuming all requirements can be met, do aerial applications include UAVs? And if yes, then are boom lift and rotor wingspan ratio requirements applicable? You know, if there's a specific requirement for that and UAV can't meet that, well, then is that a

legal application?

If a label is silent on aerial applications but not prohibited, can UAVs be used to apply a pesticide? Can that be the equipment that's used? PPE may be required; for example, gloves. But that could hinder piloting. So assuming the pilot is considered an applicator but doesn't contact the pesticides, are they actually required? And then you have questions about the worker protection standard and who is the handler. In that scenario with five people involved, who is the handler or handlers and how does the worker protection standard in an ag situation apply to them?

We also have questions about -- or things to consider under a risk assessment in ag versus non-ag. So in general states rely on EPA's risk assessment process. And, of course, from there comes the pesticide label. To date, those risk assessments have not included the use of UAVs. It looks at things like exposure with their use of the applicators and bystanders, drift issues, and I'm sure a whole variety of others. So there are implications for future use of products.

So from that you'll have amended labels, I'm

assuming in the future. So then you have that learning curve for applicators. And, also, for us as regulators, it can because as the industry becomes knowledgeable and these things become available, we as regulators also have to be aware of that.

I also had mentioned briefly that we talk about UAVs normally in terms of ag, but there are potential for non-ag uses. And so that is a whole 'nother area. While there are certainly similarities between ag and non-ag applications of pesticides, there are also differences, different exposure issues, different applications, different areas where they're going to be. You know, a hundred acres of something is very different than in somebody's back yard if you have, you know, a neighbor right there.

So those kind of things have to be considered not only by the EPA in their risk assessments, but by states. When we're looking at our laws and regulations, policies and procedures and saying how are we going to implement this; how does it work with our current laws. And, again, that will ultimately impact future use of these particular products. It will impact all the

players for pesticides.

And, finally, when you're talking about UAVs and existing pesticide regulatory programs and you're looking at laws and regulations and policies and procedures, one of the questions is, you know, do the current governing documents adequately address or incorporate UAVs? If they're silent, does that mean by default they're included or do certain provisions have to be made? And if they do, what kind of amendments are necessary? Is there something new that has to be put into place? Two very different things. Amending a regulation versus promulgating a new regulation can be two very different processes.

And then, you know, what is the process to put those things into place. Some states have a very long process. In Virginia, it's three years before we can get an amendment or promulgate a new regulation. That is what our process is. That's a long time for technology. You know, we're already behind because technology is already out there.

So you're always trying to kind of play on that catchup. And what do you do in the interim? You don't

want to -- you know, you don't want to prohibit a technology because we want everybody to have the tools that they need; right? But if our law has such provisions that you can't do it, so what do we do in the interim? Do we have the ability to put out a policy that says this is going to be our interpretation; we're going to do this in the interim; do we have the data to support that if we allow this use, in fact, it is protecting human health and the environment.

And then, again, just that whole thing about that legacy issue of consistency between states. You know, we also have to inform and educate the regulated industry and the other stakeholders regarding specific requirements for our respective states. Oregon has put out a whole policy document about UAVs and applicators, and that's fantastic. But it could be different in Washington; it could be different in Idaho; it may well be very different in Virginia based not only -- you know, based probably primarily on our cropping systems and our agriculture and our geography, but also our laws and regulations on how we certify people, how we register products.

So those are just a quick overview of some of those things that states and the pesticide regulatory officials programs have to consider when adopting or allowing this new technology into their respective jurisdictions. Thank you.

MR. MESSINA: Thank you, Liza. We're just getting the presentation loaded for Damon.

(Pause for loading presentation.)

MR. REABE: Thanks a lot, Liza. That was excellent. I won't spend a lot of time with introductions in the interest of time. I think there's going to be a lot of questions when we're done.

Just a quick note, we worked on this together with the USDA. There's an aerial application technology research unit in College Station, Texas. There Dr. Brad Fritz and I worked on putting this together.

I want to just provide my impressions of a roadmap that would implement UAS aircraft into the arena of making pesticide applications. It starts first by understanding that when an unmanned aircraft makes an application, in my mind it, in fact, is an aerial application. And the FAA clearly defines that in the regulations that are set up to regulate aerial

applicators.

And I won't read you the definition, but they don't make any delineation between a manned or unmanned aircraft. So when an unmanned aircraft performs a pesticide application, is it an aerial application? And in my opinion, it absolutely is.

Oh, we're going to talk a little bit about the things that we know. And what I did here was just went around and gathered up marketing materials that I was able to find online from various UAS manufacturers that are advertising their equipment to be used for aerial application.

They are advertising to use their equipment at scales equivalent to manned aircraft. And the reason why that's important, if this is the intent of the industry, then we need to -- we need to move quite quickly in the regulatory process to ensure that if we're going to do this amount of application that it's properly regulated so that it's safe for the environment and for workers and other bystanders.

These are the quotes. "The UAV crop-dusters are a cost-effective method to precision spray any liquid

product on smaller acreage up to whatever acreage you desire."

The next quote is, "Individual spot-spraying via hovering or mass acreage cover up to any size you require are all within our capability." So the focus here is to go into the ag market, into the crop protection on a large scale.

Here's another advertisement. This is a drone built to replace ag planes. And so, again, just to kind of -- setting the stage for an understanding of the scope that the industry is looking at. I'm not saying that they're necessarily doing this, but this is -- this is a market that UAS companies are pursuing.

We know right now at their current size they carry very small payloads. And for those that aren't in the weeds in crop protection application science, when you have a small payload, in order to get adequate coverage you need to use smaller droplet sizes. If you look at the AgDRIFT users manual, the AgDRIFT model is the model that is used by EPA to perform risk assessments for agricultural applications whether they be done by aircraft, ground sprayers or orchard blasters. Those air

-- all those tools have been through the rigorous field testing that was conducted by the Spray-drift Task Force throughout the ‘90s and into the early 2000s to come up with the data required to develop this model.

Nowhere in that model is there anything on unmanned aerial vehicles. It’s just for the three previous listed devices. Within that manual, they talk about the driftable material that comes from any of these types of application equipment, and that is for droplets that are under 141 microns. If you look in the -- in the advertisement, the spray droplet diameter that this particular manufacturer is advertising is between 60 and 180 microns. So it’s, in fact, actual driftable material as defined by the EPA. Not to say that these crafts aren’t capable of making larger droplets, it just makes their operations less efficient due to the small payload.

The next thing we know is currently the FAA is requiring visual line of sight from the pilot plus an additional visual observer. And Ed and I must have been on the same part of the internet. We’ve got the same photo. And what I’m trying to point out here is that the aerial application industry as a whole has made all of

its technological advancements at getting people out of the field. So we need to be aware of the fact that this particular application method is requiring now people to be at the application site.

Know that -- this is maybe harsh wording, but UASs are, in fact, able to deliver products under current label language to some extent. How efficient that is is yet to be determined. When the advertisement shows a droplet -- excuse me, application rates, the application rates for these two -- and when you convert these application rates to gallons per acre from the metric system, these are typically less gallons per acre than the minimum gallonage required for an aerial application.

And, again, because -- if you have a small payload, right, it's far more difficult with a small payload to have any efficiencies of scale if you have to put out large volumes. So when you reduce the volume, you gain some efficiency. The problem with that is it typically requires reducing droplet size classification, which can potentially increase drift.

Optimum spraying heights in this particular advertisement is one to five meters. All aerial

application labels state a maximum height of 10 feet. In this particular case, we're at 15 feet. I'm pointing this out, it kind of showcases a little bit of the maturity of the industry. Unmanned aerial systems are being developed by people who maybe don't have a lot of experience in either agriculture or in aviation necessarily. So this type of a situation kind of calls to the attention the need for appropriate regulation and education and compliance.

Here's -- here's something else we don't know. We don't know the pesticide drift characteristics of UAV platforms. And this is, I think, very important. Horrendous amount of field research has been done to both rotary wing aircraft helicopters, single rotor helicopters. This research has been going on dating back to (inaudible).

So we're finding ourselves in a situation where these devices don't look like a conventional aircraft. they may have four rotors; they may have six; they may have eight; they may have eight rotors and a fixed wing. Aerodynamics associated with that application out of that device are far different than anything that's been

studied.

The reason why this is important, the aerodynamics around an aircraft are, in fact, what determines whether or not there's going to be drift. If we don't know anything about it, this would seem like an important step to do research on.

These droplet sizes are oftentimes far below, far smaller, than the droplet size classifications that are specified on most agricultural crop protection product labels. So we need to do efficacy studies if that's the -- if that's the droplet size we decide to do -- use, I should say.

What's an appropriate application exclusion zone? Until we know the drift characteristics of the aircraft itself, we're unable to determine the appropriate size for the application exclusion zone. We know what the environmental and worker health impacts of the additional fills due to the small payload. So right now when you perform an aerial application, that aircraft lands; it gets filled at a certain frequency and it covers a certain number of acres. If we now have dozens of pieces of equipment that need to be refilled at a high

frequency rate, and we have to use smaller volumes per acre, that makes that final mix more concentrated. Each time we connect the hose to the aircraft, there's the potential for a spill. That risk assessment needs to be done. I'm not saying that it can't be done in any way, shape or form, it just needs to be looked at.

We need to consider how current aerial application equipment is used in agriculture. The vast majority of aerial application is conducted by fixed wing aircraft. Those aircraft are primarily -- the mixing process of those pesticides is done at a contained facility. The aircraft is then parked in a containment pad where it's filled.

So we have a central location that's highly regulated that's neat. Now we're going to do -- now we're talking about potentially doing all of this servicing out in the field. That may have -- may have environmental impacts.

So how do we ensure safety? Well, we can't make decisions based on assumptions. Right? Something that needs to be done, in my opinion, is we need to develop a Spray-drift Task Force-like group that is going to get

into the weeds of doing the studies that are needed to be done in order to accurately characterize the drift that's produced by these aircraft.

We need to develop best management practices for the operators of this equipment. What I did notice in my time doing the research for this presentation is that there are different methods that are used by the operators. When the aircraft is moved at a very slow speed, there's a lot of air movement down, and the deposition looked, in my opinion, quite neat.

As the aircraft begin to move faster forward, there began to be what appeared to be greater risk of drift. I noticed certain operators actually taking the helicopter and backing it up. All of these things, all of these techniques, have to be learned so that the operators of this equipment can do it in as a precise way as possible with as little risk as possible.

The results of all of that research need to find its way into the AgDRIFT model. the AgDRIFT model exists to help the EPA perform risk assessments for agricultural uses of pesticides. The AgDRIFT model is not used in the landscape arena, right, where you're using shielded

sprayers or other types of devices that don't have that same drift potential; or maybe the use pattern is so small it becomes unnecessary.

So -- but if we're talking about like I showcased earlier in the presentation, if we're talking about scaling up to replacing manned aircraft using this volume of work, we need to be accurately assessing those drift characteristics. It needs to be modeled. That tool needs to be available to the EPA to do that spray-drift portion of their risk assessments.

Once those spray-drift risk assessments are done, the registrants are going to have to figure out, okay, the droplet sizes that these devices can produce, are they effective? In certain pests that I treat, smaller droplets are, in fact, actually less effective. In other cases, they're more effective.

So depending upon what the unmanned aircraft system industry is able to produce in the form of droplet size classification, it's going to have a lot to do with driving the efficacy studies.

We talked about earlier the AEZ size. We talked about doing risk assessments to account for the

additional fills and the non-point mixing. These concerns that I brought forward so far in this presentation are echoed by the American National Standards Institute, ANSI. They are in the process of doing an analysis of all the various use for unmanned aircraft systems; pesticide applications is one of them. And they brought up six areas of concern: Communication, treatment efficacy, operational safety, environmental protection, equipment reliability and airspace integration. And I think we've talked a lot about environmental protection efficacy. Equipment reliability is something that also would need to be considered. Probably can take that in the question/answer time as well.

Are exemptions needed? They possibly are. It might sound like the guys from the NAAA don't want to see unmanned aircraft perform aerial applications, and that's actually not at all the case. Our association doesn't delineate between manned aircraft and unmanned aircraft. The applicators that are using unmanned aircraft in the United State at this time are certified by the FAA under Part 137. And they are, in fact, aerial application

operators.

The question comes in, how are they legally making these pesticide applications with the existing label language that is there? Are there instances where it wouldn't be appropriate to not perform the risk assessments? An example might be an application that's currently being done with a backpack sprayer, where somebody is walking backwards through a field, for instance treating parts of acres, total field size. Maybe that's something that needs to be looked at. These are all considerations for this group.

Just to sum it up, UAS pesticide applications are, in fact, aerial applications. Current aerial label language applies, and, frankly, based on the advertisements, is likely not being complied with. It seems like they're not nozzled appropriately to get the correct volume out; the width of the booms does not meet the criteria that is set forth in current aerial application language; application heights may not be getting complied with, et cetera.

Current worker protection standard rules apply and requires a more in-depth assessment due to the more

people onsite. And my -- my vision for where the EPA will go with this is eventually there will be unmanned aircraft system specific labels so that these operators of these various type of craft have more guidance as to how to safely apply pesticides.

MR. MESSINA: Damon. We'll move on to Grant, who is on the phone, and we have a remote presentation that Shannon is loading up. Shannon, just let Grant know when you're ready.

MR. CANARY: All right, great. So I've got audio there? How's that coming through as far as volume? A little louder for folks or is that okay?

MR. MESSINA: Just a touch louder.

MR. CANARY: Okay, awesome. I'll be kind of shouting over here. But -- so, yeah. So I want to talk about DroneSeed. You just heard from both Liza and Damon kind of what is the state of art and a lot of questions. And so really what I want to address is what is our business and then talk about our mission and then what our operations look like.

But just to respond to a couple things, like, what I would -- the way I would frame us is we're an

example of a great partner with a ton of experience with the FAA. We were an FAA leader in getting a 137 process, which is the permission for aerial applications by the FAA. And as a part of that process, we spoke at their symposium in Baltimore and it was really educating others on how to go through that process and get that.

I would break aerial applicators into three tiers. Damon's really alluded to some of the problematic, which is the hobbyists and farmers. You have then a next level up from that, one to three-person, like, operations. They're operating as consultants sort of moving past photography into what else can I do with this drone, and then working for municipalities, vineyards, things like that, making investments in aircraft. And even much larger entities like oil and gas, ourselves, that are making much bigger investments.

We're all in favor of the regulation. So you'll hear a little bit about kind of what we're up to as far as an aerial applicator. We absolutely follow the label. We're regulated by at least three levels of government. And we do not agree necessarily on creating a spray-drift taskforce. That sounds a lot like a five-year study.

And we can talk about the lessons learned with the FAA. But instead what I really want to point to is the FAA's Pathfinder program as really a great way to get a lot of data, which is what Damon is asking for, and an ultimate proposal there.

So let's just start off there. We've got the Team, Mission -- let's just jump -- I'm going to talk about the team for a little bit. Jenn Flonacher is here operating the slides and will be taking over most of the presentation.

But we're a venture capital backed company. We're up to 16 people. Our CTO, I'm just going to run really briefly through this here and maybe embarrass Jenn just a little bit. But -- so our CTO has led two startups, one acquisition by Microsoft, one merger. Jenn went to the U.S. Air Force Academy, then graduated from there; went to weapons school, which is the other Top Gun, and then became an instructor there. We have a hardware engineer that we had to compete with Amazon Prime Air and SpaceX to win into our organization. We have software engineers, one of which was from Liquid Robotics. They were acquired by Boeing. They do aquatic

multiple drone operations. And then we have our head of bio, which has done, you know, basically reforestation projects throughout the country. My background is about 10 years in developing companies and I've had one acquisition. So let's jump from there.

Our mission here and what we do and why we do it is to make reforestation scalable. Let's jump there. The process that we have today, and I'm going to highlight the terrain as well, is that the first step in the process for timber companies in the northwest that operate in pretty extreme terrain that makes it pretty difficult to just fly a flat line. The first step in the process is you're spraying, you're basically eliminating any competitive vegetation that would grow faster than your trees, shade them out and kill them.

Then you're planting. Let's go ahead and jump to the first video here. So we have some videos just to show kind of what it looks like. I mean, you've got sort of a flat terrain there, but then there's a cut and you should be able to see, if that's coming through clearly, like, this is a flare-out. This is what's demonstrated in the FAA's knowledge and skills test. I mean, this is how

you have to manage that difficult terrain.

Jump to the next slide there. The next step in the process is we then -- you know, you then go out and you plant the area. So this is how the most sophisticated companies in forestry are replanting the 300 million acres that have been deforested since the 1990s.

And then you can jump there. We basically -- then you follow up and you spray anything either by backpack or otherwise just to catch anything that you missed afterwards. The process is incredibly manually intensive.

So let’s jump from there. Jenn, I’ll turn it over to you to talk about our solution.

MS. FLONACHER: Yeah. I haven’t done a test yet, so how’s my volume? Am I coming through okay?

MR. MESSINA: Yes.

MS. FLONACHER: Can everybody hear me?

MR. MESSINA: Yes, we can hear you.

MS. FLONACHER: Okay, great. Perfect. So, yeah, so Grant kind of talked about the antiquated processes. So what I want to present to you is kind of

our solution to that. What we're trying to do is make forestry a precision job. We want to do that through a couple methods that we (inaudible). One, by automating the software. Through software automation, we can reduce the risk of human error by creating missions that are preprogrammed to fly particular routes with algorithms that define the altitude, the swath width, the speed, which all will come together to determine the rate of spray or the rate of application.

So from that we get a higher precision application and increase the safety of the operators around us. We have reduced skips, overlaps and drift as a result of that. It also reduces the risk not only to the personnel around, but also to the environment.

For one, the vehicles are unmanned. So there's no personnel on board in the event that there is a catastrophic crash or incident. We also carry smaller spray payloads. So if there is a catastrophic crash or incident, then the amount of pesticide or herbicide that we're spraying or is spilling into the ground is just at a maximum six gallons.

So it also reduces the chemical exposure by

reducing the amount that we utilize and the individual exposure to that chemical itself. There's only one point at which we're handling -- or two points at which we're handling the herbicide. One of them is when we're mixing and loading, and then when we're moving it to the aircraft, which we do in closed containers. And I'll talk through the operational process here in a couple slides.

Our operations specifically. I'd like to show you two videos that kind of highlight a couple aspects of our operation. The first one shows a spray over cliffs and kind of the harsh terrain that we can operate in.

MR. CANARY: And Jenn and I are going to kind of tag team on this. But what you're -- it's coming through potentially a little choppy on your end. But what you're really able to see is how we're navigating the terrain using LiDAR and software.

And, Shannon, are you able to give us some feedback from how that's coming through on your end?

MR. MESSINA: Yeah, we can see it. It is a little choppy, but I think it's coming through. And for folks on the phone, if you are not speaking, can you mute

your lines? We're getting some keyboard tapping here and there. MS. FLONACHER: So this is just a sample of one of our operations. I've got one more video that shows a little closer what some of our swaths look like, and I'll show that here.

MR. CANARY: This, by the way, is one of my favorite videos. Go ahead, Jenn.

MS. FLONACHER: Yeah. So what you'll see here is a single vehicle operating near the tree line. But what it highlights is the actual application itself a little bit better than the other video did. What I'll note is that I think that Damon mentioned earlier that UAVs have to -- or that UAVs have multiple people on site to oversee the process. And that is true. Our crew that we utilize is managed by three people.

One of those people is a ground control operator. So they manage a ground control station that oversees the actual application. Another person is a pilot, and that pilot's role is to -- is to actually fly the aircraft only in the event of an emergency, or if for some reason the software doesn't take over. The pilot's

decision-making abilities are actually binary. The software and the algorithms actually determine the entire route of flight, the spray on and off of the system, et cetera. All the pilot does is make adjustment calls to whether or not the system or the software is performing the way we expect it. And if not, they take over manually and land the aircraft.

So what you'll see in this depiction here is what our actual operations look like. I'll kind of move from far left of the screen to the far right. On the far left what you'll see is our crew setting up a ground control station. In here there's six people. This was a demonstration that we did. So we have extra crew members on site. But normally there would only be three. But the location that the people are grouped at is where our ground control station would be set up.

That's the location that the computer operator that runs the software will be set up. That person also acts as what we call a PIC typically. The PIC is the one person, like a foreman on the jobsite, that's in control of the entire -- that makes the overarching decisions for the crew on site.

Right next to them will be the pilot. The pilot, like I mentioned earlier, is only there kind of as an emergency response. They'll also pre-flight vehicles and test the vehicles. And I'll talk to the operational processes here in a second.

Then the third person would be the visual observer that would typically be located closer to the application site still outside of the AEZ. And we utilize our own AEZ that's outside of the 100-foot standard that the worker protection standards require. But we actually calculate in a 40-meter buffer around all of our equipment, our ground control station and then the known locations that we've preprogrammed for each of the observers. So that's, I think, super important to note here is that we have a plan for that and it exceeds what's already defined by the worker protection standards.

So moving from there, you'll see the big white truck. That truck is actually a mobile battery charging station. So this is where we charge all of the batteries that we use for the energy source for the drone itself. Moving slight to the right of that, you'll see the batch

tank behind the generator. That is a standard batch tank that 10 spray crews would utilize, and that's sufficient for our operation.

Next to that is the generator that powers the battery charging station. And then on the far right-hand side of the screen, you'll see our launch zone. So in this particular launch, we were launching two vehicles. And you can see each of the launch pads and their individual launch points. We typically launch vehicles about 10 meters apart from each other. And then, of course, I mentioned earlier 40 meters from the equipment and the vehicles.

So I'd like to quickly talk through our operations, too, and how it works. I mentioned the three crew positions. But -- I'm sorry, was there a question?

Okay. So I mentioned the three crew positions. So what occurs when we actually -- during our actual operations is we set up the site, and for all ground operations each of those crew positions has a particular role in the ground operations. There is one person that is designated as the chemical handler all day. And they are the person that will be mixing and batching the

chemicals as well as filling the drones. We fill the drones by first filling a closed container from a hose from the batch tank and then moving those closed containers over to the vehicle, filling them through a large-mouth funnel and then into the vehicle itself.

The vehicles, as you can see, they are on launch pads that are absorbent and can contain any small spills should they occur when the vehicle -- or during the servicing of the vehicles.

Another person will be -- will be responsible for charging the batteries during that ground portion of the servicing. And then the other person, typically the pilot, will perform pre-flight inspections of the aircraft once the two servicing components are completed to make sure that the aircraft are ready for flight operations and prepared for flight.

Once the vehicles go airborne, we do typically operate a swarm concept. Right now we're currently operating up to four drones. We have a concept of operation that defines our operations for up to five drones. And that's all managed by those three people.

So the drones take off on 30-second intervals.

They fly up to what we consider a safe altitude and then transit to their operational area where they will be performing a spray, and then they descend into that area to an altitude of three meters, which is about nine to 10 feet. That altitude, they do follow a -- I'll call it a modified terrain funneling concept where we take a -- we use the LiDAR that we talked about before and I think Grant mentioned, and they determine the median terrain for a swath and then they fly that.

We also -- it's also important to note that we do fly along the contours and we define our missions in the contour of the terrain so that that swatch is relatively the same altitude or as much as possible. So generally we are staying about 9 to 10 feet above the ground. So they take off; they do that individually on 30-second intervals.

A couple other things to highlight with our operation is that each of our crew has a very specified lookout doctrine that manages keeping eyes upon the inside, I'll call it, on the computer screen for the GPS operator that's managing electronically the work environment. And then between the pilot and the observer

themselves, they switch between eyes on the vehicles, keeping a scan pattern throughout the entire airspace that we're utilizing, and the airspace around it. And the reason that it's important to focus on both is kind of what Damon mentioned with the risk to the other aircraft in the area.

We have eyes on the vehicle that's primarily on the vehicles that are operating, is watching the spray pattern; monitoring for the effects; making sure we don't have clogged nozzles; making sure that we don't have any drift effects and that all the equipment is operating properly and that the vehicle is in a safe position. The person that's primarily on the airspace is monitoring for things like birds, manned aviation in the area, et cetera.

A couple of our statistics from 2018, just to kind of describe where we're currently at. I already talked at length about the crew complement and our swarm size. I do want to highlight that right now we're spraying approximately 30 acres a day with vehicle payloads independently of four to six gallons.

What this gives us is an approximately -- about

an 8 to 12-minute flight. We can service about three-quarters of an acre to 1.1/1.2 acres per vehicle per flight. We operate at a forward speed of 11 miles per hour. So that's dependent upon the gallons per acre rate that we're applying. We operate within the label limits. Our typical gallons per acre is about five. But we have done five to 10 depending -- doing some testing for customers depending what the customers want to see as well.

Swath width at our planned altitude is 14 feet. That again varies by the altitude that we would apply it. And that's based upon obstacles. Pump rate is 1.8 gallons per minute, and our nozzles are 500 micron nozzles that we're utilizing.

I just want to highlight one thing on this slide here, and that's kind of the prop wash aspect of it. If you look at it versus the helicopter, this is -- this flight is based upon an independent study that we did. Our GS-10 aircraft, the power of the wash is 2.8 horsepower versus the helicopter at 228.5 horsepower, and then that produces a total volume of wash of 23.38 meters cubed per second versus the 970.6 for the helicopter.

In terms of safety, I think this is a really important part, especially for this audience. Right now we require all crew members to hold Washington State Department of Agriculture operator licenses. Additionally, for the states that we operate in, we require licenses for the states that while we've worked very closely with Idaho and Oregon to acquire those licenses, I thought it was ironic that Oregon was mentioned earlier because we've worked directly with them to define the license requirements for our crew members.

And with our three-person crew with Oregon have determined that our GCF operator, who is the one actually controlling the application via computer, as well as the PIC, who holds the authority over the decision-making of the vehicle, are the two crew members that will require Oregon licenses. So we're working with them to accomplish the training required to meet that, as well as develop a training program and reinstate their aerial applicator training license that was -- I think it was instated about 20 years ago and then they got rid of it because the helicopter pilots determined it wasn't necessary. Now finding that for our business and our

operations that it is and would actually improve the safety, we're working with them to reinstate that program so that we can offer a trainee program to train our other internal employees.

We're also fully Worker Protection Standard compliant and offer worker and handler training to all of our employees, not just our operator. We have an extensive safety and PPE protocol. So we have customer -- customers that are highly regulated that we work for. We follow all of their PPE requirements and safety programs as well. And our internal programs meet or exceed all of those customer requirements.

Some of our internal safety programs include monthly safety meetings; specifics to herbicide handling for the equipment that we utilize; as well as other customer-specific requirements that are based on timeliness; and then job site-specific hazards to the time of the year that we're operating in.

We also have an internal safety program that employs our own risk management and risk assessment tools prior to every operation, and then we also do internal auditing on a notice and no notice basis to make sure

that our crews meet the standards that we've set for them.

So with that I'd like to kind of talk about our implementation process, which is how we got here; the regulatory -- the regulatory process that we've already gone through to get us to the point that we're operating today. So we are the first and only FAA approved company to use the median UAS swarms for spraying. Through that, we've been through two different extensive waiver processes, one in 2017 to get an exemption to operate up to 15 aircraft up to 55 pounds, and then one in 2018 that we -- to get us to operate our two primary application aircraft up to weights of 98 and 115 pounds, respectively. So that allows us to operate with those four to six-gallon payloads that we were referring to earlier.

Grant, I think you had the numbers on how long this process takes, but I want to highlight that we have been through -- it took us a long time to get them, but we were a good partner to the FAA and that partnership was extremely important to us.

Grant, do you remember how long those were?

MR. CANARY: The 2017 was three trips to Washington, D.C. and about 221 days. And then the 2017 was again three trips to D.C. and meeting with, in one case, 23 members of the FAA to have a meeting to explain what we were up to; and that one took 280-plus days. And then you had the FSDO with the knowledge and skills, which you're going to head to.

MS. FLONACHER: Yeah. And what I want to highlight is a part of those reviews, we had engineering and human (inaudible) reviews for all of our hardware, software and user interfaces. I think that that process was probably what took the majority of the time because we went back and forth with the FAA several, several times about the aircraft engineering and the in-house work that we had done on it, as well as the user interface and the screen characteristics of the program that we were utilizing to operate the vehicles.

In addition, they did a strict evaluation of those user interfaces and also our operational procedures and internal programs that we were utilizing to manage this process to make sure that not only at this point in time were our procedures -- or our equipment and

processes good enough to meet the requirements of the FAA, but also that we had the ongoing ability to maintain these programs. So they did these by checking our maintenance processes and our maintenance logs, our training, hiring, and other internal safety management processes.

And then Grant kind of already alluded to earlier, but as a part of this myself and one of our other operators took the part 137 skills and knowledge evaluation and we actually went through that twice. My predecessor also went back in 2017 after the approval of the 15 vehicle exemption, and then I went through it for the multi-vehicle exemption in 2018 with one of our other operators. And we worked with the local FSDO to make sure that we are -- that we've been kind of compliant with all of their requirements for Part 137 as well. So what I have now I'd like to show you --

MR. CANARY: But that also -- I'll also mention while this video is playing that, yeah, that doesn't include the WFDA on-site inspections both to our facilities where we build, operate and maintain the aircraft, as well as on-site, and then also presenting to

the Idaho State Department of Agriculture also what we were up to. And then in addition to that, the customer safety meetings and the aerial applicators, basically us out on site with our customer. Our customer has a forester that basically is similar to operating a helicopter is there the entire time. So there's definitely multiple layers here of regulation.

MS. FLONACHER: Correct. So this video is the actual demonstration that we did for the local FSDO for the Part 137 skills portion of the test.

MR. CANARY: And the interesting thing about this demo, too, is that behind the camera here there are six FAA inspectors because we're pioneering this knowledge and skills test. So normally you would have one and you would demonstrate your flare-outs which I alluded to at the beginning, amongst other aspects of the knowledge and skills test. But because we're pioneering this, they sent six inspectors out, one heading up what's happening -- you know, basically the drone regulatory space, and the other five for training purposes.

So, yeah, as you can see, we kind of try and keep this as confidential as possible and internal. But

for purposes here, it's useful.

MS. FLONACHER: And what you're not hearing are the very strict protocols that we have for communications. We utilize a two-way radio for constant communications with -- between the crew members. I'll also mention that we have on site a VHF radio where we're constantly monitoring the guard frequencies as well as any other local frequencies or common frequencies for the area.

As an example, one of our customers has a fire watch that continually goes at the same time every day. We were able to coordinate through the customer with the fire watch to be in constant communication during our operations when we knew that they would be in the area. We also, in accordance with our -- in accordance with our exemptions, we have a COA and we post a NOTAM for every flight, and that depicts the area that we're operating and the altitudes that we're going to be in. It notifies all of the traffic in the area that we will be in operations there.

MR. CANARY: How are we doing on time, Ed?

MR. MESSINA: A little over, and we're going to

let folks break at noon. So we've got about -- and I do want to save some time for questions, too.

MR. CANARY: Okay, cool.

MR. MESSINA: So maybe you just want to wrap up in the next minute or so, we can open it up for questions.

MR. CANARY: Sure. Jenn, let's just jump one slide and then wrap up there.

MS. FLONACHER: Sure. So to this point, kind of what we want to highlight is that we have been working within the label restrictions for all the chemicals that we've been applying. But we're looking for a way forward that is specific to the UASs. So like Grant mentioned at the beginning of his presentation, what we'd like to recommend is kind of an EPA version of the FAA Pathfinder program where we're partnering with the EPA, sharing our data and continuing to operate so that we can advance the industry and do so in a safe and efficient manner. And with that, I'll wrap.

MR. CANARY: Yeah. And I'll just close there by saying that I think that there are a lot of lessons learned from what the FAA did and that they really --

they really did an admirable job of not sort of stonewalling and saying, hey, we need, you know, three/five years worth of data before we, you know, let drones operate out of anywhere other than this small, tiny area in, you know, three acres over here in Connecticut or something. They did a great job of engaging the leaders in the space for both the software and the hardware, and I think there's a lot of lessons learned there.

And we'd really like to point to that and say, yeah, we're absolutely in favor of more data; we're absolutely following labels; we're absolutely in favor of safety culture and continuing to build it just like the FAA wants. But from our perspective, it's important to engage as opposed to sort of, you know, stonewall or say what it's like. It's not a -- you know, nothing can happen until more data is available.

MR. MESSINA: Great. Well, thank you for our three presenters. I thought that was -- hopefully you found that really interesting. I thought that was incredibly exciting new technology.

So questions from the group? And I can't see

all of your name cards. I might rely on Rick to --

MR. KEIGWIN: Okay. So, Sharon, then Dan, then Andrew.

MS. SELVAGGIO: Well, first of all, thank you so much for including this. This was really, really helpful; extremely interesting; appreciated all the overview information. A lot of really important questions that you've raised in your overview documents in particular and it's really interesting to hear the perspective from a company that's doing this.

I'll share a very brief, little story just as a very small example. Last summer I took my 19-year-old son who loves his drone to Iceland. And any of you who have been there know what an amazing place it was. So the most memorable experience that we had was losing his drone. And I have no idea how much he paid for that. He wouldn't tell me. But we spent three hours finding it.

We did find it. Partly I realized that I hadn't taught him much about really how to understand maps and what the capabilities of his phone actually were. But it -- in just remembering that experience, it does point out the possibility of an unexpected circumstance, what we

would normally term an incident, a spill associated with that, a crash, you know, a loss of equipment that's carrying toxic chemicals.

And I know -- I'm surely not the first person to have thought about this in regard to drones. But I just think that these types of things really need to be considered as the technology moves forward through whatever the process, the regulations, that will ultimately unfold.

I'm curious because this is so new, but it sounds like it's in place and it sounds like the recognition that we don't really have yet as sort of the regulatory and scientific landscape that has actually really foreseen this technology that we have more questions than answers at this point.

So I'm just curious about a couple of things really quick. First of all, have there been so far any incidents, and if there have been, what has any -- you know, what has that incident taught us? Is there any case law associated with that, so on and so forth?

Secondly, you mentioned the policy document that's been put out by the State of Oregon. I'm a little

embarrassed to admit this because I live in Oregon; I didn't know about this and I feel like I should. But is it possible to share that with the members of this group? And you call it a policy document and I'm assuming then it doesn't have the force of any kind of regulation in Oregon. Okay.

MR. CANARY: So a lot to unpack there. I want to first hit the, like, what happens in a lost link scenario because that was one of the things that the FAA explicitly asked us to demonstrate, which is what your son experienced. It's most commonly caused by not setting the home location of the aircraft. So if you travel from Oregon and then you're in Iceland and you haven't reset the aircraft to say it has a home location, that's how really sort of the hobbyist drones work.

Jenn, can you talk a little bit about the knowledge and skills and what we've demonstrated there for the FAA about how that works? And then I think -- and then we'll unpack the rest of that.

MS. FLONACHER: Yeah. So in the knowledge and skills section for the FSDO demonstration, we demonstrated a couple different emergencies; one of those

emergencies being that the spray systems failed to turn off at the end of a swath and how we would overcome that and what we would do. The second of those emergencies being what Grant talked about, which is a lost link scenario. And we demonstrated that from two aspects. One, that we lost link with the RC controller, which is the control in the pilot's hands that they use in the event of an emergency; the second one being a lost link from the computer that actually defines the flight path for the application.

In both of those scenarios, there's a designated amount of time that the vehicle will essentially time out and then it will return to that home location that Grant said. In our case, we have an additional failsafe that a lot of the hobbyist drones don't have, and that is that from wherever the vehicle takes off on that flight, it will return to that point at a designated safe altitude that we've predetermined through those LiDAR studies. So it will always go back to that home point.

We've had over 20 different failsafe scenarios due to lost links. Usually it's a lost line of sight in the terrain that we're operating in. And in every single

on of those, we've successfully come back to the home point or we've regained the signal once the vehicle initiates that process. So in all of those it's maintained that geofence that we've programmed in. So we've never had an issue.

The second one in the spray application where the sprayer didn't turn off, we have two or three failsafes built in for that, two on the computer; one on the RC controller. The first one of those initiated stopped the spray immediately within a half a second of when it was called for. And then we returned to launch that vehicle successfully as well.

So I'll also highlight in terms of the incidents, we have had a number of incidents. We've had hardware fail. We've had software fail. In all of them, we have had -- we have response procedures in place, an emergency checklist for each one of those and have had successful responses to all of those.

MR. CANARY: The FAA defines, like, what's -- the reportable incidents as you have monetary value, and then the EPA has its definition for a spill incident. And we've had no incidents along those lines, and

1 therefore no case law.
2 The -- what Jenn is referring to there is in our
3 operations as we're testing aircraft, you know, there are
4 a number of features that are built into the aircraft for
5 the hardware, for the software, and one of the things
6 that I'll highlight in that is that should an aircraft
7 crash, it's got designated crumple zones much like a car,
8 carbon fiber as opposed to bumpers, and those absorb the
9 shock for the tank.
10 And so in terrain flights, R&D flights, we've
11 had no reportable spills and we've had no FAA reportable
12 incidents. You know, it's aircraft, it's R&D, so we set
13 up very specific parameters for how we operate and how we
14 test the aircraft. So, of course, in that you would
15 expect that you're like, hey, what happens when we do
16 this? And then, yes, we see what happens when there has
17 been a crash.
18 MR. KEIGWIN: So, Dan?
19 MR. KUNKEL: Yeah, thanks Rick. Just a couple
20 comments. With specialty crop growers, I think they'll
21 probably continue to rapidly adapt this technology
22 because of the small spaces that they're -- small

properties for the various commodities that they're working on. So that the regulatory programs keep up with the adoption would be much appreciated.

And it was mentioned a little bit, but also these aircraft are also very important for deploying some of the beneficial insects. We see that in the specialty crop area.

MR. KEIGWIN: Okay. Andrew; then Damon; then Liza.

MR. THOSTENSON: I'm Andrew Thostenson with North Dakota State University. A question that I have is regarding a slide that you actually kind of skipped over where it talked about prior guidance from EPA; a quote from Don Lott there. And I guess my question is, has EPA actually issued guidance regarding the -- you know, the use of drones and "exemptions" or whatever from rotor or fixed-wing, you know, boom heights or boom widths and those sorts of things? And has EPA contemplated empaneling some group or workforce to come up with some kind of official guidance on that?

MR. MESSINA: Yes, great question. This is Ed. So I was brought into this issue and someone cited the

Don Lott guidance. And I said, oh, you know, after working on this topic, maybe I should take a look at the Don Lott guidance.

And the Don Lott guidance is an email that says that aerial application includes the UAV. So that's sort of a step one decision, which I think as Damon pointed out is probably fairly consistent. And then it does say that UAVs need to comply with label requirements. There's one exception in that, which is the boom length because the rotor sizes are different from -- and the payloads are -- you know, the footprint of this device is different. So in that email it says that's the only exception.

So that's the current "policy." So obviously, you know, my introductory remarks were sort of setting up the example of where you have this new technology and you have existing regulations; how do you then fit this new technology into the existing regulations where that language necessarily didn't contemplate that thing existing? And I think all the great points that Damon brought up in terms of the health and safety and the testing.

And I agree with your point. I think this is part of that beginning discussion around this where I think we want to get ahead of this and want to create some understanding about what are the things you want to look at first; what are the things we want to develop.

On the one hand, the drift potential is almost fairly small, right, compared to an aircraft that's got to do these giant flare-outs that's flying 10-feet above. You can almost have a UAV device, like, at the crop height; right? I mean, inches above if you want it. It's almost analogous to a hand sprayer in some cases, right? So they're -- that's one aspect.

I think the fine particle size is an important area we need to explore and the differences that creates in drift. The precision of these things where you -- right up the property boundary and it's using LiDAR and it's using computer imagery to really -- the difference or maybe additional precision that these devices can do versus an airplane where it's sort of maybe more line of sight and you're kind of overlapping and you can really have the precise movements of these devices; right?

So that's an area to explore as well. So that's

exactly why we're having this. All great questions. And that's kind of the current status of things. But, yeah. Follow-up question?

MR. THOSTENSON: So just to follow up on that, is -- we talk about how the label is law, except when it's not in the law in this situation. When it comes to spacing, swath spacing, on rotary and fixed-wing. And I completely understand that, you know, the ground, travel speed, all those other sorts of things are different. I mean, I get that they're different. So what is EPA's position on saying this is an exception for UAVs or, you know, in working with the manufacturers of the pesticide label companies to keep the label the law instead of whenever it's really not the law?

MR. CANARY: Yeah, I can jump in on that.

MR. MESSINA: If you want to jump in, yeah. I mean, I don't -- hopefully that's not the takeaway; right? I think the takeaway is that the label is the law. I think the takeaway is you have an emerging technology that we want as a tool for growers that we want to make sure we've protected public health and the environment at the same time.

And so it will take some time to develop that. I think, you know -- and, Damon, if you want to recite -- you know, you think about the beginning of the fixed-wing aircraft industry and how that sort of took off, we also don't want to make this maybe potentially some of the same (inaudible). Damon --

MR. REABE: Yeah, I'd like to comment on a few things because I think you're bringing up an excellent point. And for starters, I think, Ed, you just characterized the issue perfectly. You explained how an unmanned aircraft might be able to be inches above the ground and have a deposition that hits the target; right? We need label language that sets a maximum application height if we're not going to do spray-drift risk assessment; right?

So if we're going to be 10-feet off the ground with a manned or unmanned vehicle, we need to do spray-drift research so that we can model it, so that we can do proper risk assessment. The reason why the EPA doesn't do spray-drift risk assessment for shielded sprayers is because there's no risk. When we release -- and, by the way, I've got to back up a second. If every

single company in the United States conducted business like DroneSeed, we wouldn't all have to take time out of our day to come here. Would we? Right? If everybody was as thorough and professional as DroneSeed, the need for regulation wouldn't exist at all.

The problem with our industry is just that; right? The reason why we work with the EPA on various issues is because we have to go to worst-case scenario to the person who doesn't know any better. We have to provide direction under the auspices of law so that mistakes aren't made.

In the case of DroneSeed, we're dealing with a group of people that are very, very competent and very, very conscientious in setting the standard at which this should be done, which is wonderful. The point is that that doesn't mean that there isn't the need to do these -- to do these various studies. And as Ed said, the maximum height is a great example of that.

We talked a little bit about incident information. And I think it's wonderful that DroneSeed has not had any incidents. I think we're talking about a fledgling industry that hasn't conducted enough

operations really to have any actual meaningful data. Not to say that it can't be done reliably; not to say that DroneSeed isn't doing it to a very high standard; it just means there's not enough background information.

In regards to the precision application things that were discussed by DroneSeed, I want to make it very clear to this entire committee that other than the maneuvering of the aircraft itself without a pilot, all of that software is the actual technology. The on/off control, the use of Shapefiles, the flow control, these are all things that are onboard our aircraft right now.

We can have automated on/off controls. It's existed literally for about 25 years. Use of Shapefiles for mapping treatment areas has been around for a very, very long time. This is -- this is not in any way -- that part of it is not in any way new technology. Aerial application of manned aircraft can perform precision application at appropriate scale.

And that's where I think these particular devices have such a wonderful fit, is because they are, in fact, scaled down. And I think you brought up a great point one of the potential uses. I think maybe what

DroneSeed is doing, I'm not involved in forestry work or operation, but what they're doing looks remarkable.

MR. CANARY: I'd love to jump in at this point if that's -- if I've got the stage there. The -- first of all, thank you. We're very proud of the operations. I'd love to hit the max height issue. That language there, we've got, for example, on the Alligare label, applications must not be made at a height greater than 10-feet above the top of the target plants unless a greater height is required for aircraft safety. And that's really what most of the helicopter applicators utilize when they're saying, you know, this is how we do the flareouts and this is why. And so some of that language is already there.

I would love to talk a little bit about the FAA because what's been alluded to is -- and their Pathfinder program. What's been alluded to is, like, hey, we need data, we need information. And, also, you know, who -- who are we trying to legislate? Are we trying to legislate for the lowest common denominator or are we trying to legislate for higher common denominators? And so if you take the FAA, they had a choice early on where

they said -- you know, they had people asking for, hey, how do drones affect humans when they land on their heads? And they had people that were like, well, we need to get cadavers and we need to study it, and those studies are ongoing. And, hey, how do drones affect 747 engines when they go through them? And so they actually have done that.

But they didn't stop and say, hey, you know, we can't let anybody operate until that data is acquired. What they did -- and this speaks to who is legislated too -- is they basically said, wow, we're behind the eight ball a little bit; we're getting inundated with applications; so what we need to do is we need to create a Pathfinder program for some of the most professional operators we can find to basically acquire more data.

The FAA is a data-driven organization. They do a great job of that. And so they didn't say, like, okay, none of these people can operate. They said, hey, we're going to set up an application process for pathfinders to be able to do things that we don't normally -- we aren't normally big fans of as manned aviation.

And that really allowed them to acquire a lot

more knowledge and then legislating what came out of that is the 107 process, which took all of the legislation related to UAVs and put it into one statute and then codified it be under 55 pounds; completely arbitrary. It had nothing to do with cadavers or, you know, how -- how a drone impacted a human if, you know, they were hit.

But that basically created the framework for that. And they did a -- you know, I would highlight that that did two things for them. One was that they didn't -- it basically -- if they had tried to say we need all of this data before anybody can operate, what would have happened is it would have forced the good operators out of the space because they'd have said we can't operate legally. That would have been the Boeings, the Northrops, the Yamahas, et cetera, that are doing things in this space. And it would have -- you know, the people who were bad actors already would have just continued as-is because they didn't care about the legislation in the first place.

And by doing that, they actually reinforced a safety culture where very similar to hunting when you -- you know, there is a safety culture of I would

actually -- you know, a hunter would actually -- if they see something that's not okay and they know it's not okay, it doesn't reflect good on them or what they do or the pastime that they love, so they'll report it to agencies.

And they actually created a self-policing, self-beneficial program to help them because, you know, had they stonewalled and said, hey, we don't -- we don't want to allow anything to happen until we have this data, what would have happened is it would have been just the next victim of the Airbnb or Lyft or Uber-type mentality of our company is just operating and doing it and then getting to plow all of their budget into enforcement.

Instead, they said let's get data, let's create partnerships with great actors, and then they created a culture where the community helps police it itself. And that's really what -- one of the things that, well, we're not one of the Pathfinder members -- basically we came along a little too late for that -- they basically said, great; come to our symposium; speak on behalf; help us educate. And that's something that we've done despite the fact that it's just creating competition for ourselves.

So that's something I want to put out there for everyone.

MR. Messina: Thanks, Grant.

MR. KEIGWIN: Okay. So, Liza, then Richard.

MS. TROSSBACH: Just real quickly to follow up on Andrew's comments. And so the group known as APCO has put together a technology workgroup, and one of the first things that they're looking at is UAVs from a pesticide regulatory perspective and some of those issues to help the states come along. They're doing that.

And then also for, of course, any work that EPA does, SFIREG stands ready to help provide that perspective from pesticide regulatory officials.

MR. KEIGWIN: Thanks, Liza. Richard?

MR. GRAGG: Thank you. I find this very interesting and very promising. But I didn't hear from the person online where their research was addressing any of the issues raised on what is not known in terms of these type of vehicles and application processes for what we don't know in the presentation, pesticide drift characteristics, efficacy of droplet size, and the other ones that were mentioned.

So are they interested in doing that kind of

research and getting that kind of data? Because they kept referring to the FAA, but I think the FAA doesn't do the same thing that the EPA or whoever else is involved in this. I just heard sort of a one side of the technology part and not so much of the other issues that are very important in the success of the technology; the use of the technology.

MR. CANARY: This is Grant with DroneSeed. I guess that's addressed to me. I'm referencing the FAA because we'd love to see the EPA do something very similar; create a Pathfinder program to acquire data as deemed necessary to be able to understand some of those characteristics. We do our own internal studies for swath width, for droplet size. That's why you saw that data on the slides as far as, you know, 500 micron nozzles, et cetera.

And so from our perspective, yes, we do that and we'd absolutely love to be, you know, in an EPA version of the Pathfinder program. So I'm using that as an analogy to say, like, this is the direction the EPA should go; is create an open program for 10, 20 companies to participate and be allowed to legally operate.

Because you can't acquire that data if companies aren't operating and there aren't any partners.

The EPA is not going to go fire up five drones and their battery charging truck and go and test it itself. And waiting three to five years to acquire that data via academia is probably not the -- it's probably just going to create a huge backlog of bad actors. And that's -- or hobbyists that are not bad actors but, you know, in that there will be bad apples.

And so -- and I think the FAA was a little slow in actually getting its Pathfinder program set up. By the time they launched their 107 process, the first day they had a half-million applications. And so, like, that's a hell of a lot of applications to process through. And I don't think the EPA wants to be there.

So I think it's a much better process to go, great, like, you know, here's five, 10 companies, like Yamaha is there, they're creating the Fazer, they've got -- you know, that was alluded to and there was a slide shown. They'd be a great partner for that. DroneSeed is there; would be a great partner for that. You've got other applicators in the space.

So that's really, like, where we see that headed, but don't -- you know, the emphasis on being, like, don't say pause, stop everything, nobody can operate until we understand "X". I think that just creates a huge backlog of bad actors and then the EPA gets to plow most of its budget into enforcement.

MR. KEIGWIN: Let me check with Gina and Lori Ann and Leyla on the phone to see if they have any questions or comments.

MS. BURD: Will you be able to send the videos that you guys are reviewing around? I don't believe that those were sent to us in our materials.

MR. CANARY: Those are not public currently. So we wanted to provide those as a courtesy because seeing is really believing.

MS. BURD: Uh-huh.

MR. CANARY: At some point in the future those will become part of press. But at the present time, no, we're not able to share those.

MS. BURD: Okay.

MR. KEIGWIN: We'll check with -- we'll check up on -- we'll check up on. Okay. So I want to thank the

panel. I think lots of questions. New technology is always -- have lots of questions that accompany them. So thank you for that. So we're a bit over. So we're not going to be able to give you an hour and a half for lunch. But maybe we can give you like an hour and five minutes for lunch. So let's try to be back here for 1:30 and we'll maybe try to make up some time on the afternoon side. Thanks, everybody.

MR. CANARY: Thank you, everybody. And also thanks to the NAA as well for taking time out of their day to be here. Our comments are strong on that, but thank you.

MR. MESSINA: Thanks, guys.

MS. FLONACHER: Thank you.

(Lunch recess.)

AFTERNOON SESSION

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MR. KEIGWIN: Okay. I think we're mostly back, pretty much on time. So we're going to start the next session. Keith Jones from BPIA and Nina Wilson from Gowan are going to give us a presentation on biochemicals and the state of the industry. And this was a topic that came up at a -- it's come up a couple times at PPDCs, and so we decided this would be a good time to put this one on the agenda. So I don't know how you guys are dividing this up, so ...

MR. JONES: Okay. Well, first of all, I want to thank you all so much for giving us time today to speak to you about BPIA and the biological products industry. We thought it was really important for this group to hear from us. I think it's probably been a few years since you've heard from us. Because we think there may be -- maybe misunderstanding is too strong, but there may be a lack of awareness of biological products, biopesticides. We are part of the pesticide community, but our products are really very different. So we wanted to share that with you.

I'm going to talk a little bit about our association and our -- who we are and what we are and we what we do, and then Nina is really going to get into kind of the real interesting part, the actual products and the technologies and how these things work.

So who is BPIA? Well, we're a trade association. And we started around the year 2003. And at that time, it was just five biopesticide manufacturers. And we'll explain in a moment what we mean by biopesticides.

But those five companies got together and they said, you know, we really -- we see a lot of potential for this industry. We think we need our own association; we need our own voice; and we need a way to, you know, work together, collaborate.

And since that time, we have grown to -- just five to the 129. We're actually going to hit 131 in the next couple of weeks. And when I came on board in 2015, we were 85 member companies. We're now going to go to 131 member companies. It hasn't been a straight shot. I mean, every year we lose 6 to 12 companies because there are so many mergers and acquisitions. There's a lot of

activity in this industry. So we see numbers go.

But the overall trend is very large growth trend. And so our membership includes manufacturers, marketers, distributors, service providers, really anybody who touches biological products as we're defining them, which is biopesticides and biostimulants. And we're global at this point. We have members in North and South America, Asia, Europe, the Middle East, really all over the world because it is a global market for biological products.

Our members range in size from -- we have sole proprietors. We have regulatory consultants that are literally two or three-person shops, all the way up to some of the largest agrichemical companies in the world. And we have everything in between. And what they all have in common is that they're involved with the biological products in some capacity. Some of those larger companies may only have a biological department or division, whereas many of our midsize companies, that's all they do are biological products.

We're in the process of incorporating biostimulants, and that's something I'll talk more about

in a minute. And we've also -- recently we've expanded t include growers and food processors. We really want to be a voice for anyone who's involved with biological products.

We used to have a fairly long mission statement. The last year or so our board made the decision to make this our mission statement. I think it's simple and really to the point. BPIA's mission is advancing sustainability through biological solutions. And those solutions are the biological products that Nina will be talking about in a minute.

So what do we do? Well, like any trade association, we try to influence; we advocate; we communicate; we educate and we collaborate.

I do not have a large staff. I'm based in Northern Virginia and I have a few people who work with me. But what I do have is a really engaged membership. Those 129 -- meson to be, 131 companies, they all allow their staff to volunteer for BPIA. And we do almost everything through our committees. So we have a large committee structure. We have a biostimulants committee, we have a communications committee; finance; government

affairs; membership; you know, all the -- a regulatory committee. All the kinds of things you would expect from an association.

We do a lot of our work through our meetings. We do a lot of meetings, workshops, symposiums, for our members but also for folks outside of our membership. We are making a switch in 2019. We're going to go to one big annual meeting that we're going to have in March of 2019 in Portland, and that's going to be our once a year large member meeting where we get some very dynamic speakers. As you can see from this photograph, you might recognize that gentleman.

We do a lot of industry collaboration at BPIA. We're not a large association, but many of our members are members of other associations. Some of those associations are in the room. And we work very closely with ASTA and BIO and CLA and EBIC in Europe, and IBMA, also European-based, and the Fertilizer Institute. We find by working with other especially larger associations, we can really leverage the work that BPIA does.

This is just an overview. It's a really good

slide that one of our members, Dunham Trimmer, they're basically economic forecasters that focus just on the biological markets. But what I like about this slide, it gives a very good overview. If you start on the left, you know, fertilizer, specifically biofertilizers, then we have this new private category, biostimulants, in the middle, and then you move to the right to biocontrol, which includes, you know, for us biopesticides and also macroorganisms. But within the biopesticides, it breaks down the biochemicals and microbials. So we just kind of get a good overview of all the different kinds of products that we're dealing with.

And, again, Nina is going to get into some more of the specifics of what these products are and how they work.

And I think this actually may be my last slide. It is just talking about the market. It's a rapidly growing market. We're a small part of the marketplace. We are -- globally we're about 5 percent of the global crop protection marketplace. But we are rapidly growing. We are, as I said, global; we are around the world. About 32 percent of our market is in the U.S.; 18 percent

in Latin America; another 32 percent in Europe; and 16 percent in Asia/Pacific.

But probably the most important thing about our market is it's a rapidly growing market. No matter what source you consult, even the most conservative sources will tell you that biological products, biostimulants and biopesticides, they're growing at a double-digit rate annually.

We were just at an event in Switzerland where there was a gentleman giving kind of an economic overview and forecasting. He was saying that normally when he speaks, he's been telling people for the last several years, well, this market is going to continue at a double-digit growth rate for the next three to maybe five years. And he said he was going to stop saying that. He's going to say now for the foreseeable future.

We're just continuing to see growth in this market. And what's driving it is a combination of consumer demand and regulatory pressure. People are more interested in this than they've ever been before. They want to know, you know, what kinds of products that they're being exposed to; what their children are being

exposed to; what their pets; you know, what's being used on golf courses. You name it.

And then also regulatory pressures. I mean, a lot of products that were available in the past may not be available to us in the future. So biologicals are a good way of potentially filling that gap.

I think it's important to mention, though, we don't suggest that biologicals are a silver bullet by any means. We're big proponents of integrated pest management. We think biologicals have a lot of benefits, which I actually will -- I think they're included in my slides. But we don't try to suggest that, you know, biologicals are the end-all/be-all by any means. We're part of the solution.

So what are biopesticides? And I don't want to steal too much of Nina's thunder. But, I mean, biopesticides are reduced risk pesticides. They're naturally derived. You know, typically biological products, they may come from animals, plants, bacteria, fungi, certain minerals. They have a lot of benefits. They allow conventional growers to integrate; as I said, reduce risk pesticides into their pest management. They

allow organic growers to have pest control options. They can play an important role in public health. As I said, they're an important part of integrated pest management. Now Nina is taking my picture.

One of the big benefits they have is with residue. A lot of these products don't have residues. They can help with residue management. Again, it's part of an integrated approach. They can be really helpful. They can actually extend the life of traditional chemistry.

Most biological products have multiple means of action, which means it's very difficult for the pest to develop resistance. So if you incorporate a biological into your growing, you can actually extend the life of other products that you may be using. Biologicals are great to be used in tank mixes. They can be -- they can be very helpful with worker protection issues and really just giving you flexibility. Most of our products, they can be applied and there's no re-entry interval or very quickly you can get people out in the field because they have little or no impact on human health and the environment. So you don't have any of those traditional

issues.

Again, we're not suggesting that they're going to be, you know, 100 percent on large scale and solves all the world's problems. We're just saying these are options to really help.

Another big area for us is biostimulants. So as I showed earlier, if you think on one side, you know, fertilizers, on the other side you have pesticides, then in the middle you have this what we consider a new product category called biostimulants. And these products are not pesticidal. They're really used to help with plant health. They can help with abiotic stress. And right now you can't really label a product a biostimulant in the United States and sell it -- or really anywhere in the world to make biostimulant claims. So, that's something that we're actively working on as an association. I don't want to get too ahead of myself. So we're integrating biostimulants.

So what happened was a couple years ago when I came to BPIA, we were actually called the Biopesticide Industry Alliance, and we started hearing from some of our members that we have these other products, these

biostimulant products, that we think, you know, as an association we should start taking a look at. And then we heard from a lot of companies that were not members that were companies that only did biostimulants. And they said, well, we'd like to be a part of your association, but you're called the Biopesticide Industry Alliance. So we actually changed our name a couple years ago, and that's when we became the Biological Products Industry Alliance. And that was so that we can incorporate this new product category of biostimulants.

And what we've done is we set up a biostimulant committee because, again, we do everything through our committees. And those folks had been working very hard with folks here at EPA and then also at USDA, and we recently got some language introduced into the Farm Bill that we're hoping is going to help define what these products are. And then ultimately our goal would be so folks could label a product a biostimulant and sell it, you know, throughout the country and make biostimulant claims.

So that's a very quick overview. I know I promised Rick I would try and get us back on track. I'm

happy to answer your questions. But before that I'd like to give Nina an opportunity to really talk about some of the products. So, Nina?

MS. WILSON: Thank you. Okay. Thanks very much for the opportunity to talk. And as Keith said, hopefully I'm going to give you some little specifics about biopesticides to get a better -- you get this weird echo, don't you? So I don't know if I -- but some specifics so it gives you a better idea of where we sit and what do and where we are.

So I work for Gowan Company, I just wanted to let you know. But I feel like I work for BPIA as well because I spend a lot of time with Keith. In fact, for the last month I think we've traveled to a lot of meetings together, including Basal, and our meeting in Rochester and then here today because Keith needs a lot of help and we are a growing industry. And so actually we just came on board full-time about three or four -- three years ago now, I guess, yeah. So we are a growing industry.

But Gowan Company sells conventional chemicals. That's where we started. And so why do we have a lot of

time and spend a lot of time on biopesticides? Well, I want to -- BPPO says tell us the story. So I'm going to tell you a little bit of the story, is that over 20 years ago -- I live in the heart of lettuce country. Lettuce, cauliflower, melons. I drive back and forth for work. I see applications, I see the picking, I really enjoy that part. I'm a plant physiologist by trade, so I'm really interested in it. I've been very lucky for the last almost 40 years been able to stay in the agricultural industry.

So a lettuce grower came in and he had two heads of lettuce and he stuck it on our desk, and he said -- and this was about 20 years ago, which is well before the advent of the natural organic program, which actually I think was codified about the year 2000, although it took them about six years to get there.

But he had -- and he had this one lettuce that was actually bigger and greener; it looked a little healthier; and then he had another one that it looked great as well. And he said, I grew this one organically. And I'm like, well, I don't even know what that means. Because before we didn't know what that meant. But, you

know, he was trying to grow it without, you know, certain kinds of pesticides.

And I said, well, you really did grow that? And I said, so why do you -- what do you want from us? And he said, well, I need -- I need a biological product that will work in this kind of sustainable agriculture because this head of lettuce took me 45 days to grow, and this head of lettuce took me about 65 days to grow. So it was in the ground a little bit longer because they weren't pushing along. You know, the way they contract out, they weren't contracted out like they do regular lettuce. And he said, they just took longer to grow. And he goes, the longer that crop is in the ground, the more I'm at risk. So I'm either going to totally be able to grow a nice crop like this, or I'm going to lose it. He said, we're the conventional guys if something comes in and we're in intense ag, you know, they can go in and they can save it.

And so that's what -- so we actually brought on an agricultural pesticide called Azadirachtin that's named from the -- I spent the next three years being yelled at by every grower on the west coast because it

doesn't have a toxic mode of action. And so it's like, well, why are you trying to say you're controlling my pests and you don't have a toxic mode of action? Well, it actually has an integrated -- it actually has a pest -- I mean, an insect growth regulator, it's slow-growing. It took us a long time to figure out when to spray it, how to spray it, how often, what rates, and it was a very slow adoption.

And I was complaining to the company that we worked with and I'm like, this stuff is not easy to sell, you know, I'm having a hard time. And so he sent me to India. He goes, we've been using these things in India for a thousand years and people in India know how to use it.

So I went to India and went to a lot of the growers and got yelled at by growers over there as well because they were at the same time on a larger production scale trying to figure out how to use this. And we did figure it out. You know, we figured out that we couldn't -- you know, when you spray this, you've got to spray it right away. I mean, these things go away very quickly. It's sort of the nature of the beast. You know, they go away in some

way. They go away in water. So we have to formulate them very quickly. We have to teach the growers, you know, that you can't wait. You know, you have to spray it immediately; no, you can't wait two or three -- you've got to go really quickly.

I woke up in the middle of the night one day and drove down to see a grower who's going to tell me the big secret, and he goes -- because he could use it. And he said, you want to spray it in the morning and not at night, because, you know, the heat units build up. So people didn't understand just the little things like that.

And so after a year is really -- one of our larger selling products now. And I also say that the biggest market -- the biggest market that we have for this product is in the conventional. I just completely lost -- it's in the conventional market. Because as it turns out, certainly the organic growers were interested in something, but the conventional growers were looking for those benefits. They were looking for the zero day PHI. They were looking for the four-hour reentry. You know, they were looking for something that they could

spray around and have better worker protection standards.

So we always use it in a program; right? It was always used within a conventional grower or used with conventional chemistry; with biotech. And so we're technology neutral here.

So the conundrum is really what is a biopesticide? We talk about that internally ourselves as well. So we use EPA's definition because it is the regulatory definition. It's what we live by. It's a biochemical, which is like a plant extract, what you're actually extracting for the components that give you the fungicidal or insecticidal activity, or your microbials. But BPPD also registers. So they're sort of the low-risk group, if you will, and they register plant incorporated protectants. So plant-incorporated protectants would be something like the component in the BT that's actually put into the plant.

So we're not -- and they don't register the plant. But certainly the BT is considered. So it's a little bit of a fine line about who we are, but we are not the plant. We're not the incorporated engineered part of the plant. We're the BT on its own.

So -- and then the new technology, which I think we're going to hear about all the time, and I think there was some confusion because we were, you know, registered in the same division. But sort of the commonality is it's all considered low-risk. And there's a lot of BPPD's in here. You can give me the big hook if I say something wrong.

But I think from the commercial side of this thing, you know, they are pesticides. You will hear them called biorationals, biological products, low-risk pesticides. They can be organic. They can not be organic. They can be -- I don't know what I'm doing here.

So when we talk about it, we're going to talk about how EPA talks about it. We're going to really talk about biochemicals and the microbials.

So what is a profile? They're usually novel modes of action because oftentimes -- like, for instance, a plant extract, there's several things usually within a plant extract. They usually try to extract either water traction or some kind of plant extract for certain components that are pesticidal. And you have to -- you

just can't come up to EPA and say here's my product. They want to know what in it is pesticidal.

So characterizing the plant is not that easy, but they make us do it. And we understand why because that's going to inform the rest of the regulatory process. They're generally -- because we are generally low-risk, we have minimal personal protective equipment, usually four-hour REIs, and zero-day preharvest intervals, which a lot of the conventional guys would use, especially fungicides -- I mean, a fungicide will come on and take a crop out in literally hours.

So there aren't many things that you can go with a zero-day. Usually caution signal words, favorable safety profile. It can be used across all technologies, IPM, resistance management programs.

Generally, though, narrow spectrum. They're very specific to the pest because usually the target side of action is just on, you know, for the insects. You know, it's an insect that's very specific. It doesn't cross over to mammals.

And this is something that I think a lot of people don't understand, is why do we want to be a

biopesticide as well. And, remember, a lot of our members with a lot of biopesticides come about from smaller startup companies or universities. They'll have one or two products or come up with one idea. If you have a new AI food use tolerance, it's a 17-month PRIA timeline, and about $32,000; where if I had a conventional pesticide, a new AI food use, even though it's with a reduced risk, it's $627,000. So that's the way EPA sort of encourages these low-risk type pesticides. That's a really big difference. I'm not going to complain about the timelines. Everybody has those issues.

But, you know, I think what also we're seeing, and I think we've been hearing from the last couple of years, is that we're not seeing the usual things that we've seen in the past. We're not seeing the essential oils that everybody is used to seeing. We're not seeing the BTs that everybody is used to seeing. People are coming up with a little bit more novel modes and those are, you know, a little bit difficult when it comes to registration. And I think that's a lot of times when we see those timelines being pushed just because we have to

-- somehow the regulatory process, which is built on not having any uncertainty and requiring some more data.

So one of the ways that I thought I would just illustrate one of the issues that we as an industry have is if you look over on the right, that happens to be one of our products. And you'll see an OMRI and a little tiny insignia that says "for national organic programs."

So we do try to formulate our products to the National Organic Program standards. And I was talking to some international growers and they say they're organic, and I always say what standard? Because there's a billion organic standards. And they said if you want to register -- or you want to keep and put something organic and sell it across the world, the U.S. has got the most stringent organic standards. So if you can be organic in the U.S., you can pretty much be organic the rest of the world.

So we are allowed to have that on our label because it's really difficult for growers, especially the smaller growers who are growing organic, to know what they can use.

But over here, if you look at this product, this

is actually an essential oil, it's d-limonene, which a lot of people -- it's that stuff that makes oranges smell citrusy. It's pretty ubiquitous. You know, it's that stuff in candles, you know, or stuff that you clean with. But once you put a pesticidal claim on it, this particular essential oil is so ubiquitous it didn't pass the screen as a biopesticide. It actually was registered over in RD. So that gives you a little bit of idea.

But it is organic you'll notice. So the organic label is not a safety designation. Like I said, a lot of us try to be organic because, you know, it's -- and a lot of our conventional growers use that sort of designation to let them know because we have no other way for them to -- you know, for us to tell that it's a reduced risk or a conventional reduced risk, like with Dan Kunkel I worked with on the reduced risk program. We don't have any labels that say this is a reduced risk product.

So that's a little bit of an issue for us because there's a lot of conflation between safety that the National Organic Program does not have any claims for versus EPA who are very stringent; don't let essential oils be a biopesticide.

So another example here -- and this is actually a very famous, it's one of the first -- it's probably what organic growers use most often. It's PyGanic. Everybody knows -- I think your growers out there, if you were growing vegetables, you want to grow chrysanthemum around your pests because the chrysanthemum extracts have been known for hundreds of years to be natural pest repellants. And it actually has a mode of action. And, again, it's OMRI certified. It's organic. But its mode of action is such that -- and it actually has a tolerance. So it is not considered a biopesticide.

So the safety standard and mode of action dictates that this is not a biopesticide. But we at BPIA would consider it a biopesticide. So that's a little bit of a difference there.

So those are all the divisions. I think those are your latest -- and Bob's division, the biopesticide and pollution prevention division, otherwise known as BPPD, they are looking at biochemicals and microbials. And that's opposed to the registration of the conventionals, right? And so Bob's group looks at biochemicals, microbials, naturally occurring or

synthetic equivalents of non-toxic mode of actions, and also -- and I guess maybe we should update this. It's not just plant incorporated protectant, but it's new emerging technology as well. So it's quite a gamut, and that's what we wanted to make sure people understood that we are those first two.

So we go by -- and as an industry -- and as an industry, you know, we actually welcome this high standard of regulation because, you know, people are coming to biopesticides because they're looking for a certain set of benefits that does confer, you know, the four-hour, the reentry, the zero-day PHI, the minimal PTE, you know, which sort of all confers a safety profile that they want on their field.

The other thing is that most biopesticides are exempt from tolerance. And we spent a lot of time talking about what that means and what's the safety factor. But that is one of the reasons why the safety bar is so high. It essentially means -- it doesn't mean that there are no residues. It means there is no residues of toxilogical concern at any level. And that's a very high bar because -- I'll give you some examples later about things that

don't pass that are kind of surprising.

But they're not -- so tolerances are -- and I guess you can say they're harmonized to an extent. Certainly there's a global recognition of what a tolerance or an MREAL is and there's an effort. But exemption from tolerances, that is, you know, a direct result of a risk assessment that's based on, you know, whatever sovereign law is dictating those safety standards. Usually pretty much the same, but how they get there is a little bit different.

And it's really difficult to get people to recognize exemption from tolerance. And so we end up registering -- and, remember, these are very -- Keith talked about they're less than 5 percent of the market. So we're talking about niche products that don't sell a lot and that we're having to spend a lot of time and money registering them in Europe, where a lot -- we can actually register them with pretty much the same data sets that we can use here in the United States, but they have a set of efficacy requirements that will triple your registration very easily. So the cost is very expensive to register them across the world.

But one of the things that we'll see -- and I tried not -- and you guys ask me this all the time. Why do we want exemption from tolerances? Well, an exemption from tolerances means that we don't have to contact the EPA every time we want to add something to the label. Because they have deemed it to be safe at any level, which means, you know, you can -- as a pesticide, you don't have to do a lot of quantitative work by crop where you can't do that as a conventional. You have to come up with a set of data for each crop.

So one of the things -- and this came from one of the universities -- is that if you look, a lot of the -- a lot of the world are changing the way they're looking at pesticides. And we're actually having this discussion about what a biopesticide is because most countries welcome to have -- they want these lower risk alternatives to complement their existing pesticide programs, but the data requirements are usually the same. We usually have to work through the same set of data requirements that the conventional folks do. And I'll talk a little bit about how to get away from them. But -- or not get away from them; how we -- how we work with them.

But you'll see that blue line. So Korea and Japan now have their own system, and a lot of crops today if you're using U.S. tolerance, they actually are above or they maybe quite can't go to Korea and Japan. So if you see that this particular chemical is at .3 ppm and Korea is at .5, if we have people trying to get those markets, you know, they stop using whatever chemical control they have and they'll use biopesticides to supplement the rest of the program. And at the end of that program, they'll also get a residue that's actually a lot lower.

So that's oftentimes how they're using that. That's getting to be a little bit harder to do because in today's world when you send a bag of lettuce or bag of whatever to Japan, yeah, they'll do some chemical detection, but really it all comes with a provenance, you know. They'll look on the -- it comes with a piece of paper that says this is everything that was treated.

So they may not be able to pick up or there's not analytical methods for a biopesticide or a microbial, but they know it's been treated because that's what the food chain is requiring right now. So it's a little bit

easier discussion to have when we can say that it has a safety standard that EPA gives us.

So, yeah, you can't just walk up to the biopesticide group and say, hey, I'm a biopesticide, give me this lower set of data requirements. And there's sometimes a little suspicion about that. In fact, I got into this because I was kind of lazy and I was in the conventional market. And I'm like, I'll go work for biopesticides and I won't have to do all these studies and all this work. And it turned out to be harder actually because you have to, you know, go by the same safety standards.

And one of the things I first learned about was a biochemical classification. You actually have to go through this process where you have to write up and say this is why -- and, you know, there's data; you have to tell them what your product is, what's in it, what's the mode of action. And, again, you have to prove a non-toxic mode of action where -- I'm going to make fun of Russ here because whenever he talks to us about what is a non-toxic mode of action and you tell a grower your use is to have a non-toxic, they're like, get away from me.

So -- but he has a picture of a fly swatter. So that is lethality, but it's not toxic; right? So that's the difference? So a lot of biopesticides will work as an insect growth regulator for smothering, but a lot of times they're physical. For a fungicide, it's a lot of dehydration. It's not, you know, actually a systemic mode of action.

So we go through this classification and you have to prove that, and then you also have to prove a history of safe use. And the history of safe use is a really good failsafe. And that's probably where we're finding some issues. Are you giving me the evil eye?

Okay. That's probably why we're seeing some issues now because there's not the history of safe use with some of the more novel and more unique biopesticides that we're seeing today. And so we're having to work with the EPA. And, you know, we knock on their door a lot and we -- you know, we have gentlemanly disagreements because we always want to have data requirements that are commensurate with the risk. And these are low-risk products. So there's no need -- and that they have a history of safe use. There's no need to do millions of

dollars worth of animal testing here.

So -- but this -- so that -- this profile actually informs a potential for reduced risk. And once you pass that, it's going to require less studies. That doesn't mean that -- and it's done in a tiered manner. So it doesn't mean that if you run into something you're forever going to be a biopesticide with an exemption for tolerance. You know, you get kicked out and frequently that happens, and you have to ask for more data or sometimes you are not a biopesticide. You're not going to get exempt from tolerance. So it is a very high safety bar.

So, I mean, this is an example of a plant extract. And you would say if you look at this profile, it's a central nervous poison, it's got an LD50 at 200 to 400 mgs per kg. It's not that great. You get some mild cerebral hyperemia, occasionally psychotic-like self mutilations -- not good stuff here. It's a stressor reaction; occasional death. There's a lot of data on this particular product. And I actually know about this because I went to the EPA and I said I have this extract. And it actually is caffeine and tea extract.

And it is -- so we're drinking every morning and it makes us feel kind of awake. Well, that's a toxic mode of action come to find out; right? So it is not a biopesticide.

It could be if we could make it so that it was organic; could be considered organic. But it wouldn't be registered as a pesticide.

So I'm going to give you -- I'm going to go really quickly. These are some of our member companies as examples just so you can get some ideas of other things that are biopesticides. I had the pleasure -- I was talking to Russ back there. I said, my first experience and I knew that it wasn't going to be as easy when they made me register soybean oil, you know, because I'm, like, really? Well, you're making a pesticidal claim. So I didn't have to do any studies because I was able to find a wealth of data, you know, good, reliable data that EPA was able to look at. But still, again, you had to register it.

Acetic acid, 6 to 8 percent acetic acid. In most towns, that's called vinegar. So vinegar and oil, if that's a pesticide, guess what, you've got to prove to

EPA that there's a level of safety. And it's not that easy. Sometimes -- well, we'll have -- we'll talk later on how we can make it easier, but that's our discussion that we're having.

So this is Rescue! It's a biochemical pesticide that's very, very specific to yellow jacket. And it's a trap. The chemical is actually from fresh apples and plums. And I think it's not considered organic because of how they make it and maybe it's synthetically produced. But basically it is a naturally derived product.

It's very, very selective under yellow jackets. It gets down in the trap and there's no harm to honey bees; any other arthropods; and so it's quite often used around residentials. I wish I had it the other day when I was eating outside.

This is polyoxin D zinc salt. It is just now -- and this is very unusual because a natural organic program does not add any -- they actually don't want to add anything to their list. But they added this. It's a fermentation product of naturally occurring soil microorganisms. It's used on a lot of fruits and

vegetables. It stops the fungus from growing. There's a whole slew of pathogenicity tests that we have to do show that, you know, it's not pathogenic. It has a very unique mode of action, and so it's a good resistance management tool in a conventional program.

There's no mammalian toxicity observed in any of the studies, including chronic studies, and can be applied to zero PHI. So this is one of the fungicides that I was talking about where people might want to use it.

This is actually another one of Gowan's products, and this is something that we do with all our natural products; is we look at what they off target. So these are beneficial to phytoseiulus persimilis or the beneficial mite that they use in strawberries in California. They actually release them. So you don't want to be spraying a pesticide on top of them that's actually going to kill what they just released. So you want to really help that beneficial population out. So we do some work. And this is another beneficial to insect Orius to make sure that there's practically little effect on beneficial insects.

Baculoviruses, this is from one of our European partners, Andermatt Biocontrol, which is a big Swiss company. And they have -- this is a very, very specific virus that's consumed by the insect and then it needs a host. And so when it's released, unless there's another host there, it doesn't remain active in the environment. And it's so specific that they probably have eight different products that are for every specific species of product. And it is registered in Europe. So it's gone through, again, another very stringent -- and we registered here as well -- risk assessment process.

This is by Valent BioSciences. This is part of Sumotomo Chemical. This is XenTari, which is bacillus thuringiensis, which has been used -- I want to say 40, 60 years, I can't remember -- decades out, and you can see that here they're looking at resistance with some of the synthetic chemistry. There's no cross resistance. So what they're advocating is a rotation with the conventional chemistry to work on insect-resistant management.

Some interesting slides from Bayer, from Serenade. Another thing, if you'll look at this next set

of slides are actually probably four to five years in the making, and that's another thing that's kind of difficult about biopesticides. They're talking about going to these growers and talking to them about our biopesticide and getting yelled at. But every year I get yelled at less because as it turned out, you know, the growing system, you know, sort of -- you know, they were proliferating more beneficials in their population. They were learning how to use it. And so after a while I could actually go to the department and not get yelled at.

But here, this is Serenade, and they're using it to reduce pathogen resistance to synthetic fungicide. And this is actually one of their fungicides. And as you can see, the untreated control, basically they show that there was -- so this is 2013, the grade is 2013, 2015, and they're showing the pesticide by itself. When they use it in a rotational program or with their synthetic fungicide, you can see it decreased the amount of the resistant gene.

And, again, they're looking at decreasing the incidents and the severity of the resistance. And still

-- you still want to get -- you don't want to get control. And they were able to show that over a series of years.

So I think that's all -- yeah, just another set of slides again to show the resistance. So, I mean, I would probably say this is probably a half million dollars worth of data just in these three sets of slides alone. I mean it's, for a very small market it's pretty expensive.

But I think that's it. If anybody has any questions, Keith and I would be pleased. We kind of went over that really fast, but I wanted to give you a flavor of what biopesticides were and weren't and how we're registered. And I hope we were able to do that.

MR. KEIGWIN: Thanks, Nina and Keith. It was important to us to have this presentation. Increasingly a lot of our new active ingredient workload is biopesticides. I think, Bob, was it upwards of 20 -- 18 to 20 new active ingredients this past year were -- and another 20 or so in the queue just for next year. So to highlight some of the types of products that we're in the processing of reviewing or have recently registered.

Questions for Nina or Keith? All right. So I have Pat; then Charlotte; then Sharon.

MS. BISHOP: Thanks, Nina and Keith. I just had a question you mentioned Nina about the animal studies. You said they were done in a tiered manner. Could you just give me an example of how that might play out?

MS. WILSON: Well, you know, like anything, you have to have a set of data -- either a set of data or they allow us to get data that's been proliferated someplace else and present it to them.

If there's anything in that data set, then they're going to ask for more requirements. If there's something that says there's some toxicity, they're going to ask for another set of data and we'll have to go back and either decide to do the data or look for where somebody else has -- you know, if it's a ubiquitous enough biochemical.

The medical community does a great favor to us. As you know, over the past 20 years they really went out and looked at a lot of natural things to see if they could be cancer drugs mostly, and so there's a lot of data out there on a lot of natural things.

So they'll just -- if there's not an issue, they'll stop there; right? Because this worst-case, there's no issue, there's no sense in looking more.

MS. BISHOP: So, I mean, like maybe in a typical situation, would you have to run some acute studies like skin and eye and oral, and then if there was nothing there you would end, or would you have to go on to, like, a repeat dose study? How would you know --

MS. WILSON: Yeah. So -- and feel free. But the requirement as -- I see Russ and the people out there -- but so the requirements are basically the same, only the fact that we have a non-toxic mode of action speaks to, you know, there's not going to be any toxicity to anything else. So you have to do -- and we go by the -- you know, the tox 21, the reduced risk package, and we -- but there's some basic data and characterization that you have to do. And if nothing looks bad in that, then there's really no need to go further. Yeah.

MR. MCNALLY: Yeah. That's essentially it. Bob McNally. If you're fine at the acute levels, you don't have to go to the higher levels of testing. In my tenure, I don't think we've gotten there. It's always

been just Tier I.

MR. KEIGWIN: Thanks. Charlotte; then Sharon; then Dan.

MS. SANSON: Nina, I just have a question on recertification. Can you explain a little bit more about the process for that? Is there a criteria

MS. WILSON: Well, it's very painful.

MS. SANSON: Oh, okay. Does EPA have any input on that, or is it just strictly from a registrant (inaudible) --

MS. WILSON: No. It is -- I mean, it is -- so the -- so OMRI is actually -- they don't like for you to say they're certifiers. I think of them as certifiers, if you will, because the USDA doesn't have their own set of people out there that, you know -- they just put the rule together. So the National Organic Program is the marketing program under USDA. And if you really dig down into where they are, you know, they make great claims. I mean, there's a lot of good claims, you know, and -- but they can't make safety claims because they're really not assessed on safety.

So it's a list of exclusion, if you will, not a list of inclusion. They'll say it's naturally derived

except for, and you have to go through the except fors. So it's -- and it's very difficult to get anything new or synthetic approved on that list. So -- and they don't even like synthetic equivalents.

MR. KEIGWIN: Sharon; then Dan.

MS. SELVAGGIO: Okay. I've just got two questions. One of them you mentioned the (inaudible) product and you said it didn't pass the screen as a biopesticide because it's so ubiquitous. What did you mean by that?

MS. WILSON: Yeah. So d-limonene actually -- and, Russ, you help me out there. But d-limonene, I believe, it has actually activity on a bunch of different things. It's --

(Inaudible).

MS. WILSON: Okay, there you go.

MS. SELVAGGIO: Okay, okay.

MS. WILSON: Yeah. So, you know, it -- that's a -- so you can't even get in the door with that mode of action.

MS. SELVAGGIO: Okay, okay. We've talked a little bit about the 21st century toxicology stuff, the in silico, and so I'm just kind of curious how do

these connect with that new set of procedures given that these are so -- I mean, are these going to be able to comply with these? There's so many different sorts of compounds and so many different kinds of modes of action, is it possible to assess these using insilico?

MS. WILSON: I'll take a stab at it if you don't mind. But I think a lot of -- they have accepted some of these alternative tests and we do abide by -- we do live and die by exemptions. So it's not like you don't have the requirements. But we have to show why we don't have to provide a certain study. But I know that -- I know a couple of registrants that have actually used some of the -- I think they were European studies that EPA or certainly BPPD has been very open about reviewing a lot of this alternate testing.

I mean, if it doesn't work, it doesn't work. But I don't know if that answers your question or -- so the -- and they're case by case. They're case by case. I mean, there may be a case where you can't do it because there's -- you know, but we tend to look at, like, plant extracts sort of all together because you don't want to be -- you know, there's 30,000 things in this plant

extract, so you sort of -- you do a lot of work trying to figure out what's in here that's actually doing the pesticidal action and you sort of concentrate on that particular set of products.

MR. KEIGWIN: Dan?

MR. KUNKEL: Yes. Thanks, Rick. And we also see obviously the growers want these products and want to integrate them into their IPM programs. They want to use them for residue mitigation. One thing we do worry about is trade. EPA registers these products. They're exempt from tolerance in the U.S. So I just want to encourage the agency to stay involved internationally. If it's OECD, if it's Codex, to -- one of the projects that are taking place in Codex -- and EPA is a co-chair, the U.S. delegation is a co-chair -- is developing an international list of exempt products so that they can be used as a standard as well. So ...

MR. KEIGWIN: All right. Let me check to see if there are any questions from members on the phone. So, Gina or Lori Ann or Leyla, any questions for Nina or Keith?

MS. MCCURDY: Yes. This is Leyla McCurdy. If I

may take a minute to respond, thank you very much.

MR. KEIGWIN: Leyla, go ahead.

MS. MCCURDY: Oh, thank you. And I want to applaud both speakers for this very excellent presentation that they provided to us. However, it has contributed to my confusion. And I want to acknowledge the fact that this is a very complicated topic. And my question is what is EPA doing or is planning to do to translate all this information in a way that the public is able to understand?

MR. MCNALLY: Yeah, thanks, Leyla. This is Bob McNally. Maybe we can have further discussion. You know, one thing we've tried to do through our webpage and other efforts is as the folks today did is to describe what these products are and how we look at them; in some ways how they're different from conventionals.

So any ideas or thoughts that you have how to make that more clear; more transparent; maybe to draw the distinctions better? You know, we're certainly all ears to try to improve our communication of how these products are looked at and also how they're different from conventionals.

MS. MCCURDY: Yeah. One thing that I may suggest based on your response -- thank you for being so open for input -- have you considered to create a stakeholder group, you know, some of us that have been doing a lot of work in translating complicated science for public consumption and, you know, how to risk communicate that sort of thing. So if you would consider maybe putting together a work group, stakeholder group, beyond this committee. I'm not talking specifically about this committee, but in your work on this topic at the EPA.

MR. MCNALLY: Yeah, thanks for that suggestion. If it's okay with you, I'll reach out to you and follow up. I mean, we're always open to input as the folks describe. One of the things that's driving this as we see it is the demand in the marketplace from consumers; that they're interested in biopesticides. So let me reach out to you and we can talk and see how you can get more involved, and if you have other folks you think who might want to participate in at least chatting with us in some meetings, I'd be open to that.

MS. MCCURDY: That'd be wonderful. I'll wait

for you to contact me. Thank you very much.

MR. MCNALLY: Welcome.

MR. KEIGWIN: Thanks, Leyla. Lori Ann or Gina, anything?

MS. BURD: Not from me.

MS. SHULTZ: This is Gina; I don't have anything.

MR. KEIGWIN: Okay, thanks. Richard?

MR. GRAGG: Yeah. I would agree on the -- I guess more simplification. And when this comment was just made about clarification, I'm thinking about biologics and the pharmaceutical industry. And so I think just that alone calls for more clarification and distinction between these type of products and everything that goes along with that.

MR. KEIGWIN: Okay. Thanks, Richard. Any questions?

(No response.)

MR. KEIGWIN: All right. So, again, thanks to Nina and to Keith. We really appreciate it. We're going to move on to the next session, and this was another topic that came up last time. And I think Stan had

offered to give us an update on some of the work that the American Mosquito Control Association has been doing.

DR. COPE: Okay. Boy, the excitement in this room is palpable. I'm hearing it and I'm feeding on all of you for the energy that I need for this presentation.

I'm not used to talking while I'm sitting down. I would -- in a 15-minute presentation, I would walk around this table at least five times. So I'm going to try to behave.

AMCA is very grateful for the opportunity to share with you today what we think is really a good news success story, and I think nowadays we can all use some of that. And, Rick, I'd like to thank you for putting your -- he's not listening, but that's okay. Thank you for putting your -- thank you for putting your considerable reputation on the line by putting me on the agenda today. And that concludes my talk.

MR. KEIGWIN: You see why I picked you.

DR. COPE: Yeah. I'm known as Stan "get the group back on time" Cope. It's okay, it's her first time here doing this and I know I've made her nervous. And then do I just -- it may not work from way back here.

Ms. JEWELL: (Inaudible).

DR. COPE: I've got a Ph.D. here. You can roll them if you don't mind.

MS. JEWELL: Okay, sure.

DR. COPE: So let's roll them. Let's go to the next one. Just a little bit about AMCA, our National Mosquito Control Association. Click forward, please. I also put various viruses in my slides to see how good she really is. I can do some hand puppets.

Okay, there we go. AMCA has been around for well over 80 years; a lot of experience; a lot of lessons learned. It started out in New Jersey in 1935 primarily to control salt marsh mosquitos so that the land along the coast there could be developed. People didn't want to live in a place where they were going to be exsanguinated.

And just so you know, there's a very friendly rivalry among three states about who does the best job at mosquito control. New Jersey, Florida and California. The association has about 1,500 members in over 50 countries. The majority of those -- the large majority are in the United States, but we also have a significant

membership in Australia, Latin America; As a matter of fact, we have separate Latin American sessions at our annual meeting, and some parts of Southeast Asia.

The makeup of the group, the membership is really variable. You can see them listed there in the third bullet. The one sector that's left off of there is the military. We have a lot of military members.

But notice mosquito control employees. These are the people that on any given day might be running around in sewers or catch basins. They might be climbing over piles of tires and falling into them occasionally, which is really hard to get out of, by the way. I know from personal experience. Or they may be walking out into marshes filled with snakes.

And then you have on the other end of the spectrum you have scientists. And I proved again that if you don't start your timer, you get extra time. There we go. Ph.Ds, scientists, academic types. So it's really a diverse group.

I thought this might interest you. This is the -- this is what started all this training. This is the epidemic curve from the Zika virus outbreak which started

in -- you're all familiar with this. I don't need to tell you when it all happened.

But you can see it really tailed off considerably. And this is not unusual with these types of viruses that are only maintained in humans. You don't see this with West Nile, but in this case with Zika and with some of the other related viruses, you see this rapid decline.

Just to fill out -- sort of fill out the curve there, in 2016 there were 5,168 imported cases of Zika, meaning people got infected somewhere else and came back here and had their illness; 224 locally transmitted cases. That was the Miami/Winwood episode that we all went through.

In 2017, there were only 452 imported cases and seven locally transmitted in the U.S. by mosquito bite. And to date in 2018, this thing has almost disappeared. There have only been 48 imported cases and no mosquito transmitted.

So, anyway, in April of 2016 when I happened to be -- talk about bad timing. I was the American Mosquito Control president during that time. I thought I'd just

go to a lot of meetings and drink a lot of beer and give a lot of great talks, but I actually had to work for the whole year.

The White House decided to have a Zika summit, and I got an invitation by email. And on the top it said, "White House Zika Summit." And I thought, this is cool; I'm going to get to go to the White House -- "to be held in Atlanta, Georgia." And it was there that CDC first approached AMCA about a contractual agreement to update and come up with some really good basic and revised training and certification to try to help with this problem.

And so that's what this is about. But here's -- I didn't do that -- maybe I did. Here's a statement of the problem, and it's pretty simple. These mosquitos that we're dealing with are primarily daytime feeding mosquitoes. If you asked 100 people on the street when do mosquitoes bite, they're going to say at dusk or in the evening; right? Not these. They breed in and around peoples' homes. And I will stress, "in their." These mosquitoes will complete their entire life cycle within peoples' homes.

So they are not traditional targets of organized tax-based mosquito control that most of you are familiar with the trucks going down the street, et cetera. That was designed primarily for nighttime feeding mosquitoes like the Anopheles group that spreads malaria, and a lot of the nuisance mosquitoes.

So here are the pictures that you've all been waiting for, and these are suitable for framing. This is the yellow fever mosquito, Aedes aegypti, which has had a major, major impact to the history of this country. Two examples are the Louisiana Purchase. Napoleon had had enough of the New World and his troops all dying from yellow fever. So he called his buddy Thomas Jefferson. And if you've seen the ad, it was done by email on one of those phones that the purchase had gone through.

I didn't put whatever that box is up there. That's not my language. And the second one is a long enough story that I can tell it before the slides come back up. Is this working okay? I'm not hearing it very well.

Okay. Now I'd like to start my presentation. The second one was actually the formation of the -- what

became our United States Public Health Service, which was the Marine Health Service, due to yellow fever and a few other diseases in the south. So that mosquito has been in our country for more than 500 years, primarily occurring along the Gulf Coast. But in the last few years, it's spreading, and it's a significant public health issue. That little six-legged insect is marching right up the central valley of California and we're not able to stop it. It's almost to San Francisco now. So if you're going to San Francisco, be sure to wear insect repellent. That's a takeoff on an old song that probably most of you don't remember; right?

This mosquito is also -- it's one of -- if not the most efficient vector -- and vector is what we use for insects and arthropods that spread these pathogens -- it's such an efficient vector because more than 95 percent of its blood meals are on humans. Most of the 3,000 mosquito species that we have don't bite people. They prefer to bite birds or large mammals. Not this one; more than 95 percent.

So not only does it spread Zika, but it spreads yellow fever, as I mentioned; Chikingunya virus. By the

way, there's at least one person in this room that's had one of these diseases, and I was just told about it here recently. Dengue fever, Chikingunya, and a new one that we'll probably hear about in the next three or four years, it's called Mayaro virus, M-a-y-a-r-o. It's broken out of South America and is now making its way through the Caribbean. So good luck with that.

A little closer to home here. Eighty percent of the people around this table live in the state that has this horrible thing now, the Asian tiger mosquito. Some of you may recognize it. It has this nice white line right there. This is the thorax where the legs and the wings are attached. That white line tells you that it's the Asian tiger. Relatively new in our country. It was discovered in 1984 in Harris County, Texas, and it has rapidly spread now to 40 states. And of even greater concern, it's starting to over-winter in places like Chicago, Illinois, where we thought it would never establish. It now over-winters in Chicago.

Strangely enough, since we're in Washington, D.C., by the way, there's a population of the yellow fever mosquito that shows up in Washington, D.C. every

year and the same person finds it, which I guess that makes it a little suspicious, doesn't it? And we don't -- we've never been able to figure out where it's breeding. It's probably hooked up down in some sewer system.

So as I love to say, mosquitoes don't read the textbooks. They don't know where they're supposed to be breeding and they'll use whatever they need to carry on biologically.

And if that's not bad enough, there's a third invasive mosquito now. It's called the Asian bush mosquito, Aedes japonicus, that is also spreading in the United States. We're assuming that it can transmit all these diseases, but we're not completely sure.

Okay. You can advance to the next one, please. So CDC gave AMCA some money for one year with the option of renewing the contract for the second year if the money was available. It turned out, as often happens with some of these public health things, the money dried up. So we had a little bit to carry over.

But we were given task areas, and I'm going to briefly go over those. The first one was to establish

this industry expert panel. Those are not people from the chemical industry. They are people from either mosquito control or academia who were engaged in research on these container breeding Aedes mosquitoes.

Their task was to revise that book that you see there on the top right. We had a 2007 edition of it -- a 2009, I'm sorry. But we wanted to update this. This was best management practices for mosquito control with a distinct focus on the mosquitoes that were spreading Zika virus.

I'll give you the website address at the end of the talk. It's pretty easy to remember. It's mosquito.org, but I'll repeat that later for those of you who have forgotten it by then.

The good news is this is available free of charge on the AMCA website. It's written in a very easy to understand, non-technical way. The points are bulletized so they're easy to turn into speaking points or teaching points, and it's also available in Spanish. There's been a lot of discussion today about is this available in Spanish and fortunately this is. So it's available on the website free of charge.

Next, please. And the book, by the way, is backed up with 93 references. And I just wanted to tell you briefly there are nine areas of recommendations. The emphasis in this document and in this training is on surveillance. It's on community outreach and community participation because these mosquitoes are generally found in people's back yards.

How many of you, by the way, have experience with the Asian tiger mosquito? Let's be honest. Yeah, look at that. The public health menaces that we all are.

And so we've really emphasized surveillance, community participation and trapping and non-pesticide ways to control this mosquito. Because it's not very easy to control these, particularly with adulticides.

So the areas where the recommendations were made just very briefly are surveillance for the eggs and the other live stages, mapping, and setting action thresholds for when you activate your plan. We want to get away from what were the older days of -- we want treatments to be based on historical surveillance data or a public health event such as the Zika outbreak. And that is stressed throughout this training.

Source reduction, which is the whole key to controlling these mosquitoes and the diseases that they spread, and then biological control, chemical control. And the last one I want to mention is monitoring for resistance. Insecticide resistance in these species is high. We know that in Puerto Rico it was off the maps -- off the charts, I should say, not the maps.

And so there's a component in here of teaching folks how within their local districts they can do insecticide resistance using an assay that CDC developed.

So tasks two and three revolved around developing and delivering the train-the-trainer type of workshops. You can see there's four goal points there of what the curriculum for these workshops was built on. It was input from the industry panel.

Oh, I should mention that we contracted with an organization to help us redo that manual and we had professional medical writers in the room capturing the thoughts, and they were the ones that wrote it. So that's why it turned out so well.

We established 10 workshop locations within the United States. You can see them in the map. They're the

yellow dots and they were selected for various reasons. And then we brought in 19 folks from those 10 hubs and created a group of master trainers who then went back to their areas, to these 10 places, and provided the training. So there was a really good cascade effect from this program.

Next, please. So one of the things my time in the Navy taught me was we spend too much time measuring our effort; how many things we did and not what good came out of it. What you did and what good it was are two different questions. So we do have some metrics. At those training hubs now, there have been more than 400 certifications handed out. And as you can see, we've trained individuals in 31 states. Something like this has never been done before and we're very proud of it.

Next, please. This is good. My thumb is feeling better. Just a couple of pictures from these things. These were not death by PowerPoint. These were honest to gosh workshops with a lot of hands-on training. The people there on the left are looking at the myriad of mosquito traps that are available on the market. They learned when to use which ones, to name them, and each

one of them had to stand up and talk about one of the traps, the pros and cons of it.

And then the group on the right there is working on their capstone activity. These work-groups had to present a -- they were given a scenario, and it wasn't one of these things where they work together on it and then they just had one person who liked to talk stand up and brief -- outbrief for the group. Each person was given a designated role whether they were public education or perhaps the operations director or et cetera, et cetera. And they each had to talk about their part of what they did in this scenario. So they were groomed pretty heavily by the master trainers.

Next, please. Okay. This was the one that might interest you a little more; even moreso than this riveting presentation has so far, I know. These are the e-learning modules that are online and free of charge that we also developed. You can see them there under the dots. The first one was mosquitoes and disease. The vast majority of mosquitoes don't spread any pathogens to humans. The Aedes mosquitoes are the ones involved in the viruses that I mentioned. The Culex group there,

they're the West Nile mosquitoes; St. Louis encephalitis; eastern equine encephalitis; a lot of really, really nasty things.

So that was the first module. The second is how these things live. And, again, this focus now was on the Aedes mosquitoes, the container breeders. The more you know about how something lives, the better you can do a job of killing it. And then the third was surveillance and the fourth module was control.

Let me just check my notes here for a minute. And as I said, these are available free online. They do have an exam with them, and we set the passing level at 85 percent. My days in the Navy, our passing level was 70 percent. This is 85. They're not easy, but you can pass them. I know because I passed them. And the theme of the modules is chaos to calm. The contract people came up with that.

Next, please. So what's the metric for this? There's been more than 1,000 instances of engagement; about 760 total users, which equates into certification; 43 states or territories. So, again, this type of broad, large scale training is something that we're very proud

of and hasn't really occurred in the mosquito-control industry before.

The other good news is a lot of people who are doing private industry mosquito control, the back yard thing, what I call soak and hope, a lot of their technicians are getting online and getting this very basic training about integrated mosquito management, and that's never a bad thing.

Next, please. I'm almost done. And this has become an international event. You can see there Australia, some places in Europe. The Canada folks who have about a week-long mosquito season up there, but it's very intense, they're taking the training as well.

Next, please. I'm not going to talk too much about these, tasks five and six. Task five was just basically coming up with some type of way of evaluating the program, and that's been through the examination scores as well as the capstone activity. All of those data are being fed back to AMCA for evaluating this. They have a huge database of who's taking what and which questions they're not doing very well on, et cetera, et cetera. And so that training will be tweaked in the next

year online to sort of clear some of that up.

And then the last task, which is on the next slide, is one that really was for year two. And with the loss in the funding or the cut in the funding, I should say, that some of this is probably not going to get done as well as we wanted to do it. Again, this was just evaluating the overall program and then figuring out ways to make it better. A lot of times we just put these programs in place and we let it run its course and nobody looks back and says, hey, how are we doing?

Next, please. So a selfless plug for our annual meeting. The mosquito control community is a lot of fun. So if you're in any of these areas, our next one is coming up in February. The registration is relatively reasonable. It's about $350. And then you can see the outyears there. We go to some pretty nice places because we're small enough we don't have to go to the larger places all the time. So Portland, Salt Lake, for their 75th anniversary, and then Jacksonville, Florida. And I will personally give you a tour of the exhibit floor and introduce you to all my friends if you're interested in that kind of thing.

And last but not least, on the last slide, there it is, www.mosquito.org. There's a lot of good information on there, not only these modules and the training materials, but you can see a lot of frequently asked questions and interesting facts about mosquitoes. It seems like everybody thinks they know a little bit about mosquitoes.

There's also a lot of really good public outreach material on there that you can customize for your own group if you need it. And with that I will take any questions about AMCA, the training; if you have any burning questions about Zika virus or mosquitoes, I might be able to answer those as well.

MR. KEIGWIN: All right. Thanks, Stan. Any quick questions for Stan?

DR. COPE: With even quicker answers.

MR. KEIGWIN: Richard, I don't know if your card is up from before or -- either way.

MR. GRAGG: Thank you, Stan, for not only a great presentation, but for protecting all of us. So what's the -- is it CDC's responsibility to sort of anticipate and search for what the next disease vector

might be from mosquitoes?

DR. COPE: Well, I don't want to speak for CDC, but I can tell you that there are several ways that that is done. State health departments sometimes are responsible for mosquito surveillance. Sometimes it's the local mosquito abatement districts. The U.S. military has several overseas labs that monitor these types of diseases. We knew about Zika back in the 1990s because it was hopping across the Pacific islands, but we never paid attention to it because it was a very mild illness and we never knew about birth defects until it showed up here.

There are also other -- the World Health Organization, the Pan-American Health Organization, but certainly CDC has an interest in that. And just to mention, when people hear CDC they generally think of Atlanta but there's a large facility in Fort Collins, Colorado that handles a lot of the vector-borne diseases, and then the CDC also has a dengue lab in Puerto Rico. So they have three different places.

But certainly, yes, they have limited resources with their entomology people, but they are certainly

interested in that type of information.

MR. KEIGWIN: Okay. Jim?

MR. FREDERICKS: Thanks, Stan. And great presentation as always. And congratulations on this program.

DR. COPE: Jim and I went to the University of Delaware together and he owes me one from those days.

MR. FREDERICKS: From one Blue Hen to another.

DR. COPE: Yes, sir.

MR. FREDERICKS: Awesome job. No but a real question. I was just kidding about the other stuff. Do you have any idea --

DR. COPE: No.

MR. FREDERICKS: -- and maybe you said this, but do you have good numbers on how many people have taken the online training, and then --

DR. COPE: Were you asleep during my talk?

MR. FREDERICKS: Perhaps. But the real question is I know you mentioned about some private industry and that sort of thing. Is there -- and so mosquito control professionals for sure and whatever stripe they might be. But has there been any impact or any interest from

citizens, from people, who just might be -- who need to be trained? Because one of the things that I know from the structural pest management industry is that the hardest thing to do is to get the client to participate in the integrated mosquito management process. And so if this can make some inroads with that group, I think that will be extremely valuable.

DR. COPE: You're talking about Joe Q. Citizen? Until we have the ability to find people like they do in some other places, like Singapore for instance, for breeding these mosquitoes on their property, I don't know how much good that's going to do. I've taken a personal interest in private industry and trying to train them more. I'm going to Puerto Rico and Jamaica soon to talk about integrated mosquito management with these groups.

I don't -- I don't -- the answer is on one of the slides. There's been about 1000 -- about almost 750 or 760 people that have taken the training. Also, the University of Florida, in conjunction with CDC's Southeast Regional Center of Excellence, has just gone online with a public health focused mosquito training of 11 modules that is geared specifically toward private

industry.

I think if the private industry folks who are doing backyard mosquito control and have day to day contact with those people, if they can help educate them about what's going on in their yard and what they can do, I think that's one way we can certainly work together with NPMA, which we've already been doing for several years, as you know, to float that boat.

MR. KEIGWIN: Liza?

MS. TROSSBACH: Just for Stan, just so you're aware, members of my staff took this training and thought it was a great tool also for pesticide regulators.

DR. COPE: Did they pass on the first time?

MS. TROSSBACH: Yes. And, you know, so just a plug for that, that it's certainly, I guess, geared towards the applicator community, but certainly it's beneficial to other groups as well. And just from a regulatory perspective, it's very helpful. And I'm assuming that other states probably did that as well.

DR. COPE: Yeah, we're hearing that. Thank you.

MR. KEIGWIN: Okay. Let me check with our members on the phone. Leyla or Gina or Lori Ann, if you

have any questions for Stan?

DR. COPE: I hate being so thorough.

MR. KEIGWIN: Let me ask -- Gina or Lori Ann or Leyla, let me just -- can you confirm that you don't have any questions for Stan? That way we'll know, if we can hear you.

MS. BURD: No questions. This is Lori Ann.

MS. SCHWARTZ: This is Gina. I have no questions.

MR. KEIGWIN: All right. So we're almost back on time. What's that? Come back at 3:10. Thanks.

(Brief recess.)

MS. MILLER: Are we ready to get started again?

GROUP: Yes.

MS. MILLER: All right. So I think we still have a few folks out in the hallway. Do you want to round them up, Dea? Okay. So why don't we get started. My name is Wynne Miller. I'm the acting deputy office director who's taken over for Arnold Layne. I'm just going to admit right up front that I'm not as good looking as Arnold. I don't dress as well. I'm not as funny as Arnold. But I'll do my best. I'm the chair for

the Public Health Work Group. And so I'll just be taking over for him temporarily until he comes back from his detail.

So you guys may have to lead me along a little bit just because I'm not familiar with this workgroup. But Dave Jones apparently drew the short straw yesterday to do our presentation and our report out. No, seriously, he did volunteer to do this.

So we're going to let Dave talk a little bit about the progress that the group's been doing on developing the recommendations for the emergency preparedness plan. And one of the things that we'll talk about at the end as well is that we do have some vacancies on this work group, and we may be soliciting some additional folks to fill in for those vacancies.

So let me let Dave Jones take it away. Thanks, Dave.

MR. JONES: Sure thing. Thank you, Wynne. Good afternoon, everyone, and, again, happy Halloween. I found a little bit before lunch. I did come in costume today. I'm Bono. So it was the glasses threw everybody off. So it was unplanned but welcomed.

But, no, as Wynne mentioned, I'm here to give you an update on the Public Health Work Group progress. We have come up with our objectives, and this is a good way to give you an overview of what we've been talking about. And we've been striving to develop recommendations to the PPDC to help the Office of Pesticide Programs to be able to respond more effectively during an emergency, particularly when it comes to interactions with other agencies and communication materials about pesticides. So that's what we've struck as our goal. Oh I've got it.

I guess I am Bono. Let's see, going the wrong way. All right. We had a meeting yesterday. It was a good discussion. We -- Wynne has already addressed we've had a change of leadership. So Wynne explained her experience related to public health. So we're in good hands; we've hit the ground running again.

We're going to work on developing an outline for the contents of a formal recommendation to the PPDC. Right now we're looking at five topics. We covered four yesterday. So we've covered a lot of ground. And I should add, a lot of the members of the team are in the

room, too. So, please, if I miss anything as I go along, chime in and help me get this message across thoroughly.

But the four topics we did discuss yesterday were first the OPP roles and responsibilities in this effort; second, to identify and engage stakeholders; thirdly, talk about pesticides, integrated pest management and other control tools, not necessarily pesticides in the strict sense; and lastly we covered communications.

We do have one remaining topic we will discuss in future meetings, and that would be talking about the technology, innovation and science related to these public health needs for emergencies.

So now I'll hit each of those buckets that we had discussed yesterday. Start with the OPP roles and responsibilities. First we were talking about there will be a need to sort out roles by crisis type, identify when EPA/OPP is either lead or support. And we did acknowledge in most cases OPP is appearing in a support role. We were having a hard time on the spot trying to figure out, you know, when EPA would take a lead on that natural disaster, for instance.

So we are looking at, you know, addressing all players early on. That would include other EPA offices. Once you get into the throws of a disaster, you know, adrenaline is running high as are emotions; this should be figured out ahead of time. So that will certainly be a component of our recommendation to the PPDC.

EPA role in communicating with the public and having them differentiated between other stakeholders. Obviously EPA has their area of expertise. That will need to be explained. I'll go into that in a little more detail in the communications section.

But the plan would be to allow OPP to be proactive in participating and identifying areas that would need pesticide-related information input. And one other aspect of the role and responsibility would be more in the aftermath, you know, like the example of Zika brought up earlier is, you know, it's always good after one of these events occurs to sit down and do a postmortem; what did we do well; what could we have done better; and how could we have done it? So that also will be a recommendation of their role.

Also included in this process would be the

identification and gauging of stakeholders. You know, there is a broad and exhaustive list and types of stakeholders that could be involved with any scenario that would be involved with an emergency situation. And it would be important for that group to at least identify the types and categorize by purpose. That way it would be, you know, easier to identify the stakeholders appropriate to different types of emergencies and how to include them. And then, too, it would be part of that organization of thought to determine if EPA was in a lead role, support or merely advisory role, but still a key player in any of those scenarios.

One way to do it was suggested that a matrix be developed of stakeholders and the types of emergencies to help identify key areas, messages, et cetera, and use past emergencies as a template to validate the method; kind of a pretrial, if you will. And, also, it would be important to work with other federal agencies to promote a unified federal message on pesticide usage, risks, benefits, et cetera.

There were repeated mentions of the role of using control tools. So, you know, we need to look at all the

options and see what fits the scenario best. And then how can OPP take the lead to ensure that best control tool is selected?

So for pesticides, IPM and other control tools, there was discussion around adapting the existing education materials on regulatory processes. Like, if you need a different product, a different chemical to bring into a scenario, how can you get it there fastest; make sure it is the right tool. And you would talk about the different processes and get some preconceptions around which would be the best mechanism to get that material into the situation. You know, would it be section 3 or 18, an experimental use permit, an existing, a new product? You know, later on we'll talk about new technology. Different meeting. But, you know, all of these just specifically address, you know, the public health pesticides need.

It will be a discussion of roles and options for using pesticides that are not registered. Sometimes that tool does not yet exist or it needs to be created or it needs to be registered; one of the other suggestions for that group to handle.

It would also establish clear guidelines to announce a policy to expedite applications for pests during an emergency. If there's a situation where the tool is not clear, the public needs to be assured that the agency has a pathway forward to determine what that best tool is. And if it's not registered yet, then it can be identified and brought in to allay whatever concerns or threats to the public health may be presented.

It will also create materials for using IPMs in different types of emergencies and different pest needs, including antimicrobial pesticides. There were discussions earlier about some of the disasters -- hurricanes, for instance -- that create pools of water that normally don't exist. Drain the pools, an elegant solution, no pesticides involved. So, you know, common sense, bring in IPM whenever possible.

Response should also include or should use examples such as the viral emerging pathogens policy for antimicrobial pesticides. That's one where there's an organism, there are no products claiming kills against that organism -- I'm talking about pathogens primarily,

viral pathogens in this case -- where CDC, EPA, work together to determine a surrogate. And then products that already have a claim for that surrogate or a similar material can be instituted to control that pathogenic threat. And once tests are actually conducted against an organism that is a suitable, if not the exact pathogen, could be put in place. But it is a designed mechanism EPA put up to be able to implement a quick tool to solve problems that have not yet been seen.

We also talked about communications. Seemed this was half of our meeting consumed with talking about communications or communicating about communications. Under this one, we had actions and alerts for the public on any particular pest control tool that is being employed. It’s somewhat of a playbook, if you will, where the messaging is already set up. Again, when the adrenaline is high, emotions are high, having a template to transvey the message to the public that’s clear; thought out ahead of time; you know, would be invaluable.

Materials to discuss the risks of tools versus disease or risk of doing nothing. I learned during discussions yesterday of the concerns with Naled when

used with a mosquito trap. And, you know, had there been materials available or, you know, we were ready to go to communicate those to the public instead of, you know, if someone doesn't know what's going on today, they do a Google search and, you know, heaven help us what they find when they do that; right? So if that material exists, it's ready to go and people know where to look. You know, it could avoid a lot of confusion and, you know, settle things quicker.

Papers discussing issues that arise during most emergencies. For example, ES and EPA pollinators, NPDES, organic farming concerns, you know, should be in place. Those can be thought out ahead of time. Just assume they're going to happen.

Consider developing a generic public health emergency response template for pesticide related issues. I mean, let's face it, if you think about how many pesticides there are; how many public health threats there are; different scenarios that may exist; the public health threats, you know, that's a large number. A template where you could pretty much select one, fill in the blanks, having that done ahead of time would prove

invaluable as well.

And, lastly, a clear, consistent message at the federal level for issues related to pesticides. You don't want those involved with a particular public health incident giving different stories. It's got to be one unified message to be clear and concise.

So racing along, conclusions and next steps. A plan is needed for when, not if, a crisis is going to occur. We know there's a crisis coming with mosquitoes. You know, the gentleman prior to me, those four-foot mosquitoes are going to bring a new virus into the equation here sooner than later; right? So, you know, this is a need. We should start planning now.

Proposed timeline for us to finish this is aggressive. We're targeting May. But we think we're capable of doing that. We've split this into four buckets. We're going to divide it, work -- take up monthly calls and, you know, we think that we're going to get it done because it will be more efficient by splitting the workload, and we'll be able to get this to you by May. That's our plan; that's our goal.

We will provide those recommendations to the

full PPDC at the May meeting. And Wynne has already mentioned the vacancies. So I'll turn it back to you with that plug, if you will.

MS. MILLER: Okay. So for this particular work group, we have about 16 to 20 members right now, I think it is. And there are a few vacancies that we -- we have. I think, Susan, you counted two to four --

MS. JENNINGS: Two, three, yeah.

MS. MILLER: So I think what we want to do is just have folks think about whether or not you want or are interested in being on this subgroup. What we'll do is follow up with an email, and then if you're interested -- because we don't want to put people on the spot unless you want to volunteer right now.

But -- so what we'll do is follow up with an email within the next week and then see if anyone is interested in being on this subgroup so we can get started to meet the ambitious timeline that we have. So I think at the end we have -- and I can't read from here.

MR. WAKEM: Yeah. I'm Edward Wakem with the American Veterinary Medical Association. I'm sure many of you people in this room are aware of the news about

the exotic tick, the Asian longhorn tick that's been reported now for almost a year. I think November will be a year.

And there are no EPA-registered acaricides for host animal application in the United States that have an indication for this tick. And so what we're finding in the veterinary profession is that manufacturers and marketers of host supplied acaricides and veterinarians are in a quandary in terms of promoting products for use against this tick. Because as we all know, the label is the law.

And so within the organization and in consultation with industry representatives and the EPA, we're still struggling to come up with a communication plan for veterinarians, you know, in turn to communicate to their clients when approached about protection for pets or livestock or -- you know, it's been found on humans. So eventually that question will come up as well.

So I only bring this up because this invasive tick has not risen to the level of a crisis, but I think the work that this subgroup is doing can help to

anticipate issues like this and address them in a more rapid fashion. Again, right now, as an organization, we still don't have a communication plan for our members to be able to address concerns about this tick, which I'm sure are being expressed now and will continue to be expressed.

So I only make these remarks to endorse what the importance of what the subgroup is doing. A problem doesn't need to rise to the level of a public health crisis in order to be able to implement, you know, some of the conclusions here. And I'd certainly be willing to participate in the subgroup.

MS. MILLER: All right. Thanks, Edward.

MR. WAKEM: You're welcome.

MS. MILLER: Stan?

DR. COPE: Thank you. I can tell you from personal experience as AMCA president that if some of those things that you're working on had been in place at the time of the Zika issue, I'm not going to say things would have gone smoothly; they would have gone a little smoother when it came to choice of products and a few other things. So that's good stuff.

I have just a little bit of a concern here, and that is that some of the things that it seems like you're working on or that you want to do are things that our colleagues at CDC do. And so I don't know if you have anybody from CDC on the work group, but I -- and I don't know if they're a full participant. But I'm just wondering if you've considered that and what the different roles might be. And the last thing you want to do is have two federal agencies at a crisis butting heads, and that happens sometimes as we all know.

MS. MILLER: Yeah. Actually, we have Walter on the work group from -- he's from CDC. And that topic did come up yesterday; is thinking about, you know, what role would EPA be playing versus being the lead versus being a support role for another agency like CDC. So that is something that they did discuss yesterday about roles and responsibilities. Thanks, Stan.

Okay. How about on the phone; any PPDC members on the phone who have any questions or comments?

MS. BURD: Not from me.

MS. MCCURDY: This is Leyla. I don't have any comments. Thank you.

MS. MILLER: All right; thank you.

MS. SCHWARTZ: This is Gina. I have none. Thank you.

MS. MILLER: Thanks, Gina. Okay. If there are no other questions or comments --

MS. JENNINGS: No, I think they did a great job.

MS. MILLER: Thank you, David, for drawing the short straw. So, again, we'll be following up with an email to see if anyone is interested in being on this subgroup again. It is an ambitious timeline and we do expect to start meeting monthly. So if folks are interested, we hope you can participate.

So I think we're -- we're about 15 minutes ahead. Where's Shannon? Keep rolling? Oh, we'll send her a quick note.

(Brief pause.)

MR. MESSINA: So folks on the phone, we're just getting our speakers situated and we'll get started in a couple of minutes.

MR. MESSINA: Okay, we're going to get started.

MR. MESSINA: All right. You guys ready? Okay, we're going to get started. It's all yours.

MS. PERRON: All right. Thanks, everybody, for sitting tight for us while we wait for one more

presenter. But we're going to go ahead and get started and she should be able to come in halfway through. So, if not we can at least stop after the first piece and then we'll just go ahead and answer some questions at that point if we need to if the other presenter is not here yet.

All right. So just as an introduction, my name is Monique Perron. Can you not hear me? Oh, okay. I'm just not being loud enough. That's not usually a problem for me. I'll do better.

So my name is Monique Perron. I'm a toxicologist in the Health Effects Division. We're going to give you a little bit of information to update you on some work that we're doing in the alternative research area. And you'll have to bear with me; the first few slides I wasn't going to give.

So as many of you may know that we've been -- we have a strategic direction in place for our program where we're working towards moving towards the toxicity testing in the 21st Century, the division that was put forth by the NRC. And this basically is using a broader suite of computer-aided methods to predict potential hazards and

exposures, and to focus testing on likely risks of concern; also, improved approaches to more traditional toxicity tests to minimize the number of animals used while expanding the amount of information obtained. And, lastly, improving our understanding of toxicity pathways. So moving away from that animal testing down to using more cellular tissue level information.

We have guiding principles for our data requirements to provide us with consistency in identifying data needs and promote and optimize the full use of the knowledge and data that's available. This will ensure that there's sufficient information most importantly to support our registration decisions and be protective of public and environmental health, but also we want to avoid the general evaluation of data that really isn't going to impact our risk assessment decisions. So we're trying to avoid unnecessary use of time and resources, data generation costs and animal testing.

And I think this is the last slide as an intro. We do have some flexibility in our data requirements. We can grant waivers under Part 158.45. Additionally, we

can use alternative approaches to replace those traditional in vivo tests under 158.75. So we don't -- we can always have some flexibility in those data requirements.

So I'm going to turn it over. Our first thing is about the avian retrospective analysis.

MS. PANGER: All right. So my name is Melissa Panger. I'm from E-Fed, and I'm going to talk about projects that I've been involved with where we're doing retrospective of avian acute studies. We just want to provide an update on that.

So just a little background. 40 CFR 158, Test Guidelines for Conditional Pesticides for Outdoor Uses, we typically get two types of acute avian studies. We get acute oral studies typically on two species, either a bobwhite quail or mallard duck, usually, and a passeri or songbird. And then for a subacute dietary study, we typically get data from mallard and bobwhite quail.

And so when we're doing our risk assessments on the eco side, we use both suites of data and we basically calculate risk quotients for using the available data. And we basically -- for our risk management decisions and

risk concern decisions, we use the RQ that results in the highest RQ, so the study that results in the highest RQ out of those four studies.

And so what we wanted to do is we've been working with PETA on this and we collaborated with them to look to do a retrospective of these data to see basically can we basically confidently assess acute risk for birds using a reduced suite of the effects studies just focusing on the acute oral studies. And basically we're asking how often are these subacute dietary studies actually playing a role in the risk management decisions both quantitatively or qualitatively?

So we focus on risk assessment outcomes or the RQs, risk quotients, because we wanted to integrate effects and exposure. We just didn't want to look at hazard. And this allowed us to basically compare across different bird sizes and dietary categories and that type of thing.

And the data sources that we relied on for this retrospective is we focused on the pesticides that have been registered through RD or come in to RD from 1998 to 2016. So we wanted to kind of get an idea of the most

recent classes of pesticides that are coming in.

And what we did was PETA actually did a review of the most recent publicly available risk assessment, and they also determined the mode of action for each pesticide. And the importance of that we'll talk about in just a few minutes.

Now, for what we found -- and then for each risk assessment, what PETA did was they extracted and compared the single oral dose and the dietary-based risk quotient, and then they summarized and looked for any qualitative information that was being reported in the risk assessments from the subacute dietary studies.

So what they found -- or we found that EPA identified 181 pesticides that were new to the agency between 1998 and 2016, and PETA was able to look at the risk assessments that were publicly available for 119 of those chemicals. So for most of those 119, 79 of those, the chemicals just didn't -- we didn't have RQ values because the studies were based on limit tests. So they were tested up to the highest concentration with no effects. So there was no RQs calculated for those. But the risk inclusions were identical using the acute

oral or subacute dietary studies in that case because there was no risk found.

For nine of those cases, they were based on kind of nonstandard applications or uses such as indoor uses. And then there were 40 of those risk assessments that did do RQ calculations where we could compare the acute oral and the subacute dietary studies. And in 37 of those cases, the RQ from the subacute -- or from the acute oral study dominated the risk inclusions; meaning the RQs were the highest from those acute oral studies.

In two of the cases, we had RQs for the dietary only because the oral studies were based on limit tests, but, again, in those cases the conclusions were the same. There were no risks identified for birds either using the subacute or the acute oral studies.

There was one case where we did see that there was the dietary RQ was higher -- for the subacute dietary RQ was higher than the acute oral RQ, and that was for an anticoagulant rodenticide.

So the bottom line here is that in over 99 percent of the cases, in 118 out of 119 of the cases that we considered, the subacute dietary approach did not

change the risk conclusions already reached using the oral -- acute oral-based, dose-based RQs.

But if you do the math, which I'm sure a lot of us can do, we -- there were 181 chemicals, and we did the analysis on 119, which left 62 chemicals that we did not include in that RQ comparison. So we wanted to get an idea of whether or not those 62 chemicals were covered by an analog, so a chemical already in the same class of chemicals; you know, was it already considered in that 119 chemicals?

And what we found is out of those 62, there were only eight of the chemicals that had modes of action that weren't represented by an analog in the analysis. And those all had unique modes of action.

So the bottom line in this case is that the majority of the unevaluated cases, those 62 chemicals, the subacute dietary approach was represented by a chemical analog. But it does indicate that for unique modes of action, additional retro -- you know, additional analysis may be needed in the future.

So that was what we found. And so what we wanted to update folks on now is kind of the next steps.

And what we've done is we've written a manuscript and it's been submitted for review in a scientific journal, and the lead author is from PETA and it's Gina Hilton. She actually is back here. So PETA is the lead on the authorship and the agency is co-authors.

And, like I say, we've submitted it. It's been submitted to regulatory pharmacology and toxicology, and so it's currently under review. And in the meantime, while we're waiting back -- waiting for that review, we're developing a policy for some guidance basically outlining the analysis that we just talked about and pointing hopefully to a published paper at the end.

And then what we're going to be doing is for recommending for new chemicals, or this is a proposal, is that we're going to propose to recommend for new chemicals with mechanisms of action that were covered in the analysis that we rely on acute oral-dosed based studies for birds and we hold the subacute dietary studies for those chemicals in reserve.

And we're going to recommend on -- for an evidence-based kind of consideration for the dietary testing for unique modes of action, chemicals that

weren't covered with classes of chemicals that weren't covered in our analysis. And then cases where the data and the MOA suggest a mechanism of accumulative damage such as the anticoagulant rodenticide or those with a high potential for bioaccumulation or facilitated transport mechanism of absorption. Things like chemicals with high octanol water partition coefficients, molecular weight, high bioconcentration factors, and chemicals that are showing accumulation in some of the mammal toxicity and residue studies and basically anything where you expect multiple doses would be more conservative than the one dose for the dose-based studies.

So we're going to be proposing that. We're outreaching to international and other partners. We've talked with PMRA. They're interested from preliminary discussions and kind of staying in touch on this. And then the plan is to release a draft policy for public comment on this.

And so I don't know if there's any questions on that.

UNIDENTIFIED FEMALE: I'm just wondering, I'm kind of confused about the math.

MS. PANGER: Okay.

UNIDENTIFIED FEMALE: So from 79 they didn't have an RQ value calculated with that -- no RQ for either?

MS. PANGER: That's right. There was no RQ for either the subacute dietary or the acute oral.

UNIDENTIFIED FEMALE: So wouldn't it be more appropriate not to include those?

MS. PANGER: Well, we're looking to see if we reach different conclusions. Because we've still got the acute oral studies. We've still got the subacute oral studies. So we both -- we've still got the studies. But they were showing no effects at the highest concentrations tested. So those -- we felt it was -- you know, those actually should be included in that analysis because we're showing that there's not a separate -- there's not a different conclusion we would reach.

UNIDENTIFIED FEMALE: Okay. So you did have data; you just didn't --

MS. PANGER: Right. We didn't do that analysis of -- we couldn't do the comparison of the RQs.

UNIDENTIFIED FEMALE: Right, okay.

MS. PANGER: Yeah, yep.

MS. LOWIT: Okay. Hi, everyone. For those of you who don't know me, I'm Anna Lowit. I'm the science advisor here in the pesticide office. I'm going to quickly go through one of our big successes this year. It's a policy that we put out in combination with our colleagues in the toxics office with a lot of help from friends and colleagues at the National NTP Center for Alternative Test Methods and ICCVAM.

So in short we have a brand new policy out on skin sensitization. It's grounded in years of science internationally but also here in the U.S. The skin sensitization adverse outcome pathway, if you're familiar with that phrasing, is -- was the first adverse outcome pathway or AOP identified by the OECD a number of years ago.

An AOP is essentially an organizing framework where you put information from different levels of biological organizations. So you start with the structure, what's happening at the chemical level and at the cell level, and moving up to the organ and then

finally the organism response.

In the case of skin sensitization, we have OECD guidelines for each of the key events in the adverse outcome pathway. And obviously we have in vivo studies for the organism response.

And the LLNA, the mouse on the right, and the guinea pig, are the kinds of studies we typically get here and are conducted for pesticide chemicals. The green represents the three in vitro guidelines at the OECD, which we're now moving to accept in lieu of the animal studies.

So there's been a great deal of international activity. One of the big milestones that occurred to allow this policy to happen is a couple of years ago there was an important workshop held by -- convened by our European friends in Northern Italy which was the first ever workshop of the International Cooperation of Alternative Test Methods, or what we often call ICATM, which is made up of the U.S., the Europeans, Japan, Korea, Canada; most recently Brazil and China.

And what was unusual about that workshop is that our European colleagues actually paid for regulators to

come and attend this meeting. So we had over 40 regulatory organizations from around the world represented to talk about the elimination of the use of animals for skin sensitization, which is a really unique event and has led to a number of important milestones.

So what came out of that workshop was the conclusion across the world that the in vitro, in chemico and in silico approaches were equal to, if not better, performing than is the mouse study that we routinely get, which is kind of cool; right?

With a lot of help from Nicole Kleinstreur, who is a deputy director at the National Center for Alternative Test Methods and NIEHS, in April we put out a policy comment announcing that we would begin to accept in-house the in vitro and in silico and in chemico approaches and moving towards elimination of the animal studies for skin sensitization.

We -- part of that policy is that we've actually already began accepting the in vitro and in silico approaches, and we've had a number of meetings already with some registrants intended to start submitting those studies instead of the animal studies, which is pretty

exciting.

There are some limits to the policy as we continue to work. It's -- right now the policy only applies to active ingredients and inert ingredients, and in the toxic space it only applies to single chemicals, not mixtures. And the reason for that is the OECD guidelines right now, mixtures and formulations are outside of the applicability domain of the assay. And we're working with NTP to expand that.

But in essence we'll accept two different ways of submitting those data and analyzing them. What's often -- what's being called at the OECD level as defined approaches, which is essentially a fancy word for how to combine the studies and make a conclusion.

So the two ways that we'll accept the studies and the first one, it's essentially two out of three. So like the Red Socks, just won, you know, they won a certain number -- pardon me?

MR. KEIGWIN: I think it's four to one.

MS. LOWIT: So they -- in this case it's best of three. It's not best of seven; it's best of three. So there are three OECD guidelines and essentially you do

two of them. It doesn't matter what the order is. If they match, you're finished; if they don't, you do the third assay and the higher number wins.

The other way is a sequential testing strategy where you actually do the assays in a certain order. You start with what's called the h-CLAT. If it's positive, actually you're finished. So in a lot of cases one in vitro study can replace an entire animal study, which is pretty cool. But if the h-CLAT is negative, the recommendation is then to do the DPRA, which is another key event, and two negatives come to a negative.

So as we're working to expand the policy outside of the active ingredient inert space, we are working collaboratively with the National Toxicology Program, who is in the process of systematically looking at a variety of formulations and mixtures and difficult-to-test substances from across the federal government, including a number of exam agencies recommended things to be tested. EPA's OPTP Toxics and ORD submitted a lot of substances; the Consumer Product Safety Commission, FDA, and some of our international partners.

And to be honest, we're doing ours first because

we've moved so fast on this policy they've agreed to do the pesticide products first. So the hope is in the next year or so we'll have an expansion of the policy.

And I think that's the end of this piece. So I'll take any questions before Monique comes back up to the mic.

(No response.)

MS. LOWIT: No? Thanks.

MR. PERRON: Okay. Thank you. So I'm just going to give you a little bit of information on inhalation approach for refining inhalation risk assessment with an in vitro assay.

And just starting off, the anatomy and physiology of human and rodent respiratory tracts differ in several ways that can impact changes in air flow and deposition of inhaled substances. For instance, the airway size and surface area; the complexity of the nasal turbinate system; the branching patterns; cell composition; and anatomy of the larynx.

So these critical differences can therefore affect the ability of in vivo testing in rats, which is typically the species that we get these tests in, to

correctly predict effects in humans.

Furthermore, the traditional in vivo studies are resource-intensive in terms of animal use, expense and time. With respect to respiratory irritants, damage in the respiratory tract can often occur at very low concentrations. So we may not be able to establish a concentration where no effect -- adverse effects are being seen. And we also may run into some issues with animal welfare.

So as a result, efforts to develop new approach methodologies, which would include alternative methods and strategies for inhalation toxicity, are being supported by the agency. In particular, these new approach methodologies that take into consideration the inherent differences between the rats and the humans respiratory tracts may serve as a refinement for our human health risk assessments.

There are several in vitro tools available to evaluate inhalation toxicity such as lung-on-a-chip; ex vivo lung slices; and in vitro cell cultures, whether they be simple or three-dimensional models. There are advantages and limitations to each of these. However,

selecting an appropriate and relevant system we think should be determined on a fit-for-purpose context.

We recognize that the science is going to continue to evolve as we -- in this research space as more tools become available. However, at this time to address our current science questions, we really need to use the best available tool that's currently available based on the state of the science.

So at this time we've been considering the in vitro models that allow direct exposure to add the air-liquid interface such as the three-dimensional models to be the best available tools to evaluate human respiratory tract toxicity.

So a proposal for refining inhalation risk assessment using one of these in vitro models was submitted by Syngenta for the pesticide Chlorothalonil, which is a respiratory irritant. We recognize the value of this approach not only for Chlorothalonil but possibly for other respiratory irritants and eventually beyond that. So we definitely encouraged them to develop their approach more.

We also reached out to the NPT Interagency

Center for the Evaluation of Alternative Toxicological Methods -- I had to write that down because I call it NICEATM -- to collaborate with us on that review. And, additionally, our sister office, OPPT, was also involved in the review since this approach may be applicable to industrial chemicals.

So as part of their submission, Syngenta provided a biological understanding of the respiratory irritation that you're seeing in vivo studies caused by Chlorothalonil exposure. And as Anna already kind of showed you, put it into a sort of adverse outcome pathway starting with this initial damage from the initial contact of Chlorothalonil with the tissues in the respiratory tract.

And I'm not going to go through this. I'm just putting it up here to say that this biological understanding guided Syngenta's decision-making when it came to what in vitro model they should use for assessing the damage in the respiratory tracts.

So they identified the MucilAir model as the optimal model for answering the science questions that they were trying to answer. It's a three-dimensional

model using human epithelial cells from nasal, tracheal or bronchial tissues. And the results from that in vitro testing were used in conjunction with deposition values that were predicted through a computational fluid dynamic model. And this actually also allowed them to use human relevant particle information. So we actually had a coupling of human data for on the tox side coupled with exposure data that was human relevant.

We're going to be presenting this approach in December at an SAP meeting from December 4th to the 7th. I was about to say the 17th. That would have been a very long meeting. The charge questions are mainly about how does that biological understanding that I spoke about inform their applicability of the in vitro testing and the model that they selected. The general use of the in vitro system as we move forward, we want to make sure that these are conducted in a way that is appropriate and also reported correctly to the agency so we have all the information.

Some of the assumptions and calculations that come into that computational fluid dynamic modeling to calculate cumulative deposition and then ultimately the

human equivalent concentration that's being calculated for human health risk assessment.

And, lastly, the strength and limitations of using this approach for not only contact irritants but also the potential to use it for other chemicals that cause portal of entry effects in the upper respiratory system. And that's the -- the link is there for anybody who -- all the background material has already been posted. I'm not sure -- I don't think the bios for the panel members are quite up there yet, but hopefully soon.

And I think -- and we're just -- we're leading up to our guiding principles for data requirements just as another reminder that, you know, when it comes to all of these alternatives that we're talking about, we're talking about some of the many different projects that we have going in this space. But all of them go back to, you know, we need the information to support our registration decisions.

Any questions on the inhalation talks?

MR. KEIGWIN: So, and really any questions on anything that you've heard during this session. Sharon?

MS. SELVAGGIO: Now, I don't really understand a

lot of what you're saying. I'll acknowledge that right up front. But I guess it kind of goes back. I'm -- I'm wondering about this concept of mode of action and toxicity because you brought it up in your talk. And what confuses me about this -- and I know it's been said in probably previous PPDC meetings that I've heard this that there hasn't been a new mode of action discovered for like 20 years. So they seem like very unique, but at the same time we know that we're working with biological systems that are infinitely complex and that we've barely begun to scratch the surfaces on.

So my question is, how do we know that we've discovered all the mode of actions out there for toxicity? And so my question partly goes to the biopesticides talk, like, if we're waiving data requirements because we don't have a known mode of action for toxicity, do we know that there's maybe one that we don't know about that might be present in that substance?

And when it comes to the in silico, that's kind of the same question. Do we know enough about potential modes of action that might exist in nature to know that we can move to an in silico approach?

So not really understanding this topic very well, that's the best way I can frame it.

MS. LOWIT: Do you want me to start?

MS. PANGER: Go ahead.

MS. PERRON: Well, I will say going back a little bit to, you brought up waivers. You just have to remember also that it's not just the hazard that we use when we're making those decisions. We are also using the exposure and risk calculations to figure that out. So we may not know actually anything necessarily but the mode of action. But if our risk estimates are in the millions, is that additional data really going to impact our risk assessment going back to that?

And I think to just focus on the inhalation at least for your question, for irritation it is a little bit more of a simpler space, and I think that's why we're asking the SAPs for some advice on, you know, is that -- can this be translated to more complex damage in the upper respiratory system? If we protect for initial damage all the time at an in vitro level, could that then be translated into something that needs repeated exposures and has a more complex mode of action than an

irritation.

So a little bit of that we're hoping to get from the SAP as many of them are experts in the in vitro alternative world. And I think that's -- I can't remember the rest of the question. I don't know if Anna wants to add a little bit more.

MS. LOWIT: So there's a lot in your question. I could go on for a long time. But, so I think the essence of it is that you have to remember there's some context to all of this. So in the BPPD space, when I talk about modes of action, they're thinking about targeted biology of the compound against the pest. So in the conventional space, we often know that chemical A is targeted towards X enzyme or X protein in the pest, whereas in the BPPD space where we're using natural products, often that knowledge is not known.

So in the conventional space often that knowledge is known because those compounds are engineered to do a specific thing to the pest. And more and more often we see those pesticidal modes of action to actually be non-mammalian relevant, which is a good thing for mammals and humans because they're targeting the kinds of

systems that are specific to fungus or specific to insects that don't occur in mammals. So that's a good thing for humans and mammals.

So as we think about the idea of mode of action for toxicity testing, we actually know a lot in the pesticide space about how these compounds work in the body either through the research done by the companies themselves or things out in the literature. And so the numbers of modes of action in the pesticide space is relatively finite and we can actually take advantage of that. So we can understand a lot of how a pesticide works in the body to elicit cancer or elicit neurotoxicity. And by knowing that knowledge, we can then make smart choices about what the toxicity testing we need to target that biology so that we're doing good government, not asking for wasteful testing but actually getting the information we need to make good decisions.

MR. KEIGWIN: Pat?

MS. BISHOP: Yeah. I have a question for Melissa about the bird study. You mentioned in here that you have some outreach maybe starting with Canada at

least. But, I mean, I think this is a great study. I think it's certainly, you know, certainly a basis to move this forward. But my question is, you know, we saw -- I mean, if we go back to -- and I hate to keep bringing up the one-year dog study, but if you all remember, you know, pesticide required a 90-day study in dogs and a one-year study in dogs be done.

And I think the first paper that came out that showed that the one-year wasn't needed was like 1998. And EPA finally came out with a policy in 2007 that said we don't need to do the dog, and it's taken -- I mean, Japan finally published their results this year and we don't need the one-year dog.

So my point is, you know, it often takes a long time from the initial study to get other people on board. And obviously if somebody is selling internationally and they're going to do a bird study whether, you know, you have this data or not. So maybe things will move more quickly in this day and age. I doubt it.

MS. PANGER: Don't doubt it at this point because I think we are actually moving fairly quickly on this. Because we're not -- we're not changing

guidelines; we're not -- we're going to have some guidance for suggesting how chemicals -- or propose some ways that chemical companies can ask for waivers. We're not going to get rid of the studies.

MS. BISHOP: Mm-hmm.

MS. PANGER: So the studies can still be held in reserve. So I think the speed could go quite a bit faster with that, and I think our plan is to move faster.

MS. BISHOP: Mm-hmm.

MS. PANGER: And, you know, draft a guidance as quickly as we can and get it out for public comment as quickly as we can. Because this is a win-win-win for everybody, I think, in terms of the -- you know, the animals not having to be used; the cost to the chemical companies; and we're still going to have robust risk assessments.

So, you know, I think there's a real push to get this done as quickly as we possibly can. So don't -- don't be doubtful at this point right now because I think we're moving fairly quickly on this one.

MS. BISHOP: Right. I mean, I'm not doubting that you're not moving forward. I just think, you know,

maybe there needs to be a workshop or some kind of an international forum to get other regulatory agencies together and show them your data and, you know -- and maybe that way it will get out a little quicker and other people will understand.

MR. KEIGWIN: So, Pat, that's her point; right? On the international side it took even Japan -- I mean, we waived it over a decade ago and they're just now getting there. So how do we truncate that so --

MS. BISHOP: Yeah. I mean, basically every country did their own study, you know, before they followed suit. So, you know, you hate to see that happen when you've done some -- at least some good work to start with. You know?

MS. LOWIT: And we have started dialogue with Anne Gourmelon from OECD to find a venue that we can give to Melissa and Ed, Gina, to -- whether it's some OECD webinars or the submission of a project plan to get some other countries on board. So we are looking into what some of those options are to speed it up, like you said.

MR. KEIGWIN: Richard?

MR. GRAGG: I'm just curious as it relates to the human health issues in using these type of tests. How do you account for or study potential long-term impacts?

MS. LOWIT: So the presentations you've heard -- so the standard pesticide data sets. So we have standard data requirements for biopesticides, for antimicrobials and for conventional pesticides. Most conventional pesticides that are few use have a rat and a mouse two-year cancer bioassay. They also have a -- either a two-generation or an extended one-generation reproductive study. And they will most often have two species of elemental toxicity studies.

So we do get extensive data on many, many of our chemicals. The presentations that we've done in this session are about our efforts across the program to move towards a smarter testing or hypothesis-based testing approach that's less reliant on the checkbox. So historically we have data requirements in the 40 CFR that's largely a checkbox. And internationally pesticide data requirements look like that. That's why in these studies it's part of the registration processes.

But as we do our retrospective analysis, as the scientific community progresses, as we see their opportunities to either eliminate the wasteful testing or move away from a whole animal study to something in vitro or in silico based so we can actually do a better job at predicting human health than we can with the animal, we're going to continue to make those moves because it's good government but it's also much better science.

But in the meantime, those cancer studies, the developmental studies, the more complex endpoints, we'll continue to ask for those repeat dose studies as we have done for many years.

MR. GRAGG: Right. But you're -- at least my understanding is that you're looking for ways to eliminate animal studies.

MS. LOWIT: As the science allows, we are doing that, and through public process and through good science incrementally one step at a time.

MR. GRAGG: Okay. So my question is, do you foresee then that in vitro or non-animal studies will be able to account and capture long-term exposure impacts?

MS. LOWIT: Hopefully in my career; not any time

soon.

MR. GRAGG: All right; thank you.

MR. KEIGWIN: Okay. Let's see if Lori Ann, Leyla or Gina have any comments or questions. The line is open for those three individuals.

MS. BURD: None from me.

MS. MCCURDY: This is Leyla. I don't have any comments. Thank you.

MR. KEIGWIN: Thanks, Leyla.

MS. SHULTZ: And Gina doesn't, either. Thanks.

MR. KEIGWIN: Thank you. Lori Ann?

(No response.)

MR. KEIGWIN: Okay.

MS. BURD: Sorry, I couldn't get unmuted. I don't have any comments or questions.

MR. KEIGWIN: All right; thank you. So any other questions from people around the table?

(No response.)

MR. KEIGWIN: So we're going to transition into the public comments session. We have one, Mr. Jordan. You have three minutes. That's what the DFO told me.

MR. JORDAN: My name is Bill Jordan and I'm here

as a private citizen not representing any particular organization. I wanted to comment on four of the topics that have come up today.

The first one, the SmartLabel, I think it's really important for EPA to look at developing a vocabulary for Spanish language that's equivalent to the vocabulary that's being used as the standardized label language for different terms that will appear on labeling. The same kinds of ambiguities that exist for English also exist in Spanish. And if you want to have consistency across labels that are presented in Spanish, then I strongly recommend that you look at that as an adjunct effort for the SmartLabel.

Second point with regard to that is -- and this is really not just for EPA but for all of the stakeholders that are represented here at the PPDC. I think a much more efficient way of -- and collaborative way of implementing SmartLabel once it becomes operational would be to have a provision in PRIA, perhaps it's PRIA-5, maybe PRIA-4, depending on when that happens, that reflects the understanding and approach that gives EPA the authority to require registrants to

submit electronic labeling. It would certainly be faster for EPA and it would create a level playing field, I think, for all registrants.

Third point with regard to SmartLabel is that a lot of the people who are stakeholders representing users have spoken up in terms of the value that electronic labels could have for user communities. And I think that the web-distributed labeling concept which EPA has already developed and put in place, that policy could be used to make information that's streamlined available to users that give them information about their particular location, their particular crop, their particular application method, without all of the additional information that appears on many labels which run into the dozens and sometimes over 100 pages in length.

I encourage EPA and the companies that are participating in the pilot to begin thinking now about how to use web-distributed labeling as a method to satisfy what was clearly articulated around the table today as a desire by the users to get information in a much more useable fashion.

Turning to the emerging application

technologies, what I'll call drones, I think this is an exciting new technology and one which I think also offers the opportunity for reducing pesticide-related risks. And I hope that both USDA and the EPA and the technology providers will look at this technology as not just another risk assessment challenge but also as something that could significantly reduce application risks.

Related to that, I think one of the potential consequences of drone technology is to apply pesticides in places where airplanes and helicopters really can't reach. And I'm thinking of terrain which is quite uneven in terms of its elevations. And that, I think, presents particular kinds of concerns that EPA ought to be paying attention to.

Third point, it strikes me that there are potentially very significant differences between a drone which is operated according to an algorithm and one that is piloted using visual observations. And I hope that EPA will take that into account as it does its assessment of this new technology.

And finally, I think there may be some issues with regard to adverse incident reporting under FIFRA

Section (6)(a)(2) that are different for this particular technology versus anything else that might come up with regard to other application techniques.

Shifting to the biological products presentation, I found it interesting that the presentation by the industry folks drew a distinction between biostimulants and biopesticides. The inference that I drew is that biostimulants are not regulated under FIFRA, and I'm -- I must confess I'm unclear about the distinction between a biostimulant and a biopesticide. I understand that EPA has been thinking about that -- where to draw that line, and has been developing a policy statement on that point.

I strongly encourage EPA to try to move ahead with the development of that policy; to take public comment on it; and to make it clear for everybody both in the regulated community and those who might be concerned about the environmental impacts of biostimulants to understand how EPA would draw that distinction.

Finally, I wanted to offer a thought about the 21st century toxicology program and particularly the effort focusing on avian toxicity testing. This is more

in the nature of a question, but I did not hear in the analysis that the folks in EFED have done how reducing the data requirements from four tests in three different species to potentially only two tests in only two species, how that might affect ESA assessments and particularly the calculation of species sensitivity distributions. It seems to me that reducing the number of species that are available to EPA for analysis of species sensitivity distributions might increase the apparent level of risk as derived from that particular step in the analysis. Thanks.

MR. KEIGWIN: Thanks, Bill. So we're going to get you out of here really early. Thank you to everybody for participating. But before you all pack up -- oh, so I'm reminded we need to check for the public on the phone if there are any questions or comments. So the line is open for public commenters who are participating over the phone.

(No response.)

MR. KEIGWIN: Okay. Now we're going to get you out of here early. But before we do, so Dea Zimmerman is the DFO so I wanted to thank her publicly for all of her

efforts.

(Applause.)

MR. KEIGWIN: And this is also Dea Zimmerman's last PPDC meeting as an EPA employee. So I think we should thank her for -- I think she served as the DFO for nearly four years, since Margie Fehrenbach retired, and has just been invaluable to the program in this capacity as she has been in many capacities throughout her EPA career. And so I just wanted to publicly thank her not only for her service to the PPDC but for her service to EPA and the public for your career. So thank you.

(Applause.)

MR. KEIGWIN: And so just a plug for tomorrow for the biotech seminar. It's not a PPDC meeting, but it is a public meeting. So we may configure this space a little bit differently tomorrow. But we do encourage all of you to attend. There's some really exciting things that are going on in the biotechnology space and some interesting challenges that we're facing as a program as we figure out how to assess these types of products as kind of the technologies continue to emerge. So I encourage you to come back for that. And, again, thank

you all for your participation today. Safe travels and happy Halloween.

(The meeting was adjourned.)

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