UNITED STATES

ENVIRONMENTAL PROTECTION AGENCY

PESTICIDE PROGRAM DIALOGUE COMMITTEE MEETING

June 5, 2014

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. JONES: Good morning, everyone. I'm Jim Jones. I'm the Assistant Administrator for Chemical Safety and Pollution Prevention here at EPA. My job this morning is pretty straightforward. I'm here to welcome all of you and also to introduce the new chair of the PPDC, Jack Housenger, who I think many of you know, but probably not all of you.

It's great to see so many faces who I've worked with over the last 20 or so years in the area of pesticide regulation in the United States, and some new faces. I'm only going to be here shortly, but I will have an opportunity for the go around for everyone to introduce themselves.

For those of you who have worked with me, certainly in the context of the PPDC, some of what I say will not be all that new. For those of you for whom this is new, some of what I say may seem a little bit lofty, but that's how I get at meetings like this.

What I say at these kinds of meetings is that this is really a very important part of participatory

government, which I think in this country we take great pride in our democracy that we have, the kind of participation that this kind of a meeting represents.

I think actually today, the eve of the 70th anniversary of D-Day, is a good reminder of just how important it is that we have this kind of a government and how many before us have gone and sacrificed so much so that we could have the opportunity to have this kind of a government, where it's not only a democratic government but a government that listens to the people of the country on important issues.

This institution, the Pesticide Program Dialogue Committee, is an expression of that, of letting the people who have a stake, a meaningful stake in our decisions, which in the United States is everybody, have an opportunity to talk to the government about how it does its business, what business it does, to give us the feedback that we want to have to make decisions that are in the best interest of this country and to protect the citizens and the environment of the United States.

Participatory government, what I often will also then go on to say, is hard to do. These are not

simple issues. They're not real easy issues that one can spend just a day and a half and not feel like you've pretty much got your arms around them and you've given informed advice to decision makers in the EPA. These are very dense issues. They're very complicated issues.

You know better than anybody that it isn't just a day and a half that you're giving to us to benefit from your advice. We fully recognize that those of you who are around this table are spending hours way above and beyond that. You pretty much have to. The issues sort of demand it. They are complicated, and they involve a fair amount of investment on your part to be able to meaningfully participate. We are very aware of that.

We know we put significant demands on the members of this committee through work groups that meet above and beyond just the day and a half that the committee as a whole meets. It's that investment on your part that allows us to get the benefit of your insights and advice to us. We recognize that, and we're very grateful for the time, the energy, and the commitment that all of you bring to these very weighty issues.

I'm not going to go through the agenda. I'm

going to let Jack do that. But you know how weighty the issues are that are in front of us. So, with that, thank you for all that you have done and all that you're going to do and how meaningful it is to all of us. I'm going to introduce someone who I think many of you probably know, Jack Housenger.

I first met him 20-some odd years ago. He was doing existing chemicals in what is now PRD. It had a different name back then. Since that time, Jack has been in leadership roles in most of OPP. He has worked in the Antimicrobials Division in senior leadership. He's been in the Health Effects Division in senior leadership, what is now PRD in senior leadership. He was the Director of the Biological and Economic Analysis Division, and he was the Director of the Health Effects Division before becoming the Director of the Office of Pesticide Programs about a month ago.

So, it's a great pleasure that I have to introduce Jack to his first meeting as the chair of the PPDC. So, with that, I will turn it over to Director Housenger.

MR. HOUSENGER: Well, thanks, Jim, and welcome

to everybody. Jim already expressed a lot of things that were in my written notes to say. I've been going through and crossing them off. But I just want to acknowledge that this is a very large group of people, so I don't feel any pressure at all. I'm glad I have everyone here and behind me, although the people behind me said my hair was messed up and I couldn't do anything about it. So, I apologize for that. They give me good support.

We have 44 panel members and all but 2 are here today. One of those is on the phone; the other one is sick so won't be joining us. It's a large group. As Jim said, this panel has, in the past, provided us with a lot of good advice. A lot of times we think we know everything, but then you come to a group like this and you find out you don't. It's always a better decision because of the input that we get from this group and other stakeholders that we get input from.

I want to remind everybody that this is a federal advisory committee that is regulated under the Federal Advisory Committee Act, the FACA. FACA provides guidance and the requirements on how the federal government gets advice. It's designed to get advice from

everyone. There's an equitable opportunity for all stakeholders to be heard. We don't listen to one stakeholder in lieu of another one; we listen to everybody.

There's obviously a diversity of views here. Because it's such a big group, when you're expressing yourself, don't get on your soapbox. Make your point, get off, and let others be heard as well. Whether you agree or not, it's always helpful to have collaboration, transparency, and a constructive dialogue to our work.

These meetings are open to the public, and we post everything up on their web so everyone can see what we've done if they're not here. A transcript of this meeting is also posted on the web.

Let me go over the agenda first. We're going to start out in session one. Marty is going to give us an update on the budget and our resources, PRIA 3.

Session two is going to be kind of where we are on Tox 21, and Lois is going to give us an update on non-animal testing and her role of co-chair on the ICCVAM. Then, Jennifer McLain is going to talk about the work group's efforts on the Tox 21 front.

The third session is something that we've received a lot of comments for over the years. It's on international initiatives to promote harmonization. Lois Rossi is going to chair that, and she'll be joined by Daniella Taveau, who will provide an update on the international trade negotiations. That will go up to lunch. Then, when we come back from lunch, we'll have discussions regarding that.

Session four is on pollinator protection. It's a hot topic now, which I'm just beginning to learn about all the things that we're doing. It's one of the big issues for our agency. I think probably the number one thing that the administrator gets questions on, maybe not after the power plant rule this week, but it certainly was. It's going to be chaired by Rick Keigwin, Don Brady, Lois Rossi, and Sheryl Kunickis from USDA.

Then, we want to provide you in session five on an update of our IT activities. I think OPP has been working in the dark ages and hopefully we're coming up to the 21st century by some of our initiatives in this field. We ant to share that with you.

Session six, Bob McNally and BPPD is going to

talk about the activities of the workgroup on integrated pest management. Then we'll have opportunities for public comment at the end of the day. So, if you want to make a public comment, please sign up on the public comment sheet at the registration desk.

On Friday, we're going to be talking about endangered species. That's chaired by Don Brady and Rick Keigwin. We're been working closely with Manera (phonetic) colleagues from the services, as well as USDA, to protect endangered species. I believe after all these years we're making good progress, but we want to give you some update on that.

Then, David Dix will join us to talk about our efforts on the endocrine disruption screen program. I think you'll find that interesting on how we're approaching that in a good way. It's kind of consistent with our Tox 21 initiative.

Then, our final session we'll talk about feedback and suggested topics for the next meeting.

Since we've met physically -- the last time we had a webinar, but since we were all together, we had a number of changes in leadership here. That's the people

behind me. So, as I introduce you, please stand. When I left HED, Dana Vogo (phonetic) took over as acting director of the Health Effects Division. Oscar Morales left our organization and went to Jim's front office. And backfilling him on an acting basis is Michael Hardy.

Bob McNally left the Field and External Affairs Division and went to the Biopesticides and Pollution Prevention Division. And Brian Frazier is acting as the director of the Field and External Affairs Division now. Utang Gillaron (phonetic) is the Director of the Benefits and Economic Analysis Division. Susan Lewis was promoted to the Director of the Antimicrobials Division last summer. So, there's organizational charts in your packets, so it will explain who is who, but there's been a lot of changes.

So, maybe now is the time to go around and introduce ourselves. If you're on the phone, please mute the line unless you want to speak. If you're at the tables, mute the speakers until it's your turn to talk.

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

MS. KUNICKIS: I'm Sheryl Kunickis, Director in

the Office of Pest Management Policy at USDA. On behalf of the USDA, Jack, we'd like to congratulate you on your selection. We look forward to working with you, as we have in the past.

MR. SOUZA: My name is Paul Souza. I'm the Deputy Assistant Director for Ecological Services within the Fish and Wildlife Service.

LTC CARDER: Good morning, my name is Lieutenant Colonel Mark Carder. I'm the Deputy Director of the Armed Forces Pest Management Board.

DR. CALVERT: My name is Captain Geoff Calvert. I'm with the Centers for Disease Control and Prevention.

MS. PATTISON: Good morning, I'm Fawn Pattison. I'm Senior Advocate at Toxic Free North Carolina.

MR. SCHERTZ: Hello, I'm Scott Schertz with Schertz Aerial Service, Central Illinois, representing the National Agricultural Aviation Association.

MR. BARON: Good morning, I'm Jerry Baron, Executive Director, IR-4 Project.

MS. BISHOP: Hello all, I'm Pat Bishop, Research Scientist in the Regulatory Testing Division of the People for the Ethical Treatment of Animals.

MR. DELANEY: Tom Delaney, Director of Government Affairs for the Professional Landcare Network, the lawn and landscape industry.

DR. CLEVELAND: Cheryl Cleveland, BASF, part of the Global Consumer Safety Division there.

MR. SHEEHAN: Pieter Sheehan, Director of Environmental Health for Fairfax County Health Department in the Commonwealth of Virginia.

MR. PEARCE: Chris Pearce, Government Relations for SC Johnson, filling in for Steve Smith this morning.

MS. STARMANN: Allison Starmann from the American Chemistry Council Biocides Panel.

MR. TAMAYO: Dave Tamayo, Sacramento County Stormwater Program, representing California Stormwater Quality Association.

MS. KIM: (Inaudible) Kim. I'm here on behalf of the biopesticide industry.

MR. HOUSENGER: And whoever is on the phone, please mute your line.

MS. FULKERSON: I'll try this again. Laurele Fulkerson. I'm the Director of the Healthy Wildlife and Water Program for Northwest Center for Alternatives to

Pesticides.

MR. TAYLOR: Donnie Taylor representing Agricultural Retailers Association.

MS. RUIZ: Virginia Ruiz, Director of Occupational and Environmental Health at Farmworker Justice.

MR. McALLISTER: I'm Ray McAllister with CropLife America.

MS. GOUGE: Good morning, Dawn Gouge from the University of Arizona representing the National Environmental Health Association.

DR. LAME: Marc Lame, Indiana University School of Public Environmental Affairs.

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

MR. VUKICH: Good morning, I'm Jake Vukich with DuPont Crop Protection. I manage our U.S. registrations group.

DR. VERDER-CARLOS: I'm Marylou Verder-Carlos from California, Department of Pesticide Regulation,

representing the American Association of Pest Control Officials.

MR. COY: Steven Coy, Coy's Honey Farm. I represent the U.S. bee industry.

MS. SIMPSON: Aimee Simpson, Policy Director and Staff Attorney for Beyond Pesticides.

DR. WILLETT: Mike Willett, Northwest Horticultural Council, Yakima, Washington.

MR. HANKS: Douglas Hanks representing the National Potato Council, Environmental Affairs Committee.

MS. LUDWIG: Gabriele Ludwig, Associate Director of Environmental Affairs for the Almond Board of California.

DR. KEIFER: Matt Keifer, Director of the National Farm Medicine Center and Professor of Public Health and the University of Washington, representing the public health voice.

MS. PALMER: Cynthia Palmer. I run the Pesticides Program for the American Bird Conservancy.

DR. WHALON: Mark Whalon. I'm a Professor of Entomology at Michigan State University, and I run the Pesticide Alternatives Lab.

DR. FERENC: I'm Sue Ferenc with the Council of Producers and Distributors of Agrotechnology.

DR. JACKAI: Good morning, I'm Louis Jackai from North Carolina A&T State University, the only (inaudible) university in North Carolina.

DR. ROBERTS: I'm Jimmy Roberts. I'm Professor of Pediatrics at the Medical University of South Carolina.

MS. LAW: Good morning, I'm Beth Law, the Consumer Specialty Products Association. I handle our Pest Management Products Division.

MR. WHITTINGTON: Andy Whittington, Farm Bureau Federation.

DR. GILDEN: Robyn Gilden, University of Maryland, School of Nursing.

MS. TROSSEE: Lilly Trossee (phonetic), Registration Division, Office of Pesticide Programs.

MR. JORDAN: Bill Jordan, Deputy Director in the Pesticide Office.

MR. JONES: All right, well, I want to thank everybody for all of your time, not just for today and tomorrow but for all the time you've put into -- oh,

right, sorry. We have some folks on the phone who need to -- I think one. Is there one individual on the phone?

MR. SANCHEZ: Hi, good morning, everyone. My name is Valentin Sanchez, Community Worker with the Oregon Law Center representing farmworkers.

MR. JONES: Welcome, and thanks especially to you. I know how hard it is to participate by phone for this extended period of time.

Again, thank you all for your time and your service. I am going to leave this meeting in the capable hands of Jack and his crack team, so I'm expecting to hear some very good things by the end of the meeting tomorrow afternoon. So, thanks again. Bye-bye.

MR. HOUSENGER: Okay. Marty is going to give us an update on the resources, the budget, and PRIA 3.

MS. MONELL: Good morning. It's always nice to start off these meetings with good news. Anyway, you can see my presentation up on the screen. You also have it in your packet. The first slide is essentially the Office of Pesticide Program's budget, appropriated budget. This includes our EPM and S&T. That's the science and technology. We have a bit of research

funding that is allocated to OPP for purposes of our labs. We have three labs.

So, you'll see we started in 2012 because we wanted to give you sort of a two-year trend. 2012, if you will recall, if you've been around that long, was the first year that we began to see a pretty significant decline in resources. It's also the year which formed the basis of the minimum appropriation under our PRIA Fee Act, the most recently reauthorized act. So, we thought we'd start there because that was the beginning of a downward trend, but it also reflected an important statutory milestone.

You'll see that the $96.3 is the amount allocated to us, particularly, and then $24.8 million is what's allocated to the regions. That's a stag appropriation, state and tribal activities account. That goes specifically to the states and tribes. So, it's done by a formula. We have no say over it, so to speak. It is just allocated out to the regions and then ultimately to the states to support pesticide programs.

The $7.2 billion is the AA's office and other. This is other portions of OCSPP that support the work

that we do in pesticide. Funding comes out of our budget accounts for that support, as well as we support an individual and activity in our Office of Administration and Resource Management. That is to help facilitate our contracting activities. So, that's reflected in that 7.2 million.

You'll see in '13 a slight decline of a couple of million dollars for the Office of Pesticide Programs as well as in the other accounts. The '14 situation becoming a little bit more dire. The '15 president's budget would bring us back up to an appropriate level, what we believe would be an appropriate level, given the overall constraints on the federal government's budgeting authority. But its success remains to be seen.

The next slide is a new slide for us. Because the past two years, '13 and '14, we have endured appropriation levels that were below the PRIA minimum threshold -- when I say that, I'm talking about a provision in PRIA 3 -- actually, it has existed in all iterations of PRIA. But the most recent one in PRIA 3 provides that the agency cannot collect fees if the appropriation falls below a certain threshold level. For

PRIA 3, that level was the 2012 appropriation. So, after 10 years of PRIA 1 and PRIA 2, PRIA 3 finally recognized wait a minute, you know, the appropriation level should really be raised to reflect the reality of the budget world across the federal government.

So, they took the 2012 level, which is $128.3 million, or .277 according to this chart, and that is now the required amount. So, you'll see that was what was passed in 2012. That's the threshold. And then, for 2013, the president's budget put us a little bit above that threshold. Congress appropriated a significant amount below that threshold.

And what they did to get around our statutory inability to collect fees was they provided language in the appropriations act that basically said, notwithstanding the PRIA minimum appropriation requirement, the agency is authorized to continue to collect the fees, the PRIA fees.

So, they did the same thing, as you will see, for '14. The amount appropriated was significantly lower than the threshold amount. Again, they inserted authorization language notwithstanding the PRIA minimum

appropriation requirement. We could still collect fees.

And then, you'll see in 2015 president's budget, again the president has shown his continued support for PRIA by providing in the budget an amount for the Office of Pesticide Programs that would exceed by a little bit the amount required in a PRIA. We have yet to see what happens in congress.

The next slide, slide 4, the FTEs. So, the last time I did this presentation, we did not have a slide on FTE. FTE is government lingo for full time equivalents. So, it's the way we track people on board for whom we pay salary. It is a construct for a body that could have been hired at a certain point in the year, in a fiscal year, so that they would not really be one full FTE. They would be .8 or .4, depending upon when they came on board during the fiscal year So, this is a government construct for tracking people or personnel.

As you know, the pesticide program is heavily dependent on people. We make our decisions by people. The statute enables us, obviously, and contemplates our using contractual support to do some of our work to help

us with preliminary review of data submissions and the like. But the ultimate decision-making authority rests with the administrator, and then it's delegated down to our people. So, unlike a lot of other programs, this is a very people-oriented program. So, FTE are very important to us.

So, if you'll see by this chart, we were actually authorized 553.6 FTE in 2012. In 2014, that number is down to 483.4. That's 70 FTE. That's probably more than 70 people. It just depends on the portion of their time during the fiscal year. So, that's a huge reduction for our program over a fairly short period of time.

Then, again in 2015, the administration recognizes that it's important that we regain some of that lost ground and that we be authorized to hire up to a certain extent. But, at the same time, the agency, along with the rest of the federal government, is recognizing that because of the budget constraints, it's really important to be more efficient and effective in our utilization of our human resources. So, there have been various attempts to cut back on the overall number

of government employees. Certainly, the EPA is a part of that effort.

The next page is just a brief overview of the various fees that we're authorized to collect. You know, most of you are familiar with this. The registration service fees, that's the PRIA fees. Those were originally enacted not to replace the work that the agency is funded to accomplish through appropriations, but specifically, it was to provide enhanced service so that there would be some predictability in the industry, in particular, and the user community on when pesticides would be able to come to market.

So, before PRIA, it was a crap shoot as to when your application would be reviewed, when the data would be reviewed, and when the decision might come forth. Under PRIA, there are set time frames for each of 190 actions I believe now in return for which you pay fees. The industry pays fees. It's obviously been a win/win for everyone because it's been reauthorized twice. In the climate on the Hill where not much was getting accomplished, PRIA 3 was passed. Albeit at the 23rd hour, it was passed, nonetheless.

Thus far, for the enhanced registration service fees, we've collected 11 million. I think I saw a report today that we're now up to 12. So, we're on track to be about fairly even and consistent with what we've been collecting historically.

Maintenance fees, PRIA 3 provided -- this is to maintain a registration for a product on the market already. You pay a product fee. That's the industry, folks. That helps support what we call the old chemical program, or the reevaluation program, and various components thereunder which includes compliance with the Endangered Species Act.

When we do these reevaluations, and you're going to hear a lot about this over the next day and a half, so I won't go into it, but the funds from this maintenance fee collection, in part, help us with some of our compliance with other matters in the registration review program.

So, the amount was increased from PRIA 2 from 22 million to 27 million initially. We believe that the additional five million a year was really critical to help us with the completion of the registration review

under the now statutory requirement, also under PRIA, that we complete the review of chemicals every 15 years. The first bell tolls in 2022. So, in order to maintain sufficient pace to get there, we believe that we needed additional resources. The coalition was able to convince congress that we deserve them.

We also, in discussions with the coalition, talked about, you know, some of the efforts in the information management realm that we had been trying to effectuate since the very beginning of PRIA. We weren't getting any traction. Either we didn't have sufficient resources or manpower or planning opportunities to bring us into the current century, quite frankly, in the IT arena.

So, the coalition agreed it would be appropriate to have a set aside of $800,000 a year to basically help effectuate some of the things that we considered important. You're going to hear this afternoon from Phil Villanueva about, you know, specifics on those, but they include a tracking system, like a UPS tracking-type system status of registration actions that would be available through the website. The first step

towards getting there you're going to hear about this afternoon, but that's been implemented.

You're going to hear about a conditional registration database so that information about registrations that are granted conditionally under the statute, that that information can be publicly available as to what the conditions were, when they were met, when the data was reviewed, and any subsequent action. We've taken first steps there as well. We have a ways to go. But those are the kinds of activities -- electronic confidential statements, a formula that we've been working with PMRA on, that's an effort that's funded with these set asides.

So, the bottom line is we're authorized to collect $27.8 million in maintenance fees every year. Last year we did not quite meet that threshold amount because PRIA 3 also provides for an additional small business waiver to what they call the ultra small business businesses. We had no way, because we weren't authorized to collect data on registrants submitting applications under those thresholds, so we didn't know what the universe looked like or how many we might have.

So, as a result, there's actually quite a few very ultra small businesses under the new definition. So, we just weren't able to collect as much as we thought we would. We've since adjusted our algorithm and we're on track to collect a little bit more than the $27.8 million this year to make up for the amounts we didn't collect last year. So, that's basically that slide.

Then, the next two slides, the first one shows the PRIA collections, $15.6 million in '12, $15.4 in '13, $12 million thus far in '14, and we're anticipating $11 million in '15. We always anticipate less than we think we might collect because you just never know. We don't want people to assume we're going to collect any more millions than we really feel we can because we're apt to be cut on the other end if we go that route. So, we do lowball our anticipation. Certainly, in light of the last three years, it looks like it's a lower estimate.

FIFRA maintenance fees, you'll just see a different depiction of this on the next slide, 7. This basically shows you in FY '12 we were authorized -- that was the last year of PRIA 2 -- we were authorized to collect $22 million and we did. For '13, we were

authorized to collect $27.8, but due to that ultra small business waiver provision, we collected a little bit less. We're on track to collect a little bit more this year because of adjustments to the algorithm by which we set the per product fee.

Any questions? Beth?

MS. LAW: Thank you. This is really more in the nature of maybe some additional information for people. You know, PRIA provides very important services not only to the industry but also to the agency's ability to do its work and accomplish its mandate. The trend we've seen over the past couple years of the appropriations level being reduced is one that is troubling, in particular in light of the president's budget this year does provide the adequate appropriation funding level. It has not been acted upon.

As a result of that inaction by congress, the members of the PRIA coalition sent two letters, one to the Senate Appropriation Subcommittee on Interior and Environment and one to the House of Representatives that oversee the appropriations process. We asked that in light of the results that PRIA has produced -- and this

is the third iteration of the statute. In light of what EPA has set out as its needs in order to accomplish its objectives, and in light of the benefit that PRIA provides to the registrant community, that this group, this coalition, which, actually, is comprised not only of industry but also of public interest groups, we felt it was very important that the appropriations committees understand how crucial we view it that EPA receive adequate funding so that they meet the $128.7 or so million threshold. So, this letter, or these two letters, convey that position.

The reason we wanted to raise it here is because here everyone on the PPDC, you know, sort of by default understands how OPP works, understands the impact PRIA has on the work of that office. We wanted you to be aware of the problem, wanted to give these letters to you and just underscore how important it is that congress provide this threshold so that we don't face the specter of having to deal with an agency that is not fully funded.

So, what I would like to do is I have copies of these two letters. I will circulate them around the

table. You can take a look at them and take a look at the signatories. Actually, there was a third letter, too, that was submitted by the Commodities Association. Again, the same message was conveyed.

I mean, the other thing, too, about PRIA is that this system is unique to the United States. We have PRIA fees, we have a set of time lines which the agency meets, and it works very well. I think all of us can remember the days before PRIA. So, having some certainty about the time frame it's going to take to get that registration is important for everyone.

So, again, I just want to underscore that point, and I will circulate these two letters. I have to confess, the way the letters are copied, they're back to back. So, you need to take the first two pages because that then will give you both letters.

Thank you very much. That's the point the coalition wanted to make.

MS. MONELL: Thank you, Beth.

Others? Ray?

RAY: When I see your figures showing a 10 percent drop in personnel between 2013 and 2014, that's

alarming. We've heard from the agency about loss in personnel, but 10 percent is a big cut. That combined with having to keep up with pay raises and last fall's government shutdown has really put a dent in what the agency can accomplish. We're seeing a gradual ongoing erosion in the ability of the agency to meet some of the time lines under PRIA.

I'm wondering if there are additional efficiencies that we from the registrant community can assist the agency with in order to keep the ability to meet those time lines.

MS. MONELL: A couple things. First of all, unbeknownst to us, the federal government has a variety of different hiring authorities. We stumbled upon one that we thought was quite interesting over the past few months. It's called term hire authority. What it enables you to do is bring folks on for up to a year with all full benefits of a federal employee. You can extend that year to up to four years under the same conditions. It enables us to pay those individuals completely out of the fee account so they don't --

(Whereupon, there was an

interruption.)

MS. MONELL: Could you mute your line on the phone, please?

So, what we've been able to do is start replacing some of our losses at the entry level positions to get folks on board to actually do the work contemplated not only under PRIA but under registration review as well and pay them solely out of the fee accounts. They are not supposed to count against our FTE ceilings. So, we've already authorized 33 of these positions.

Our intent, once we get a good sense of where we're at in terms of the payroll implications, we intend to do more of this hiring. It won't completely take care of the losses that we've endured in terms of that FTE ceiling because some of those losses are in senior and management positions. You can't just hire somebody right out of college to do that kind of senior level work, but it does provide for opportunities within our existing personnel to be promoted, to be recognized via a grade increase perhaps. It also, most importantly, provides us with the manpower to get the work done.

The most significant element to our inability to meet deadlines over the past six months was the government shutdown in October. Two weeks without a soul being here or being able to even work remotely, not able to look at phone messages, restricted from looking at your Blackberry, had a significant toll, and not just to catch up from that work but there's an echo effect.

If the scientists can't do their data review and the contractors supporting those scientists doing preliminary reviews can't do it, then that slows down the work of the next person and the next person, and the decisions are then slowed down.

We made a conscious decision, quite frankly, to miss some dates because the transaction costs of renegotiating dates were higher than the cost of just plain missing the dates. We notified the industry that would be most impacted, as well as the grower groups that perhaps were relying upon products being in the marketplace sooner rather than what we were able to deliver. I think that there was general agreement that, yes, that did make some sense. We are now in a catch-up mode, absolutely. We have become pretty efficient in our

work processes.

You're going to hear again from Phil's discussion this afternoon, but we believe that some of the technological efficiencies that we're embarking upon will really save us the FTE resources and enable us to make decisions ever so much more quickly.

Others?

MS. GILDEN: Robyn Gilden. Given that you weren't able to -- because of the government shutdown and the 70 FTEs lost, were any important tasks not able to be performed related to protection of public health?

And also, you mentioned that you do a review, it just was in passing, every 15 years. The clock is ticking. How do you prioritize what pesticides are reviewed first?

MS. MONELL: Oh, you're way ahead of us. Two things --

MS. GILDEN: If this isn't an appropriate time to discuss that, I'll get it later.

MS. MONELL: I'll just give you a threshold comment and then I'll leave it to others. You'll hear much more detail over the next day and a half. But we

recognize that with regard to your last item first, the registration review program and the completion of the review by 2022, that it's going to be a challenge.

Two issues. First, sometimes issues come up that makes it obvious that you need to advance certain chemicals in what was otherwise a schedule. Pollinators could be one of the issues that might arise.

Then, another issue that we're tackling with and we're working as a management team on is maybe we should be also thinking about approaching the work from a risk-based approach to get your sort of health issues or environmental issues, depending.

So, we've got a team of folks looking at how you might approach the work so that you -- just because you haven't met a schedule doesn't mean that you sacrifice environmental protection and public health protection as a result. So, that work is ongoing.

And then, to your question about public health issues that may have arisen during that two-week shutdown period, because that could always happen anywhere in any federal agency, there were certain accepted personnel identified. So, for instance, we had lab capacity should

a pathogen arise that needed our immediate review and attention.

We had Steve Bradbury here to call upon appropriate folks. I think a section 18, in fact, came in during that period of time for which there was an emergency. So, you have to do some economic analysis and scientific review and so forth into the need.

So, we had enough people that were available or could be contacted under a provision of the shutdown that allowed for those kinds of activities. So, emergencies were taken care of. Certainly, public health emergencies would have risen to the top.

UNIDENTIFIED MALE: Just to add another voice to the federal perspective of the decreases we faced. I'm not at all surprised to see that you lost 10 percent of your workforce. Over a two year period, our agency lost 10 percent of our entire workforce. We've got about 9,000 people in the Fish and Wildlife Service across the country, down from 10,000 just two years ago. So, the sequester obviously has affected all of the federal agencies greatly.

I clearly know it's affected other

organizations as well. I would suspect Sheryl would say the same thing about USDA. Despite the hope of the 15 requests from the president, I think all of us recognize it's very possible we could be in a continuing resolution situation. So, I think we need to be honest about the fact that a likelihood that our staff levels are going to return is pretty low.

Getting to Ray's point, I think that we really need to find ways to be efficient. We've been doing everything in our power to make this happen already. We'll talk tomorrow about some of the Endangered Species Act ideas that we're moving forward in this regard. But it's a really important point. I think we have to really push ourselves to figure out how to increase efficiencies.

MS. MONELL: Anyone else? One last opportunity. Okay, Jack, I'm giving you two more minutes.

MR. HOUSENGER: Good. Well, not to draw attention to the people that came in late, but we did have two. So, maybe you could introduce yourselves. Mike, you want to go?

DR. KASHTOCK: Mike Kashtock. I'm with the Food and Drug Administration, Center for Food Safety, in College Park.

MS. WU: I am Mae Wu with the Natural Resources Defense Council.

MR. HOUSENGER: We won't go around again.

DR. GRAGG: There's one more.

MR. HOUSENGER: Okay.

DR. GRAGG: Hi, this is Richard Gragg from Florida A&M University, School of the Environment.

MR. HOUSENGER: Okay, thanks.

Our next topic is Tox 21. It's going to be led by Anna Lowit and Jennifer McLain. I turn it over to them.

DR. McLAIN: Okay, good morning. Now we are all organized. Today, I am going to introduce the topic of the toxicity testing in the 21st century. I am Jennifer McLain, the Deputy Director of the Antimicrobials Division. I also chair the PPDC 21st century workgroup. I'm going to talk a little bit about OPP's 21st century vision and the activities that are going on in OPP right now that came as a result of the

recommendation we received from the PPDC last year in 2013 for some OPP metrics.

Then, Anna is going to talk about work going on in her role as the co-chair of ICCVAM. Then I'm going to to come back and give a presentation that is from the PPDC 21st century workgroup focused on what one of the other activities of the workgroup is looking at. That's in the biomonitoring subgroup.

So, I've presented to this group a few times before, so I won't focus too much on our vision. But just as a reminder, our 21st century vision, which we've had in place for a number of years now, is really focused on making sure that we have a process that is integrative and hypothesis driven, in that we're using information from a variety of tools, whether they be alternative assays or existing knowledge, (inaudible) phase, chemical asimilarity. We're using that information to develop a hypothesis and focus our resources on the risks of greatest concern.

This is a process that's very incremental. We're doing things slowly over time as new alternatives or new methods become available. They are proven through

peer review and our assessment of them in terms of their readiness to be used in our program. Really, it's something that, over time, we'll also be changing, not only the information that we're looking at but also how we are assessing the risk.

So, that's why the partnerships that we have are so critical. First of all, stakeholder engagement with groups such as this one allow us to make sure that the folks who are directly impacted by much of the work that we're doing understand how we're doing it and what we're doing.

That we have this level of transparency to have conversations when there may be disagreements or different views on information that we are considering, to have those conversations and to really gain through those conversations a public trust that the new approaches that eventually would be folded into the program leave us in a place of our risk management that says good or better than before.

So, one of the major ways we're having this conversation is through the 21st century toxicology/new integrated testing strategies workgroup that I mentioned

before. It's been in existence for about four years. We haven't been successful in changing our title into something simpler, but we've done a lot of great work.

Also, through the collaborations that we have with industry groups and public interest groups, federal agencies, and international governments, that's some of the work that Anna is going to be talking about in a few minutes.

So, our 21st century workgroup, the objective of this group is to focus on communication and transition issues as we advance our vision. Some of the activities that the workgroup has done so far is we've held stakeholder workshops on a number of different issues. We've talked about advancing research for biomonitoring tools.

We've put together a proposal for OPP program metrics. That's what I'm going to focus on here. That was a recommendation from the workgroup to the PPDC that OPP adopt metrics to demonstrate the advancement of the OPP 21st century vision.

I'm just going to go over a couple of the slides that Kristy Sullivan presented last year to

understand the context of the recommendation that came from the PPDC last year. So, the goals that the workgroup put together in terms of big picture ideas was to have a phase out of animal testing for the acute 6-pack endpoints and to have consistent regular reductions in the numbers of animals used for acute tests, and also to have consistent and regular increases in the use of non-animal methods and existing information used to make a regulatory decision.

For specific goals, though, workgroup recommended some advancement in our program of work going on in OECD in particular. They were very specific in terms of recommendations of the OECD approved in vitro skin irritation methods, advancing those into adoption by the program. 2015 was the recommendation, a recommendation that OPP accept a suite of in vitro tests for skin sensitization, which is also an OECD project. Also, to phase out the use of tests that are looking at multiple routes of exposure and allowing us rather to use a route-to-route extrapolation. Anna will also be talking about a couple of these activities that are going on within our office in terms of trying to reach these

specific goals.

This table is hard to read. It was something that the workgroup put together. It just shows you, if you just sort of look at the big picture, the number of alternative assays that are currently in some advanced phase of development for the 6-pick. So, it really is the richest area in terms of setting some first near-term goals.

These are the specific recommendations for the OPP metrics. What the workgroup proposed was that OPP measure every year the number of in vitro tests submitted per endpoint per year, the number of acute animal tests submitted per endpoint per year, the number of animals used in acute tests per year, and the number of submissions that have alternative approaches that are submitted per year. So, those are the ideas that the workgroup came up with.

What we've done since receiving this recommendation in 2013 from the PPDC was to put together our own internal workgroup to look at the recommendations and make some decisions as to what we think are feasible goals for the program in terms of our ability to measure

and what we think would be good measures of demonstrating our progress in the advancement of the 21st century vision.

So, this workgroup is charged with developing the metrics, putting together some criteria of how we would measure those internally in our program and do that tracking, and how would we report out on those. We have participants in the workgroup from multiple divisions. Internally, they're under our construct of our OPP's Science Policy Council and the OPP Risk Management Forum jointly.

So, I'm going to turn it over to Anna now. She's going to talk about some of those federal collaborations, particularly the ICCVAM work that she's doing. As I mentioned, this work will really get us closer to some of those goals laid out by the PPDC groups.

MS. LOWIT: Thanks, Jennifer. So, good morning. Hopefully, as we get through this presentation, you'll see the work we're doing through ICCVAM and some collaborative projects with NIEHS. We're actually building efficiencies into our process by working

collaboratively with our federal partners, but also working to meet the recommendations of the tox 21 group.

So, one of my hats that I wear right now is I am one of two co-chairs of ICCVAM. If you're not familiar with that acronym, it stands for the Interagency Coordinating Committee on the Validation of Alternative Methods, which is very much of a mouthful. We're essentially a committee established by congress back in 2000 comprised of 15 federal agencies that require, use, generate, or disseminate tox data. So, it's a combination of EPA, FDA, CPSC, OSHA, several parts of NIH, but also, for example, the National Library of Medicine has a representative, as does USGS and a number of other agencies.

The component of NTP at NEHS that manages and supports the administrative role of ICCVAM is called NICEATM. That's another big long acronym. But NICEATM and ICCVAM work closely together to promote, develop, validate, and promote the regulatory acceptance of alternative methods. That quote on that first bullet is almost verbatim out of the statute.

The committee was established in 2000. Rear

Admiral Bill Stokes had been the director of NICEATM for a very long time. In late 2012, he retired from federal service. At that point, Dr. Warren Casey took over as Director of NICEATM.

In concert with Dr. Stokes' retirement, Linda Bernbaum (phonetic), who is the Director of NIEHS, put out an editorial in EHP in February of that year thanking Dr. Stokes for his federal service but also laying out a new vision and a new path for both NICEATM and ICCVAM that aligns NICEATM and ICCVAM with the vision out of the National Academy of Sciences in line with toxicity testing in the 21st century.

Not long after that editorial from Dr. Bernbaum, the members of ICCVAM responded in kind with a response thanking Dr. Stokes for his service but also embracing the new vision and new opportunities.

So, between the early part of 2013 and things actively being worked on right this moment, I can tell you, there's been quite a bit of activity to create a new vision and a new direction for ICCVAM. With the new director and the new vision, the previous chair of ICCVAM stepped down and myself and Dr. Abby Jacobs (phonetic)

from FDA were voted as co-chairs. So, we share activities within ICCVAM.

About this time last year, we released a draft document that's only about five or six pages, but it is really chalk full of a lot of stuff. The draft covers essentially three areas, which I'll hit on briefly here. One of them I'll talk about a little bit in detail because there's a direct link between some ICCVAM projects and the metrics for acute toxicity testing that Jennifer just talked to you about.

So, the draft covers three major areas. One is how ICCVAM is now setting priorities and immediate science focus areas of projects ICCVAM is working on.

Plans to improve communications with stakeholders and the public, previously and prior to 2013, there had been a lot of comments from the public that ICCVAM and NICEATM weren't as transparent as people would have liked them to be. It's not open to public input. So, we've been working very hard on that front to change that. Being here today I think is a statement of that.

Lastly, very briefly, the document covers an

idea that within the federal government, we'd really like to think about changing the paradigm for validation so that we can speed up the use in regulatory testing.

So, primarily one of the biggest changes within ICCVAM seems intuitive but is quite an about face for the way things have been working. The member agencies are now taking an active role in deciding what projects are worked on. In fact, any project that's worked on at ICCVAM now has to have an agency sponsor.

There's also been a streamlining of the number of projects. Before the approach was to have a finger or two fingers in as many projects as possible, which led to not many things moving forward at a very fast rate. We've taken a new approach as to have a small number of projects for which we think we can advance relatively rapidly and keep our eyes open to other things that are moving forward with the scientific community.

We are working to develop new procedures for submission and nomination of new assays to ICCVAM. This is still definitely a work in progress. One of the most important components of that is that we are working actively with our friends in Europe at ECVAM, so that's

an E instead of an I, to work more collaboratively with the Europeans.

If you're familiar with ECVAM at all, through Reach and also the Cosmetics Directives, the Europeans have a great deal of funding going into alternative areas. In fact, each member state has a lab that's been commissioned for doing these kinds of validations. It's a huge network of laboratories. They have a giant infrastructure for which doesn't exist here within the U.S. ICCVAM is a committee, literally. There's no labs.

So, part of a lot of what we've been doing is working with ECVAM to start the cross talk better. In fact, we're so excited about the work that we've been talking with ECVAM about. In September, so just a few months from now, ICCVAM and NICEATM will be meeting SACATM, another acronym, which is essentially the FACA for NICEATM and ICCVAM. It's a scientific advisory committee for alternative methods.

It's meeting in mid-September down in North Carolina. We believe at that point that we'll be rolling out a proposal for how we'll be collaborating and coordinating with ICCVAM. We have some figures and some

texts that we've been working and how literally the two organizations will be cross talking substantially. We hope to have federal government employees on most projects within ICCVAM pretty soon. That's the goal. I don't have anything to talk about today because everything is still under a forum for another month or two.

So, the drafts from last year identified three projects. The first one is the USDA sponsored project, which I'm not going to talk about. The second two have to do with EPA, particularly the pesticide office. The first one I'll go into a little bit of detail because I feel like we're on the verge of having some exciting things.

So, in line with what Jennifer had talked about with the recommendations with metrics from the tox 21 group, we are looking into a comparison of oral and dermal toxicity tests, particularly for mammals. We are in the middle of doing a project to compare them, in fact. It's a three-step process of which we're pretty close to being done with the first step.

So, just a minute to give you some contacts for

those of you who aren't aware of how these kinds of studies are used. One of the examples that's of interest, particularly to HED, is the acute dermal testing and oral testing, which is often used for labeling, for pesticide handler labeling. So, there's a table there that I pulled directly out of Label Review Manual. Obviously, it's way too small, but the point is that different toxicity categories lead to different kinds of personal protective equipment.

So, in line with this, we get 6-pack data, which is on the other table on the other slide, for a variety of acute. We get acute oral, acute dermal, acute inhalation, eye dermal irritation, and skin sensitization. The idea is to think about the comparison of oral and dermal data and to ask ourselves in the end do we really need both of those studies or is just the oral data sufficient for labeling purposes.

So, we set out a three-step process. The first one is to compile a dataset. Although intuitively that would make sense, it's actually a monumental effort. You'll hear from Phil Villanueva this afternoon, I believe, as Jack has already alluded to, our IT is in the

dark ages, which means, to some extent, we've had to manually go into a lot of these studies. So, it's been monumental, and with the help of a couple college students, we've come a long way.

So, a little bit of background. A few published studies have done this kind of thing already. There are three papers out, either a combination of pesticides or industrial chemicals, that have compared oral and dermal studies. They generally show that having only an oral study would be adequate. You don't really need the dermal study, according to those authors.

But, for purposes of our needs for regulatory decision making, these are only the technical active ingredients. I'll mention it a little more in a minute. The formulations are really where the animal savings would come. And also, none of these studies have looked at the OPP four-level categorization system, which is also an important component of this.

So, in 2012, before I became chair of ICCVAM, I had collected some data out of primarily the reds from the early 2000s and had a small dataset of pesticides. They concluded at that point, under the direction of Bill

Stokes, that you could not use the dermal in lieu of the oral. This was in direct conflict with these papers that I mentioned on the previous slide. The analysis and the approach to the analysis was, quite honestly, heavily criticized by a number of groups in both the animal (inaudible) arena but also in industry.

So, in 2013, one of the first things that Warren did when he became director, I think within an hour of finding out -- in fact, he called and asked if we could redo the analysis, which we were very excited about but wanted to change some of the content of the dataset in order to ensure that it met our regulatory needs.

From Warren's point of view, there were some things that needed to change. Those are definitely in process. The 2012 analysis, which the current analysis will handle the limit test issue quite differently. There's a much better QAQC focusing on the rat so we don't have to mix up rats and rabbits.

Work on this project continues even right now. The dataset is being finalized. We have studies compiled for both formulations and technical active ingredients, but we are, to be honest, focusing on the formulations.

It's the formulation studies that are used to label for the pesticide handlers, and the animal savings will really come from the formulation studies. The technical studies are generally just done once at the time of registration. From that point, it's the formulations.

Also, our friends who do ecological assessments often use the technical studies. So, we'll be having engaging discussions with them on the technicals before we really move forward on thinking about how to handle that.

So, we do have a draft dataset that is, in my mind, very close to completion, within a couple of weeks in fact. The most important thing we're doing right this second is evaluating what I would call the chemical space coverage, if you've heard that sort of lingo. So, this is the first time we've done this kind of thing, and we want to make sure that the dataset that's compiled fits the needs of the regulatory program.

So, we want to make sure we have a depth and a breadth of toxicity categories but also chemical classes. We're doing the doublecheck right now. But it is actually a relatively large dataset. We have

conventionals, antimicrobials, biopesticides. We have quite a bit of information pulled.

For example, we're looking a lot at formulation type because the dermal absorption is heavily driven by the physical form of the compound. We have data from 12 different formulation types. Right now we have over 400 combinations of AIs and multiple AIs. So, it's actually a very robust, very large dataset.

Once we feel like it's compiled and everything is QA'd, we'll be sending that dataset to NICEATM, and that's hopefully within the next couple of weeks. NICEATM will be conducting the statistical analysis on our behalf.

So, once they complete that and we have conversations, that project will be written up for public comments. The hope is that the analysis will be available by the end of the fiscal year. The plan is to be fully transparent so the dataset and the statistical analysis and all the (inaudible) that underlies that will be part of the package.

One more sort of in line with toxicity testing, the third area identified last year under ICCVAM is the

skin sensitization. At the OECD level, the adverse outcome pathway was first established at the OECD. So, there isn't a significant amount of worldwide progress in line with that with the development of in vitro and chemical and in silico assays that don't use any intact animals at all.

Also, about fall of last year, we put out a PR notice asking for public input on the state of the science above and beyond some things that we already knew about. We got a lot of really good comments, and we're in the process right now of developing a draft plan of what to do.

We think the plan of working towards an integrated testing strategy that's entirely non-animal is within grasp. We're going to do this in two phases. The first phase will be a focus analysis on comparison to LLNA, simply a yes/no answer, which will, if you know our process in house, should help us quite a bit. The second phase will be more complicated because we'll need to look for potency, and that will probably take a while.

In line with the things that I've talked about, as you saw from Jennifer's really small table with all

the assays that are close to being ready, there's quite a bit of alternative assays for skin sensitization, dermal irritation, and skin irritation that are either already OECD guidelines, already validated by an international body, or about to be OECD guidelines. And there is in existence some datasets out there.

There's been discussions at a meeting about a month ago between ourselves and Canada PMRA, the animal welfare groups, and members of CropLife to put together some pilot studies of looking at the existing data to moving towards non-animal. That's really in its infancy, and we hope to come back to you later and give you all the fun details, and it is fun.

All right, a couple more things I'll go through quickly. Communications issues, in the past, ICCVAM has been heavily criticized for being closed door and not open. We're working hard to change that. There is a meeting on June 25th at NIH Natcher Center which is intended to be a public forum. All the federal agencies will be giving updates on their work and alternatives. We hope to hear feedback from the public on what new things we should be looking at.

Just to move quickly, if you are interested in this arena, we are working towards developing a community of practice webinar series. The hope is in the late part of this year that we'll begin that series. So, feel free to contact myself or Warren Casey about getting on those e-mail lists in case you're of interest.

The international arena is absolutely vital in this area, not only because of validation but also acceptance of guidelines through OECD, but also just to be efficient with uses resources. Dr. Chris Sollinger (phonetic), who works here in OPP, is the OECD national coordinator for guideline development. She is a new ad hoc member of ICCVAM and is attending most of the meetings.

One more area, because I'm running over, last, but definitely not least, with respect to the long-term goal of working towards integrated testing strategies, the current paradigm of a three-lab round robin that takes three or four years is not going to keep up with the state of science in the alternatives arena. So, many people around the world are thinking about how to better align the process of validation with the process of

developing assays.

But a couple of things that are important to think about is it needs to be a fit for purpose validation. You may want to think about assays used for screening, quite different from something to replace a guideline.

So, in summary, I think you can see we're working hard very quickly to make a lot of changes within ICCVAM, but we're also using the Office of Pesticide Programs. The collaboration we have with other federal agencies through ICCVAM can really speed up our own implementation of non-animal testing.

DR. McLAIN: We'll have questions now and then probably the break and then the next presentation from the PPDC workgroup after the break. So, are there any questions for me or Anna?

Cheryl?

CHERYL: It's not a question; it's just one of really good support in this presentation back to back to the budget cuts and the recognition that everyone here at EPA is so taxed. I just want to come out and say again how important it is for EPA to support the commitment to

working the international community. I just want to go on record that that's so important. So, thank you for that. Thank you for being the really engaged and credible voice in that.

UNIDENTIFIED MALE: I just have a general question. It was a little hard following your delivery, but I think it came up in the new vision and direction for ICCVAM. You were talking about active sponsors. I wonder if you would illuminate a little bit what that means, explain it, give an example, maybe.

DR. LOWITT: Sorry if I wasn't clear. I looked at the time and realized I'd talked way too much.

On record, on the ICCVAM web site, there are a series of procedures if there is a group that has an assay they like to submit for validation. Those procedures are being completely rewritten and reconsidered.

One of the important components of that is that ICCVAM will not take on a project unless there's an agency that's "willing to sponsor it." I don't have the details of what that means because we're still working through a couple of examples to figure out what

sponsorship means. But what's vital is that the work of ICCVAM is aligned with the needs of the agencies so that ICCVAM or NICEATM isn't doing things that aren't relevant to the needs of the federal agencies.

So, one of my slides about the vision, I intentionally had in the parenthetical who the sponsoring agency was. So, for example, the leptospira is in the USDA project. The skin sensitization is a multi-agency project with FDA, EPA, CPSC, and, to a lesser degree, OSHA. We've only had one true submission of a new assay come from outside the federal family. That's being worked through on how that thing works. We're also using it as a pilot to work with the Europeans.

So, as we work through a couple of pilots, we'll have a better understanding of what sponsorship means. But, the true bottom line is that we have to align the needs of the agencies with the work of ICCVAM. And believe it, that wasn't happening before.

MR. JONES: Mae?

MS. WU: I'm not exactly sure, but it's about the alternative assays that you mentioned. You flew through it a little bit, so I just didn't catch exactly

what you said. But you had mentioned that there might be some pilot studies that are already ongoing or under consideration?

DR. LOWIT: There are some assays. Jennifer's slide, the one with the two point font that looks like an Excel spreadsheet with the teeny tiny font, is a spreadsheet of a number of the in vitro assays for which are relatively advanced. So, either they're in draft that we see the guideline or they're very close to having ICCVAM validation in Europe.

Given the state of those assays, and they're primarily for skin/eye irritation and skin sensitization, we feel it's a good moment in time to look at the state of those and how they could apply within our program.

So, May 20th, I think was the date, there was a meeting held where we attended and PMRA and a couple of animal welfare groups. Pat was there, and Ron Casey from NICEATM and some representatives from CropLife America talked about the idea of putting a pilot project together. It's still really an idea without a lot of concrete details around what that means.

But there is some optimism that some data

exists in the in-house files of some of the companies that can be shared, at least in a way that's blinded so you can do a pilot evaluation of using those data for regulatory decision making, just as a pilot to see where the state of the science is, what the needs would be, where are the holes, what would be the next steps to make it happen. But it's still an idea. There's not really a lot of details surrounding it.

MR. JONES: One last question from Matt.

MATT: I just ask whether an adverse outcome pathway understanding of the analogy between the in vitro and the live tests is a requirement of the validation process?

DR. LOWIT: No.

MATT: It's not?

DR. LOWIT: In the case of the skin sensitization, there's a nice overlap between the assays that are being developed and the steps in the adverse outcome pathway. But the simple answer is no. So, for example, the eye and the skin irritation assays that we've mentioned aren't necessarily related to an established adverse outcome pathway.

But when you think about moving to more complicated toxicities like cancer, they will probably intuitively be anchored in some kind of adverse outcome pathway, but there's not a direct requirement.

MATT: So, at this point, it's effectively an empirical comparison?

DR. LOWIT: I'm not sure how to -- sort of, but keep in mind that the assays are being developed to mimic some sort of biological process.

MATT: Right.

DR. LOWIT: So, if you accept the idea that the biological process and the assay is representative of something going on within the larger animal, you then, yes, empirically compare datasets and look at how it ranks and where things fall.

MATT: Right. Thank you.

MR. JONES: Let's take a break until 10 of, but be back at 10 of. Thanks.

(Whereupon, a brief recess was taken.)

MR. JONES: Okay, Jennifer McLain is going to talk about the PPDC workgroup, biomonitoring subgroup.

Take it away.

DR. McLAIN: Hello again. I'm going to talk right now specifically about some of the work that's going on in the 21st century workgroup within our biomonitoring subgroup.

In general, we have a really large workgroup in sort of name, but we have a really dedicated core group of folks who contribute greatly to all of the projects that the workgroup is doing. Typically, we like to have one of those workgroup members do our presentations here to the PPDC so that you can all see the folks who are doing some of this great work. They asked me today to do the presentation for the workgroup.

We've had a lot of vigorous discussions on this topic and multiple viewpoints. So, I'm going to talk a little bit about what we've done with the project, the history of the project, and sort of where we are now and where we hope to go next.

Our workgroup, of course, has a lot of foundation within the 2007 report that came out from the NAS, Toxicity Testing in the 21st Century: A Vision and a Strategy. On this slide, I just have the graphic that

the NAS used to explain the vision of 21st toxicity testing. The thing to point out here that's in relation to this particular project is the outer ring of the picture with his population exposure data and the risk contexts.

So, the idea put forward by the NAS is that as you transform your toxicity testing paradigm and your risk assessment paradigm along with that, you develop, in context with that, a greater ability to do surveillance in the population that is exposed to pesticides so that you have like a complete ring around your risk management decisions that are based on that new paradigm of risk assessment.

So, in order to meet this vision, one thing that we need is advancements in the fields of biomonitoring. That's one of the things that this subgroup is focused on.

So, the project history, we held a one-day workshop here in this room in 2011. At that workshop, we talked about the development of diagnostic tools and biomarkers for surveillance and epidemiological research. During the meeting, stakeholders at the meetings and

discussions and the talks recommended that we look at specific pesticides and those for which would be promising to develop diagnostic tools.

The next day after the workshop, we came to the PPDC, the workgroup came to the PPDC and talked about them, the discussions that had gone on in the workshop and offered to the PPDC to develop some proposals based on ideas coming out of the workshop. That's what the group did.

The workgroup presented two proposals in 2012. One of those proposals was to create a list of pesticides for which it would be a priority to advance research on biomarkers. So, the activities within the proposal were to bring in some scientists with broader expertise in clinical diagnostics and biomarker development and incident data, and develop criteria for putting together that list.

Then, the second proposal was to look at the other data and information that would inform biomonitoring. How to make existing data that's relevant to diagnosing overexposure to pesticides be more accessible and to explore the opportunities for having

this additional information more at the hands of clinicians to use in diagnosing pesticide exposure.

So, following the presentation of those proposals to the PPDC and the discussion with the PPDC, OPP sent a charge to the workgroup in June of 2012. The charge basically consisted of the concepts from those proposals. First of all, to go ahead and develop a priority list of candidate pesticides for developing biomarkers for researching clinical applications. Through this expert group, it has been proposed and agreed upon criteria for developing the list.

Also, to create pesticide use cases for the pesticides on the list to encourage the funding for research on rapid diagnostic models for pesticides. And then, also to identify existing data relevant to diagnosing overexposure to pesticides.

Some of the examples that had come up in the discussion of the workgroup at the PPDC was information submitted to the EU. There's, at the time, some recent guidance from WHO on clinical management of patients with acute pesticide exposure, to use some of those resources and others to look at what else existing information and

data might contribute. So, in terms of the first step, it's looking at this priority pesticide list of pesticides or classes of pesticides that would be good candidates for biomarker research.

What's happened since the charge to the group is that we did get together an expert group of scientists and public health professionals. We gave them this charge to look at th prioritization criteria and make recommendations on pesticides that would be a good research focus.

These folks met in 2013 through the beginning of this year. The goal was to look at the rapid diagnostic testing tools for clinicians to be able to test for pesticide exposure. So, with that in mind, they developed criteria for prioritizing the pesticides or pesticide classes, and they identified data sources that they were going to use. For the most part, a large portion of it were different incident data sources. They developed a draft list of pesticides.

We've had a few discussions with our workgroup about the draft list, the first one being in May, last month. Some of our members voiced concerns that having

this draft list of pesticides could be misunderstood or misinterpreted, given the level of context currently available.

So, one of the things that we thought was important was that all of our members in our conversation acknowledged the importance and agreement on the ultimate goal of encouraging research on pesticide biomarkers. So, given the concerns that folks had on the list, but the agreement on the goal of advancing research, the workgroup decided to use the draft list as a working tool.

What the group has decided to do with that tool is to try to go forward with that second step of the charge and develop what we're calling a pesticide use case. We're using this as what we're calling a proof of principle in terms of advancing the research. So, take that example from the list, bring it forward to some research groups, and try to begin a dialogue with researchers on the need for the biomarker tool and the ideas that the workgroup has in terms of which pesticides would be a priority for having a biomarker.

In the past, our workgroup has talked to DARPA

and DOD and we've talked to folks in EPA's own Office of Research and Development. We plan to continue those discussions with those groups and other groups also.

I think I will end it there and first ask if anyone has any questions or clarifications or if anyone from the workgroup has any input. We'll welcome that also.

DR. KEIFER: Matt Keifer. I'm a member of the workgroup.

I have been struggling as a member of this workgroup for some time trying to understand something. What I think I've begun to understand as a result of re-reading the 21st century toxicology report is that, written by toxicologists largely with relative paucity of epidemiologic and public health input from an epidemiologic perspective, I see that there's a great deal of emphasis in this model in the center of that circle.

Could we go back up to that model? The toxicity testing and the decision making about the safety of chemicals is made largely on mechanistic grounds in this model. We've removed the animals from this study

process, so we're not using this more empirical approach to see what happens to animals when we expose them to these chemicals.

The concern I have is the asymmetry of this model, because in the toxicity testing report, there is mention of, but little recommendations about, the use of an epidemiologic safety net or a public health safety net that would back up the toxicologic decisions that are made on the molecular basis that drives the center of this model.

So, as a public health professional, my emphasis on this biomarker committee is to say we've got to put at least a fair bit of energy to give the tools to the public health community to actually serve as that backstop for the decision making that's made in that central core of decision making. That's what I want people to understand that we're trying to achieve in this biomarker committee.

We're trying to say we need the tools. I'm a physician. I practice public health. I see pesticide exposed workers. I see probably more pesticide exposed workers than I know I see because I don't have the tools

to make the decision.

So, I'm part of that outer ring, and I want to be equipped with the tools that will allow me, when these new chemicals are coming down the line, to make the decisions I need to make, to make the diagnoses I need to make, to participate actively in that surveillance system that protects the population once the chemicals are out in the field.

I'm trying to make that emphasis that that's where I believe we should go with the biomarker committee.

MR. JONES: Thank you.

Mark?

MARK: I don't now if Matt and I were thinking along the same lines, but I was hoping we'd have some kind of time frame where we look at delivery of those biomarkers and a process outlined for how that's going to be handled in a pilot, and maybe a work through, an elaborate work through of the evaluation criteria before it hits the road here.

UNIDENTIFIED FEMALE: So, our workgroup is focused on trying to work with researchers to encourage

them to do some research that's focused on particular pesticides that we are recommending as candidates. So, what I can do with our next PPDC meeting is come back and talk to you about the progress we've made and talking to the researchers.

Our goal over the next month between now and the next PPDC meeting is to advance that portion of the project. I'm not sure, because it will depend on the specific researchers and their interest on the part of your question dealing with timelines for the development of those biomarkers. I mean, that is in the hands of the researchers. But if the information is available, we could bring it to the group.

DR. GILDEN: I know you don't want to discuss specific pesticides for various reasons, but what criteria was used to make that priority list? And I'm sorry, this is Robyn Gilden speaking.

DR. MCLAIN: Sure. The primary criteria was the number of incidents that had been reported, the acute toxicity and exposure which is also reflected in those incidents.

DR. ROBERTS: This is Jimmy Roberts. I'm also

on the committee.

I want to probably mention who was on the expert workgroup. I think that might be of help to the PPDC. We had Cheryl Cleveland with BASF was on there, as well as Mike Bartles (phonetic) from DOW. He's a toxicologist. Then we also had a number of clinical toxicologists in the emergency room setting.

Jeff Burgess (phonetic), for example, is a well-known clinical toxicologist. He takes care of a lot of acutely poisoned folks, as well as myself and Matt and some other toxicologists who work with the poison control centers.

The data sources that we used especially were the Poison Control Center reports. They'll look at the moderate and severe and fatal outcomes of different pesticide poisonings. Then we also looked at some incident reports, surveillance studies from CENSOR (phonetic) which Geoff Calvert runs, and then also the California incident reporting system had some data on usage and exposures.

We also did look at the acute toxicity, the LD50s. That was a little more difficult because there

are some that have very high LD50s but really are infrequently used now. There were much fewer human poisoning cases. So, we tried to especially look at the compounds that are currently being used but also increasing in usage.

I want to take one more point just to point out and kind of add on what Matt talked about. We are in the outer circle, and it's my responsibility as a pediatrician, Matt's as an internal medicine physician, and of course all of those people that we are in charge of teaching, they're the people that have to identify pesticide poisoning when they come in.

I've said this before, and I'll try to be brief, but I teach students all the time. I ask them in one of my talks on pesticide poisoning, all right, this is the case. I give them the case example. I say, all right, what possible insecticides could this be from. I always get them to say organophosphates. Then, I ask them, okay, well, give me a differential of other insecticides besides organophosphates. Then I have silence in the room.

So, the medical profession still has ways to go

on the education side. That's absolutely true. But my concern is that part of that is that in their second year of medical school, they are taught to the diagnostic test. They are taught that we can get a cholonesteroids level and oh, by the way, we also have an anecdote for organophosphates poisoning. So, that's what they're taught.

So, in that same vain, if somebody shows up in the emergency room and they think that they may have been poisoned by a pesticide, the medical community can do a cholonesteroids testing and say, well, it looks like you might or might not have been poisoned by a organophosphates, but I can't tell you what else that you're poisoned from.

So, looking back at that outer ring, we still have a long ways to go. We are trying to look down the line in identifying some pesticides that are being introduced and replacing some others or one other that may have a current anecdote.

MS. ACONOMIS: This is Jeannie Aconomis (phonetic) from the Farmworker Association of Florida in Apapca.

We do trainings for healthcare providers. We've been doing them since 2006 for healthcare providers throughout the State of Florida, and these are healthcare providers that serve the rural farmworker communities. What we have found is that the majority of people that we see in our trainings -- and that's physicians, nurses, outreach staff, usually it's the whole staff in clinics -- they're completely unaware. Pesticide exposure is not even on their radar screen.

Just yesterday, I was going through our evaluations since 2006 from different providers that took our trainings. Most of them say that they were not aware about this. It was not on their radar screen. They're learning new information. Farmworkers are not about to report when they're ill unless it's a very serious illness. A lot of the farmworkers that we train, because we also train farmworkers, a lot of farmworkers have symptoms and don't relate their systems to pesticide exposure.

So, there's vast underreporting. There needs to be a better way to capture pesticide exposure cases, because it's not going through poison control. In the

State of Florida, we have a sensor program. It's not being reported to the sensor program either.

Healthcare providers -- and I have it all written down -- healthcare providers tell us that they weren't aware of the state reporting requirements for pesticide incidents. Even when they are, they don't know how to identify the symptoms. So, there's a tremendous amount of underreporting.

MR. JONES: Jeannie, if you have a public comment to make, this session is for the PPDC panel members. You can sign up at the end of the session. But we have quite a few people sitting here with their cards up. We're running a little bit over.

MS. ACONOMIS: Okay, sorry about that.

MR. JONES: Let's take Mae, Cheryl, and I assume Robyn doesn't have another comment, and then we'll call it a day. Not a day. I'm sorry that slipped out. I'm really looking forward to the rest of the discussion.

MS. WU: I'm curious once this kind of happens to what extent this kind of biomonitoring information will be made to the general public, too.

And then, I was a little bit -- I have a three-

part question. I was a little bit confused when you were talking about in the workgroup that there were concerns about the draft list could be misunderstood. So, now it's being used as a working tool. I'm not exactly sure I understand what this -- is that working tool a little different from a draft list?

And then, I was interested in Matt's comments, and I was going to ask you, it sounds like you feel like maybe the workgroup is not what you're concerned about. So, I'm wondering if you think like it's going in the wrong direction or something. I just wanted like maybe one more sentence about what you were talking about.

DR. MCLAIN: So, I'll take those first two parts. In terms of the long term question, I think that the information would be available to the public where our workgroup is focusing on very initial stage in a very long term research project which would hopefully eventually get to the availability of a diagnostic tool, the use of that tool, and the results from the use of that tool. I'm not quite sure how things work out in terms of reporting, but I am sure that at some point, someone will be writing publications on that and the

information would be available to the scientific community and the public through those. I would anticipate something like that happening.

Using the draft list as a working tool, it specifically talks about those next steps I outlined. So, what the workgroup is doing right now, using the draft list to have some discussions about what we think are the best candidates for having the initial discussions with the researchers.

So, what we plan to do is focus on one or two of the pesticides -- there are pesticide classes on the list -- and bring those into development of the use case, which basically just means providing information, more information about that particular pesticide or class, and having discussions with the researchers on that specific pesticide or pesticide class.

UNIDENTIFIED MALE: So, in answer to your question about whether I think we're not going in the right direction, I think we're going in the right direction. I think we're going there slowly. My concern more is for the fact that we have a working group out of the PPDC working on a question that I think is of very

significant importance. That's what I mean by the asymmetry.

The focus on the internal workings of this model, the intellectual effort that we just heard a great deal discussed about, is intense. Whereas, we have a working group of eight of us working on this question now. There's an asymmetry there. If that model is a reality and that outer ring is important, there's something not being done that we potentially should be focusing on. It's that.

MR. JONES: Ray.

MR. MCALLISTER: This is Ray McAllister from CropLife America. I'm not a toxicologist, though I played on in an occasional committee meeting.

I'm confused by this project. I've heard mention of acute biomarkers and epidemiological biomarkers. Are they the same thing? Where is this project heading? What's the ultimate utility going to be? Is it going to improve or how will it improve the treatment of the clinical situation?

DR. MCLAIN: For this specific project that we've been working on in the expert group that was put

together that's been working over the past year, there was a lot of discussion at the beginning of the group about that focus that you mentioned, the biomonitoring tools for epi research or biomonitoring tools for a clinician to use in their office at the point of diagnosis.

Obviously, a biomarker could be used in both settings, but it might not necessarily be the same type of biomarker and you wouldn't use necessarily the same type of instrumentation because at the point of diagnosis, you need something more rapid than an epidemiologist necessarily needs.

So, the workgroup decided to focus on the rapid diagnostic tools but acknowledge the importance of the other tools at the same time. I think they also felt that the work that they were doing would contribute to both goals in the end. They also had the discussion of the acute versus chronic effects and focused on their conversations on the acute, also while recognizing the importance of the chronic effects, but also recognizing that's a tougher problem in a biomarker research venue.

So, the focus of this project has been on the

rapid diagnostic test, but the importance of those other areas that you mentioned were definitely part of the conversation.

MR. JONES: Cheryl, bring it home.

DR. CLEVELAND: Well, I'm also a member of this. I think part of what you're hearing here is I think there's still a lot of need for clarity on some of this. I think that's what we decided our next steps need to be.

I don't know that everyone on the committee agrees with everything that got said, even on the slides. I think that's part of the difficulty of working on this. I think you need to give -- maybe we tried to come a little faster than we -- we're all anxious to do something, but then this is a hard topic because we are talking about long-term research.

We're not talking about processes or -- some of the other more successful PPDC types of things are about processes; whereas, we're starting to get into things that are long-term research goals. They do start to head into specifics. You need understanding of specific metabolism and biomarkers. So, it's a little bit more

difficult than maybe some things.

The other thing I need to say is the expert panel that was put up there -- my name was mentioned, so I need to clarify. The expertise that was brought in at the beginning was to talk about criteria. The expertise that was used to implement those criteria got a little bit more narrow. That's why the list is the list, but it's not necessarily been vetted by the entire group.

However, the list was a list that was kind of a desired list. Some feasibility still needs to be done, because you can have a list of 10 things that you'd like to have something for, but the feasibility of can you have a biomarker, what's the lowest hanging fruit, what's the time frame, so it's a kinetic metabolism.

The stability, the baseline of what the ubiquitous exposure might be out there, is it actually a hazard? All of those things would have to come out in a next step if you look at the feasibility of using this as a biomarker in a clinical setting.

So, what we really decided was we can spend all our time fighting over the list and how to validate the list or we can try to move forward and get to the next

stage and have some discussions along those lines. That's, I think, where everybody wants to go. We get hung up on some of these other pieces.

I think Jennifer is doing a good job of trying to get us to go forward without having to get too hung up on some of those things so we can make some progress.

DR. MCLAIN: Thanks, Cheryl.

MR. JONES: I see a card but I think we're out of time. So, let's move on to our next topic, international initiatives to promote harmonization. I think we're going to switch up the order here. Daniella Taveau, who is the senior trade advisor in the Office of Chemical Safety, is going to talk about trade negotiations. Then, Lois, who has been on the forefront of MRL's harmonization, will give us an update.

MS. TAVEAU: I jotted down a few notes over here. You'll notice that I don't have a presentation. There is actually a very practical reason for that. In trade, what I might jot down on a Monday would change by Thursday, so I want to give you the most relevant information. I'm just going to take about five minutes or so to speak to you about what's going on in the Trans-

Atlantic Trade and Investment Partnership, or better known as the USEU Free Trade Agreement, and, basically, what's going on in pesticides.

So, I see some familiar faces here. I have never addressed this group, and I'm very grateful and thankful to be here addressing you. I have an open door. I work in the Office of Chemical Safety, Pollution Prevention. I work for Jim Jones. Some of you may not be aware but we actually have a robust trade program that is underpinned by all of the really good work that folks like Lois and Jack do over here. So, without them, we wouldn't be able to engage with our international trading partners.

So, some of you are very familiar with this particular agreement that was announced in June of 2013 by Presidents Fred Russell and Obama. Subsequent to the announcement of the FTA, there was a Federal Register notice that went out, and we received about 375 separate comments from stakeholders. Of those, the vast majority of them dealt with issues that were under EPA's purview, specifically in chemicals and pesticides.

So, we received a lot of comments from all of

you about what you thought we need to be doing or doing better and where you felt the problems were with US and EU trade. Clearly, agriculture is a very, very critical component of any trade agreement for us. So, some of the issues that came up, and I just jotted down a couple of notes, are some of the US perspective concerns that we have are with disharmonization between tolerances or MRLs.

We have a concern in general with approach that the EU takes to risk management and making sure that there is a reasonable relationship between the science of a measure and the risk management decision subsequent to that.

We also want to make sure that regulations are promulgated in a matter that is transparent and solicit information and consider all available information. Many folks mentioned concerns with hazard-based cut of criteria and precautionary principle.

While we don't like to get into an argument of whose science is better, we do want to make sure that as new science becomes available, that that science is considered. So, one party might decide to regulate

something at a point that is sooner than another, and that's okay. But when something new is available, that must be considered.

So, these are some of the issues that from the US perspective we would really like to address. From the EU perspective, not surprisingly, there were far fewer comments about agriculture, other than tariff issues, and certainly not so much about pesticides.

Another very big category of the comments that we received were on endocrine disruptors. I'm looking around and seeing some nods in the room that you're familiar with potential legislation and regulation of endocrine disruptors in the EU.

Again, we also have a robust program in the United States. We may not always see eye to eye, but the task that was given to us to accomplish on both sides, from the EU and the US, is to figure out a way forward. That is pretty difficult.

Compared to the other free trade agreements that we have with other countries -- very often we're dealing with developing countries and they say, you know, we need help with this, tell us how we can do this better

-- we are dealing with another entity that has a very developed and robust system that is very divergent from ours. So, how do we go about figuring a way to work together?

In general, the US is taking a more horizontal approach. What I mean by that is we're looking at some of the bigger issues that I mentioned, notice in comments. Is all available science being considered? Is there a reasonable relationship? From the EU perspective, they would like to see more of a sectoral approach where we take particular sectors and we discuss those and perhaps put together a regulatory cooperation council similar to what we're doing with Canada.

Again, that poses a different set of problems. With Canada, we had NAFTA, so we already had some principles, some fundamental principles that we agreed to. RCC is polishing up and fine tuning what we already do very well. So, this is something that we've pointed out to the EU.

You should also know that we are going into round six, which should happen sometime in July, with the EU. So, we're having rounds every two months. It took

up until round five for the US to get a firm commitment from the EU to engage on pesticides. They simply did not want to discuss pesticides at all.

But now that they have decided, let me give you an overview of what we're going to be talking about in general. The EU has admitted that they have a problem right now. They have a problem that they don't have enough MRLs on the books, and their ag industry is complaining to them that they don't have things that they can use on their crops.

So, actually, there was a report that was commissioned. It was decided just two weeks ago that they should get additional funding, particularly to work on minor crops. Now, I know a lot of you are very familiar with the woman sitting to my right over here, Lois Rossi, who has a prolific history of working on minor crops. I don't know if Diane Espell (phonetic) is in the room, but we've been consulting very closely with them and plan to engage on additional technical dialogues just to discuss what we can do on the issue of minor crops.

The other issue that we would like to discuss

with them is joint reviews. I was really surprised when folks on the staff mentioned that in our joint reviews that we've done with other countries, it resulted in 82 percent harmonization of pesticides. Another 18 percent is somewhat negligible, the difference somewhere between 0 and .5 parts per million.

So, clearly, these are really successful. But the issue here again is we have statutory deadlines that we have to meet. They have a different set of statutory deadlines. So, we have to get all the relevant technical people together to figure out how we can at least, as much as possible, integrate those inputs. So, that's another thing we're working on.

Now, obviously, I haven't talked about some of the big issues and how we're planning to address them, which are endocrine disruptors, as well as, again, some of these horizontal issues of risk management. So, in addition to the pesticide sectoral discussion, we will be having an FPS or sanitary and feto-sanitary (phonetic) chapter. I don't know if you guys are familiar with this term. It's a chapter that deals with all the regulations dealing with animal plants and human health.

So, in the FPS chapter, more than likely, we will talk about science and using science as the basis for your regulations. I can't give you exact language because we haven't decided on it yet, but you can look at some of our other FTAs, although I think this will probably by much more ambitious.

We also have a regulatory coherence chapter which deals with the overarching issues, again, not just science but notice in comment particular, making sure that when there is a regulation, not only are we able to comment but we're not just getting a rubber stamp. We want to know that our comments are being taken into consideration.

Now, one point that I want to make about that in the concern from the EPA perspectives, we want to make sure we have a deliberative phase when we do role making. So, after the comment period closes, we don't want to put ourselves in a position where we have to reopen a comment period because additional relevant information comes in.

So, again, I just want to make you aware that we are aware of that. My job as a trade negotiator working for the EPA is to ensure that whatever we do is

consistent with our relevant laws and policies for EPA. So, we're very protective of that. We are working with USTR on a daily basis and the interagency to make sure that we have a salient strategy going forward.

Finally, I'm saving the big part for last which is endocrine disruptors. I've heard many, many different numbers, some as high as 4 billion, some of them recently worldwide as high as 96 billion, the dollar value of the exports that this could affect.

As you are probably aware, the EU right now is looking at categorizations of substances of either a known endocrine disruptor or a suspected endocrine disruptor. For those of you that deal in trade or exports, that can be a very concerning thing, particularly when you don't have any knowledge as to what they might do with us at this point.

So, in order to address this, we are going to be working very closely with the EU on their program for endocrine disruptors. My boss, Jim Jones, is planning to go to Brussels in two weeks time. I'll be accompanying him. He'll be talking with DG trade, DG environment. He'll be talking with DG Senco (phonetic), a number of

NGO groups, a number of industry groups. He wants to hear from them. He wants to hear from you. He has an open door policy.

So, I'm going to end it here, in case anyone has any questions. But if you do have any concerns about the FTA or you just want updates going forward, please feel free to contact me. You can contact Margie and she'll provide you with my contact information.

Any questions whatsoever?

UNIDENTIFIED FEMALE: Mine is not so much a question but a suggestion that when the EU and the US are harmonizing MRLs, we would like to see the EPIA also harmonize exempt from tolerance as well for biopesticides.

MS. TAVEAU: Thank you. You don't have to answer this now, but if you can also provide me additional information of examples where there has been an issue, that would be really helpful.

MR. JONES: Jerry, you want to go?

JERRY: Danielle, thank you very much for that update. You mentioned minor uses. Lois and her team is doing a fantastic job globally, but there's a lot of

other people working in that manner. We've been quite engaged with the European minor use community as well as the growers. They're grossly underfunded with their new program, 350,000 Euros a year. At this point, all they're doing is putting the data system together that will identify needs and look at where the holes are. There are not any resources to start solving this problem. So, I don't think you can look at the European Union as a player of solving the problem on their own.

MS. TAVEAU: They can't, right.

JERRY: So, be well aware that this problem is not going to go away.

MS. TAVEAU: I totally agree. You know, one of the issues that we've had, even getting them to the table, is we have no resources. We have five people in this office. That's exactly why we need to do this. From an EPA perspective, we're not trying to prevent them from regulating as they see fit; we're trying to find some way to get the two biggest regulators in the world together to work together because we're both facing dwindling resources.

So, can we put our heads together and figure

out -- and if at the end of the day we can't, that's unfortunate. But I really think that there are areas where we can. Minor uses is definitely one of them, and funding is a huge issue.

MR. JONES: Ray, you're the last one, the last comment.

MR. MCALLISTER: This is Ray McAllister from CropLife America. We're very pleased at the plans of EPA to work closely with the European community on the endocrine issue. Given the experience that EPA has with the endocrine disruptor screening program over the years, which is well advanced now, I think Europe has a lot they could learn from and profit from the US experience. We'd strongly encourage development of a pilot program or pilot program for the two agencies to work together on endocrine screening.

MS. TAVEAU: That's really helpful. I know that our folks in the Office of Senior Science have also expressed an interest, really, in working with the Europeans. I mean, there's a lot of work on either side. We have mandated work that we have to do. I think by working together -- you know, there are a lot of

sensitivities right now.

For those of you who are not aware, the lay of the land in the EU right now is they're dealing with this legislation that a number of people and a number of government agencies in the EU do not agree with. They fundamentally have a problem. Then you have DG environment right now that is pushing forward on this.

Again, we are not a trade agency and we're not approaching this from the perspective of a trade agency. But we should, on this very important issue, work together on this and any other emerging issues that we see coming down the pipeline.

MR. JONES: Okay. Susan, last comment.

SUSAN: It's really just a question, and you just touched on it a little bit. USTR, are they involved in this too? When you start talking about not just pesticides but lists of endocrine disruptors known or theorized to be, you do come up with billions of dollars worth of chemical trade that will be affected by that. EPA will look at things in a science-based way and the EU oftentimes does not necessarily.

So, at what level are these discussions going

on about what happens if the EU starts to come out with lists like endocrine disruptors and then establish bans and that type of thing?

MS. TAVEAU: So, very concretely, if FTA, and I can't remember exactly how many chapters there are in dealing with textiles, chemicals and pesticides are coming up in a lot of different chapters right now. The endocrine disruptor issue, I'm not going to speak on behalf of USTR, but from my personal perspective, it's almost a deal breaker.

We need to figure out some way forward because it affects that much commerce. It's being addressed in the SPS chapter. It's being addressed in the chapter of technical barriers to trade. It's being addressed in pesticides and chemicals. It's being addressed in the regulatory coherence chapter. It's being addressed in textiles. It's also being raised as a specific trade concern by the US.

The US has decided to have, in addition to the chapter discussions, discussions on longstanding specific trade concerns. The criteria is something that's been raised in the WTO for the past 10 years. So, these types

of issues we feel that have components from all of these different areas, SPS, TBT, textiles, we are raising that as specific trade concerns.

So, I'm not sure what will happen, but I will tell you that I'm hearing from folks in the EU that they think this is unimplementable. They don't know how they can implement it. It doesn't make sense. For pesticides, how do you take risk into account? There is a requirement under their statutes. How do you do that and reconcile these two pieces of legislation?

So, it's fundamentally problematic, and some of you may have even seen a letter that Anne Glover, who is a senior scientific advisor, received from a number of scientists, toxicologists in the EU saying this doesn't make sense.

MR. JONES: Okay, thank you very much, Danielle. Now we're going to hear from Lois on MRL harmonization. She's going to give her presentation. Then we'll break for lunch. Then we'll come back for discussion.

MS. ROSSI: So, many of you have asked for a presentation on MRL harmonization. I don't think we've

ever really done much at PPDC on this topic or on our international initiatives. So, I'm sure around the table and in the room, the levels of understanding are quite different. So, this is a presentation that goes through the initiatives that we particularly engage in that related to MRL harmonization.

It's difficult to just address MRL harmonization. It means many things, and you're trying to harmonize with all different countries as well as Codex. There's no real one pass to get there. But rather, there's many paths. I think the synergy of these different efforts that I'll describe build the road to ultimately MRL harmonization. I mean, you heard Daniella say about MRL harmonization in the EU. Some of you who trade in the Asian Pacific area, that's much of a concern for you.

So, there are 47 slides standing between you and lunch right now. So, we'll see. Some of them you'll follow in your paper because I'm sure you can't read the screens, as I can't.

So, I like to begin these presentations by sort of stating the business of why we're engaged in the

international efforts in the first place, which is our primary business, which most of you know, protecting public health and the environment, as well as to ensure access to safe and effective pesticides and pest management technologies. So, keep in mind, that's why we do what we do.

The OPP has had a role over the last decade or so, even longer than that, but I think a lot has happened in the last decade on many fronts, as you'll see in this presentation. We have played a leadership role in promoting joint reviews, joint registration reviews, and harmonization efforts both internally and externally.

We have been a champion to identify opportunities for collaboration and cooperation. Also, we've been instrumental in fostering communication both between regulatory authorities and then a dialogue with regulatory authorities and stakeholders and also among stakeholders.

So, our opportunities, again, there are many international efforts that I'm not going to address today. But the ones I am going to address really deal with pesticide harmonization and MRL harmonization.

So, in North America we have NAFTA, the North American Free Trade Agreement, and wee have the Regulatory Cooperation Council. In the OECD, we have a working group on pesticides and a registration steering group and some expert groups which I'll describe. We have a test guideline program, and we have a task force on biocides. Some of you did mention non-ag issues.

Then we have the Codex Alimentarius Commission, and we have the Joint Meeting on Pesticide Residues, JMPR, and the Codex Committee on Pesticide Residues, the CCPR. One is the risk assessment, the JMPR, and CCPR is risk management.

Other opportunities are bilateral partnerships, commodity chemical specific issues, which we deal with on a regular basis with our colleagues at USDA, the foreign ag service. Then, of course, we have participated in international summits and follow-up work from those and workshops.

So, going to North America first, we've been engaged with PMRA in Canada for many, many years. We pretty much, as far as new active ingredients go, have a North American work plan. Primarily with Canada, but in

recent years we've seen -- and right now we've seen much more active participation with Mexico. So, I can probably say for the first time in many years that it is a North American effort under NAFTA.

The IR-4 in the US and the PMC, the Pesticide Management Council, in Canada has a partnership. We've been working together for many years, probably since 1997, actually, on joint reviews of new active ingredients, use expansions, and minor uses. It's become a routine way of doing business.

We've been resolving a lot of trade irritants and technology gaps. A trade irritant for the United States is often a technology gap for the agricultural farmers and producers in Canada, so we've been working on that. We had a grower priority database which not only covers -- it allows you to input your priorities into this database, but it's also now been even expanded beyond Canada.

The Regulatory Cooperation Council was started in December of 2011. It was signed by President Obama and the prime minister of Canada. It's a 20-item action plan to really remove regulatory barriers across the

borders. We are one of 29 projects. Our project was the initiative to identify mechanisms to encourage registrants to submit applications for joint review to Canada and the US, particularly focused on minor uses. You heard Daniella say about how the EU was looking for an RCC type thing with regard to minor uses.

Again, we were successful in this, and I'll go through the projects, primarily because we did have NAFTA for so long.

So, we did have four projects. Our first one, and I'm not going to read through all these bullets, but I'll just give a brief indication. The first round of the RCC has pretty much wrapped up. We made our time lines. There were specific time lines, 90 days, 6 months, 1 year, 2 years. We've pretty much made these deadlines.

We had four projects. The first one was to encourage joint submission of use expansions and fully aligned labels. We did complete a pilot project on spirotetramat, which is an insecticide, a fairly recently registered insecticide. It's geared toward minor uses and establishing MRL's intolerances with the submission.

So, we were able to harmonize the MRLs, which was one of the goals. We did have a shorter review time of cooperation. More importantly, we developed some principles for ongoing work that we can definitely have the benefit in our ongoing work as we go forward. That's probably one of the biggest outcomes of this.

Just to do a project on a single active ingredient for some minor uses has value but not a lasting value. So, I think the relationships we made and the agreements we made in working together and identifying where we did need to harmonize and did need to (inaudible) has really been very valuable.

So, action item two, to develop joint guidelines for residue field trials, we have done that. We have also agreed on a proportionality concept of where you have field trial data at one use rate and then the use rate changes. We do a proportionality concept rather than regenerating a whole new set of residue data. Then, we continued to work on an effort with crop groupings, and you'll see a little bit more about that later.

So, action item three, we did address some obstacles to joint registration. We did have time line

harmonization issues, which again Daniella referenced. That's one of the major stumbling blocks with us cooperating with the EU on joint reviews, is the time lines. So, we did work with PMRA on that. We aligned some data requirements, like our one year storage stability study. Also, we have been encouraging use expansions to come in as joint reviews.

The biggest output, however, from this particular action item, for the first time, according to our Office of Management and Budget, for the first time in their history, and our history too, obviously, is we developed a joint confidential statement of formula.

As many of you know who submit packages to the United States forwarded to the EPA for registration, we have to submit a confidential statement of formula. Canada does, too. We've developed a form. It's going to be called a Confidential Statement of Product Specifications. It's kind of a merger of the two forms in both countries.

We are completing a pilot to populate the new form using existing data. We're also trying in our IT world to develop a wizard tool that will support this.

So, we're in the process of getting that form through the Office of Management and Budget.

We're very pleased with that. We hope that that will streamline our processes and also allow for further collaboration and review. But this would mean you could basically submit one form to both countries in a package.

Item four was to align data collection processes and procedures for the reside trials. This was largely lead by our foreign PMC. So, they have done some pilots and they have aligned using a common format and the protocols and actually down to raw data field trial notebooks to harmonize the entries. So, that has been fairly successful.

We do have quite an active minor use program with our partners in Canada. We have currently 15 new joint review projects for minor uses undertaken. So, that is going very, very strong.

Moving forward, there is a plan for the Regulatory Cooperation Council effort to move forward. We've agreed to three major efforts with Canada to continue to enhance the product joint reviews, including

use expansion, and move to a single application for crop protection products that will be accepted in both countries. The form, obviously, is the first step in that.

The coordinated work planning, data sharing, and aligning approaches to risk assessment, there are some issues that we have come up with over the years in our cooperation. Then, most importantly, developing information technology solutions so that you could submit through a common portal an application and it could be directed to Canada or the United States.

I did want to say that in the write up that Owen did have on the future plan, this particular project was identified as one of 4 out of the 29 that did show substantial progress. So, we're pretty pleased with that.

So, OECD, global initiatives, OECD has been a major, major form for us over the years, starting back in 1990, where countries could come together and work on building the foundation and the blocks that will ultimately lead to harmonization and work sharing. We have expanded the global joint review process over the

years, and it really had kind of took off in flight around 2007.

The goal, obviously, is to share resources, try to align regulatory endpoints, MRLs, and decisions to the extent possible. We've had a lot of countries participating. Most of the joint reviews, quite honestly, are between Canada, Australia, and the United States. However, recently, in the last few years, we have had an interest in Brazil, which isn't even an OECD member country but is allowed to attend the meetings, China, same thing for that. The EU member states have participated in these joint reviews, especially in the early years of them, and Japan, Korea, and Mexico.

Also, all of the major R&D companies have had active ingredients going through these joint reviews and even some of the second tier and third tier R&D countries have participated. So, we've seen an expansion of countries interested and an expansion of the companies interested.

So, as I said, the building blocks, OECD has provided the form for a lot of building blocks that will lead to harmonization. The OECD calculator, which was

actually started as a NAFTA calculator, which actually started in the halls of the pesticide program because we were finding that even our own scientists, if you had two scientists reviewing the same residue data, they would come up with two different MRLs.

So, we needed a calculator. We decided on a NAFTA calculator. Then we took it wider. Now, actually, this calculator is used by the JMPR and Codex and many, many countries around the globe. It's even been translated into Chinese. So, it's pretty widely used. It takes at least that variability out of the lack of harmonization of MRLs.

The residue chemistry expert working group harmonized the residue chemistry guidelines, developed the policy for the proportionality, which I mentioned previously. These groups also coordinate on a lot of other issues besides MRL. There currently is a workgroup on pollinator protection where we're working with our colleagues from other countries, as well as persistent chemicals. Then, there is a workgroup, which I'll get to in a couple of slides, on actually focusing on minor uses.

So, the next couple of slides are just for your information. These are all the different global joint reviews from 2007 to 2014. You can see some of the countries. Again, heavily English speaking countries, Canada, Australia, and the United States. But you see sprinklings of some European countries and then you'll see even other countries getting involved.

Then, the joint reviews in progress, there are many of them. They're all listed there. Those currently are the ones on our work plan that we're going through now. Then we have what we are calling second entries where the active ingredient is already registered and new uses are going jointly into the countries. Again, a way to maximize the possibility of harmonization.

Then, we plan for these new active ingredient joint reviews well in advance, so we're in presubmission stages on 11 of them that will come in from now until 2017. What we do at the OECD meeting also is we do actually present at each meeting an analysis of the MRL harmonization on the active ingredients that have been jointly reviewed. The results are presented on this slide and the next. This is where Daniella got her 82

percent figure, which is on the next slide, and I'll show it in a minute.

You know, these statistics, you can do anything with statistics. Being a statistician, I know how to do those things. But I think these are raw values that show which direction we're going on. They're obviously influenced by the number of active ingredients that you do in a given year jointly and the number of MRLs that you set as a result of that joint review.

But on this slide, or on your paper, you can see in March of 2014, we evaluated or jointly established 278 MRLs and we harmonized only 82 percent. That's where she got that. You can see that, you know, back in September of 2011, it was more like 57 percent. It goes to 80 percent. It went down to 67 percent, but that was a smaller sample size.

So, it's very much influenced by the statistics, but it's just a general trend that we kind of take the temperature on to see if all this work that we're doing jointly has some benefit. I think the joint reviews clearly are one definite way, if there's a hope, of harmonizing MRLs.

So, this slide presents the summary, again raw statistics, but an indicator.

So, just to conclude -- this isn't a conclusion of my talk, however. I still have 26 more slides. But just on this segment, I think we feel that with these joint reviews, we have really a strong science review. You have the benefit of a wide range of expertise beyond your own national authority. It has definitely worked to the advantage of the robustness of the science.

We try to agree on the endpoints, and do for the most part, the residue definition and then, of course, the MRLs. It has definitely been a factor in reducing agricultural trade barriers that we then wanted to continue this into Codex.

So, the next few slides just really give you an indication of the other work that is going on with these OECD groups. The OECD residue chemistry expert groups have been meeting from 2004 to 2010, focused on guideline, harmonization, and then, of course, the calculator. Some of their current work is, again, updating field trial guidance. Again, if we can agree on these guidelines and how to do field trial data, we can

then take one more variable out of the harmonization, or lack thereof, and then field rotational crop guidance.

The minor uses is chaired by Alan Norden of Australia, who maybe many of you might have met at some time. There are three areas of work, cooperation activities, technical activities, and policy activities. So, with the cooperation activities, they are listed there on your slide.

The biggest thing here has been to try and come up with information, a central place where you could go and look and see if there was a field trial on a minor use available in some country, if you could use it, or what other countries have been doing, addressing minor use gaps, trying to exchange data, and obviously promoting the joint reviews.

One thing I think this group should be somewhat credited with is we've seen definitely, and maybe the pesticide registration fee also has a role to play in this, but we've seen with new active ingredients, they're coming in the door with a lot of uses, including a lot of minor uses, whereas, maybe 10 years ago they would come in with one, two, or three crops.

Of course, it's a lot of work and it takes time, but it is definitely getting more minor uses on the market for some of these safer chemistries early on in the game rather than waiting two or three years down the road after the initial registration for the active ingredient.

For technical activities, this group has been generating data and implementing the smart use of residue and efficacy data, efficacy and crop safety data. Of course, most countries, just about all the countries in the world except for the United States, does require efficacy data to be submitted with the package. So, they've been looking at guidelines to kind of identify gaps for efficacy and crop safety data and trying to align some harmonization there.

So, the test guideline program, again, that has been a major block, foundation block to harmonization and to joint reviews, to have the same guideline and agree on the protocols for these guidelines. So, these slides do go through that.

We do have a national coordinator in OPP, Chris Olinger. She coordinates all the test guideline

activities for the US. It also spills over into the previous discussions with ICCVAM on new methods. They meet and have a work plan. This definitely corresponds to some of the work you heard earlier, so I won't go into it too much about the different in vitro and in vivo methods and the adverse outcome pathway. But also, there has been work on larval honeybee protocol. So, it does spill over into non-MRL type issues, but pesticide issues.

This slide just gives you a bunch of web sites that maybe of interest to you for some reason. I don't know why, but the web sites come out yellow, so you can absolutely not see them on the paper or on here. I haven't figured out how to do that in Outlook and make them come out in a different color.

So, for those of you who are asking about the non-ag activities, we do have an OECD task force on biocodes. Jennifer McLain actually is the chair of this task force. They are looking at also similar things like we've done in the ag world, the harmonized regulatory approach, efficiency in the registration of biocides for both governments and industry, and helping countries to

reduce risks associated with biocide use.

It is a good membership of 14 countries and certainly the representatives from the European Union and the European Commission. They report into the joint committee on chemicals and pesticides and biotechnology. But they also are paralleling a lot of the work that has been done over the last 20 years, actually, on agricultural pesticides.

This slide just gives you their activities in a little bit more detail, if you're interested, and highlights their work programs. The next slide gives you their guidance documents and test guidelines that currently exist.

Then, last but not least, there is a recently formed group in the last few years on electronic exchange of pesticide data. This is an expert group, and it has great hope. They just actually met in Paris a couple weeks ago. Their task was developing a common method for electronic submission of documents to regulatory authorities.

So, it's like no matter what your little scheme is in your national authority, if this is developed, this

globally harmonized submission and transport standard, it will be smart enough to convert it and you'll be able to do it once and be able to send it into many regulatory authorities.

So, this slide and the next slide give you some information on that, and actually even the next slide. So, we're almost done, almost finished.

So, last, but not least, I'm going to talk a little bit about Codex, which has certainly been a very challenging experience for me. I just attended my 11th meeting of the CCPR. It was held in Nanjing, China, because China does host this Codex committee.

Just to give you an indication of what goes on at these meetings, you have many meetings before the actual meeting even starts, where you talk to the chair, and you talk to the FAO and WHO secretariats, you meet with different countries and try to line positions. But, more importantly, you do develop those relationships so that when you are reviewing a common active ingredient or a new use or even if you have a problem, you have some basis to begin a dialogue on these problems with them.

This year, Codex is certainly way behind on

MRLs. The United States has far more, probably the most in the world, MRLs established. They did advance 343 odd MRLs for 32 pesticides. Those should be adopted at the July meeting of the Codex Alimentarius Commission.

As you can see, the United States has been pushing in the last few years to really get newer active ingredients registered so that these new active ingredients can be used in the United States. Then those commodities can be shipped to countries particularly who looked to Codex as their MRL system.

So, the other things we've been doing in Codex, one of three major reasons MRLs aren't aligned, which is residue definition, calculator, and crop groupings. So, we've been kind of attacking all three of those reasons and been pushing forth a revision of the classification of crop groupings. We've been doing this largely with IR-4.

But there is a workgroup in Codex that works on this. So far, they have adopted the fruit group. If the world could possibly find a way to use one crop grouping scheme, that would be one major way to not only assure that minor uses have MRLs, but also that the MRLs would

be harmonized.

Then, of course, we participate quite heavily and influence the nomination prioritization of the compounds to be considered by the joint meeting. We usually get our way because we're one of very few countries that actually does nominate. So, we do have somewhat of an advantage there.

As you can see in this slide, we're pushing the new compounds. They also do reevaluations and periodic review of compounds. Every 15 years they are supposed to do this. They actually do revoke MRLs on chemicals that aren't supported in this periodic evaluation.

We have led many efforts over the past decades to increase the capacity of JMPR, together with our colleagues at USDA, foreign ag service. They're finally kind of considering maybe an additional meeting. But funding, of course, is an issue for them, as well as everybody.

Last, but not least, they're always bilateral initiatives. We have had quite a good relationship with the three agencies in Japan that are responsible for establishing MRLs. We're actually going to have a

visitor from the Food Safety Commission in early September.

I know Japan is a major trading partner for a lot of commodities. They've recently gotten special funding to participate in joint reviews. So, we're pretty excited about that. But we've also been a technical support to the USDA foreign ag service on the positive lists that they have of their MRLs.

Brazil attends and sort of observes in joint reviews. I don't think that they've really put their foot completely in the water, but they certainly flirt with the idea. We maintain a good dialogue with them and have hosted them, actually, here for training.

China, of course, we have a memorandum of agreement with them to do cooperation. We've done many, many, many workshops over the last seven or eight years and have had high level delegation meetings with them both here and in China. They are actually participating in a joint review.

Taiwan, which is another little country but spend a lot of time worrying about trade with them and the MRLs. We've shared our reviews, again supporting

USDA. We have hosted them for training and will continue to do that. We're hosting, I think in the next week, the woman who is in charge of registration of biopesticides. We're working with them on priority lists of MRLs.

Korea, another partner playing in joint reviews. They hosted their own minor use symposium in November of 2013. We continue to have a good relationship with the Korean Ministry of Food and Drug Safety on MRLs.

The importance of food safety in these countries has risen exponentially over the last five years, I would say. They have a consuming public that demands safe food. They are very, very, very interested not only in biopesticides but also in just getting the new active ingredients.

Then, of course, the European Union, which Danielle talked about quite a bit. But we do work with the EU member states in OECD and Codex. We've had some participation, but because of their law and their time line of having to have a draft assessment report done in a year, they've kind of been on the sidelines of a lot of the joint reviews lately. But we still talk to them and

we still share with them, and we've worked on specific issues.

So, again, we work extremely closely on some of these issues. Unfortunately, retrospectively, it's really hard to harmonize MRLs. Prospectively, it's much better. It's a better policy path forward. But there's a lot of history, and there's still a lot of work there on that.

So, the last slide is a summary of all these individual initiatives and playing in these different arenas. They have the same goals and they all build on each other. There's definitely synergy here, not only with the relationship building but you attack the problem from many angles. If you can get some consistency on crop groupings and calculators and joint reviews, then you really are working towards the goals.

I've been very fortunate in being able to play in all these arenas. It has been easy to connect the dots. That's what we need. We need some champions in these different national authorities to connect the dots. I think a lot of progress has been made. There's a long way to go, but there is some very good foundation

building blocks that are in place.

We work across our federal agencies, our national authorities, international organizations, and then, of course, with our stakeholders. A lot of stakeholder initiatives certainly compliment the government.

There is the last slide, and you can have your lunch. Thank you.

MR. JONES: Thanks, Lois.

Can we get a show of hands of how many people have questions when we return? Okay, let's be back here at 1:30. There's a number of options for lunch. There's a little wagon right out here that has tasty kebabs. I wouldn't advise that. There's the Renaissance Hotel across the street. There's a grill over in front of the Hyatt. Then, there's two places down the road, one on the right, one on the left that's a salad bar, pizza, and stuff like that.

(Whereupon, a luncheon recess was taken.)

AFTERNOON SESSION

MR. JONES: Well, let's get started on any follow-up questions for Lois on the international harmonization issues. I know we had some.

UNIDENTIFIED FEMALE: In your discussions and efforts with Canada and even globally, I know you mentioned biopesticides with some of the Asian countries. But are biopesticides a part of your activities and discussions?

MS. ROSSI: Yes. I mean, I don't personally handle the bio side, so I don't naturally include them in my presentation, because I do the conventionals. But they actually should be and they should be expanded to include the joint reviews that were done on biopesticides because they are starting to do them.

They do them with Canada. That's becoming more and more routine. Then, I have recently seen a bigger interest in other countries like Taiwan and China. So, I expect that that part of the program will grow in a similar fashion to the conventionals.

MR. JONES: Beth?

BETH: This is sort of a related question,

Lois. I just wondered, is there any activity to report on involving consumer products, consumer pesticides?

MS. ROSSI: Well, there is a little bit on the biopesticides slide. NAID, I think they're looking at harmonization of the efficacy requirements and the guideline requirements. Again, I think they're a little bit behind on the agricultural, but harmonizing the guidelines and getting everybody to accept the same docier and doing the same reviews is critical.

So, I do see that as a future. I think some household products, like some of the biocides and stuff, would be really right for this because you've got the same use pattern. Whereas, in agricultural chemicals, you don't always have the same use pattern. So, I think both that and the biopesticides are definitely right there on the edge there.

MR. JONES: Mark?

MARK: Thanks, Lois. I wanted to make a couple comments. One of them is that a lot of crops, especially crops in the upper Midwest, I think because of a lot of your efforts and the ability that we've had to make some major changes, they're seeing the light now where MRLs

are concerned and likely to stay on task because it's so important. So, moving this process forward in the agency is just really important.

I know it's not without challenges, but I would say that at least in the upper Midwest, especially crop folks, really appreciate what you do. I know you're absent from your job here quite a bit and maybe jet lagged a lot. But in the upper Midwest they call you the MRL queen. So, there you go. Compliments on what you've been doing and a tremendous effort and educational process as well. Thanks.

MR. JONES: Doug.

DOUG: Lois, you mentioned that some of this started with the NAFTA agreements and continues hopefully in the free trade agreements that continue that you'll be part of those and MRLs. I would encourage that. Thank you.

MR. JONES: Gabrielle.

GABRIELLE: A couple things. One is the crop where 70 percent of the crop goes abroad and the top specialty crop for export value. This is a really important area from our perspective and important in a

number of ways, not only just to be able to have the markets.

I think one thing that was hard for people to understand who aren't dealing with this is literally, when new products hit the market in the United States, often they will not be used until you have these international MRLs in place. So, this whole effort that -- and I would second the MRLs queen, even though I haven't heard that term before, but the whole effort is to do harmonization to try and get these MRLs to come out more on time, to be more similar in numbers.

I've personally attended these CODEX committees for pesticide residues. Everybody says, oh, how exciting. I said, well, you're sitting in a conference room for four days watching paint dry, but they make a difference.

So, I just want to emphasize how important this is and not just from a trade perspective but also from a usage perspective. Literally, what has happened in recent years is if when new products have come on the market, and this is especially where there's a close tie between a processor and the market, the processor has

said to the growers, we will not buy your crop if you use these products because we don't have an MRL in Japan or we don't have an MRL in EU.

So, the whole movement to newer reduced risk compounds is slowed down by these issues. So, I just want to make sure that people really understand that aspect of it, because sometimes people are, like, why is EPA spending time on this. But it is critical for us to make progress in pest management. That covers all kinds of pests.

I'd also agree with the sentiment made earlier that we have differences in the exemption for tolerances. That can cause friction because we don't even have the data and other countries suddenly require data.

So, I just want to emphasize how important this is. I really appreciate Lois and Danielle giving us a sense of all of the work that's been going on that a lot of us don't necessarily see.

MR. JONES: Amy? Mike? You know, you put your water bottle there, so you deserve that.

MIKE: Sorry for the slow reaction. I apologize for not reacting right away.

I don't need to take a lot of time because I think a lot of the explanation and the importance of the work has already been expressed. But, on behalf of not only our organization, Northwest Horticultural Council, we represent growers that export about 30 percent of what they produce to about 60 countries around the world.

The growth and concern about MRLs and of our trading partners ensuring that their own citizens have safe food is extremely critical. It's been growing in importance. There's a huge technical role involved in that. While there's a trade component and a foreign ag service that plays quite a bit of a role, those organizations who have responsibility for ensuring safe food in their own country are really relying on technical people to help them understand.

The US has, I think, a role to play internationally to help folks in those countries that maybe haven't had a history of these kind of regulatory programs or a history of transparency in establishing these programs. They have a role to play to help them understand not only in the short term for the work that Lois has done, but I think in the long term for the

future of trade and future of the agency. I think it's going to be important to make sure we have institutionalized this role in the long term.

MR. JONES: Dave?

DAVE: Well, I congratulate you on finding a way to take the glamour out of international travel.

You gave a number of summaries of how many things that were successfully harmonized. But I was wondering if you had any sort of summary of how many of those were harmonized to a higher level of protection and how many were harmonized to a lower level of protection?

MS. ROSSI: That's a fair question. I don't have the statistics. We could certainly look at them. But usually the United States has one of the higher gaps because of the pests that we have. So, usually we're not in a position where we have to harmonize. I mean, maybe we'll go from, you know, 4.7 to 5, but, you know, usually we're not in a position where we're going very much higher. We usually won't do that.

In the end, no national authority has to harmonize. You still have your own sovereign laws and responsibilities and decisions. So, you try to harmonize

and you particularly try where you know it's going to be a trade problem. But in the end, you still have to follow your own safety laws and you still have to do what your national responsibility is.

So, a lot of times, you know, these MRLs -- and I don't think they can be viewed by growers and maybe even supermarket chains as like a significant difference between .02 and .03, but probably not. So, we really don't do that where it's like a huge jump, more in the rounding kind of margin.

MR. JONES: Virginia?

VIRGINIA: I wonder if you could say a little bit more about the IPM issues and what are some of the issues of concern in agriculture. I don't know if that's something that you cover.

MS. ROSSI: Well, I mean, in the groups that I've reviewed today, we really were talking about harmonizing guidelines, and test requirements, and how we review them, and dociers, and kind of to make our work along the same way.

The OECD working group on pesticides has recently actually changed its name as of this last

meeting, which is now going to be the working group on pesticides and pest management strategies. There is a group, the risk reduction steering committee group, that sponsors more of the IMP thinking. That's the forum that I'm familiar with where those kinds of things have been done.

Mostly, they've looked at having seminars of applicator operator exposure, spray drift. They had tons of seminars on spray drift and things like that. That's where I think the IMP strategies fit into this whole international thing, with the work I'm familiar with. I mean, Codex is totally setting MRLs on the work that comes before them.

The joint reviews are joint reviews on new active ingredients. The working group on pesticides has focused on harmonizing the building blocks of how regulatory authorities evaluate pesticides. So, that's the one place that I've seen that topic being discussed on an international basis. There probably are others, but that's the one I'm familiar with.

MR. JONES: Ray?

RAY: There's a couple points I wanted to make.

On your slide regarding the MRL harmonization analysis, we got 76 percent harmonized, 18 percent harmonized, close, within 0.5 parts per million. But if it's 0.5 parts per million versus 1 part per million, that's not real close. If it's 4.5 versus 5 parts per million, that's quite close. So, is there a distinction to be made there?

MS. ROSSI: What that point was was to show that we harmonized exactly on the value for X percent of the time. And then, for another X percent of the time, we came within .5. That's what we meant by putting that bullet there.

RAY: Okay. The second point I wanted to make is that, Lois, you personally are to be commended for moving mountains in the Codex area, the Codex arena, over the past several years. But I think collectively we're all still fairly frustrated with how Codex functions. What more can the US government do and how can we as stakeholders help in that arena?

MS. ROSSI: Of course, you know, there's two things I like to mention about Codex. One is, when I first started becoming involved, which is 2004, it took

10 to 12 years to get a Codex MRL. We literally did sit through a couple of meetings there where you were watching paint dry. There were all these MRLs coming through and they were just staying there. They were never elaborated to the point of becoming adopted. They were on a lot of older materials in some cases and some cases not.

The other thing was that there was no structure to the decision making. You could object to an MRL because you didn't like the way the name of the chemical was spelled or something. You could raise your flag and stop it.

So, one of the things that we did was put some parameters around having scientific -- going back to the science and the basis of objecting because there's a scientific reason, which is what you should be objecting to. If you have data that wasn't considered by the JMPR, that you think would make a difference in your thinking either from their tox point of view or their residue point of view, that's what you should be presenting.

We did do that in the form of a concern form. That allowed a lot of MRLs to proceed to adoption,

particularly on some of these newer compounds where national authority previously objected because they hadn't evaluated the compound themselves. Nobody has to adopt Codes MRLs. The US doesn't automatically adopt Codex MRLs. We're required to harmonize by law to a Codex MRL, but if we can't, we just have to explain why not.

So, those things definitely have made the time shorter. The issue now is the capacity. There's far more MRLs, particularly in the United States, than there are Codex MRLs. So, the capacity is an issue. That is the frustrating part. It is extremely frustrating.

I think over the next year or so, I think we should begin to brainstorm. They've started thinking of an extra meeting. Again, funding is an issue. There are some efficiencies that we've suggested over the years that they could make better use out of. They could make better use out of teleconferencing, video conferencing.

So, we've suggested these things. I think they still have to keep -- it's a slow process. But we do find that ideas that we suggested two or three years ago suddenly come up by them, by the secretariats, as new

ideas. They want to move forward.

So, it's a slow process, as international organizations are, but I think we just have to keep at it. I can't tell you one, two, three, four, five, because we've tried a lot over the years on that. But I do think the capacity is the biggest issue now.

MR. JONES: Mike?

MIKE: Lois, I just would like to go back to the example you just gave of going from 4.7 to 5 if the US agrees that we can go to 5. Does the tolerance then administratively get changed or do you have to go through some kind of rule making to change the tolerance? I'm assuming harmonization happens when you're sitting around the table and you agree that the US could live with five. But when and how does that get reflected in the tolerance in the CFR?

MS. ROSSI: There's two processes. What I'm talking about and what's reflected in these charts is establishing the tolerance for the first time. So, we have that ability to set it at 5 instead of 4.7 or something like that. We do go through rulemaking as we do when we're establishing our tolerance.

The other thing that you're talking about is something we've been struggling with, and that is (inaudible) MRL. We set it at 4.7 and then Codex comes along and sets it at 5 or 3 or 2 or 1 or something like that. Probably, if they came along and set it at 5, that's not going to be a problem because we're going to be in compliance at 4.7. If they come along and set it at 3, it could be a problem. Then, what do we do? Then, where do we go?

What we've been doing is there's an opportunity in reg review, but we don't really have a process right now to come in line with Codex's MRL when the Codex MRL gets established after the US, which is most of the time. But, really, we only have to worry about the ones that really present issues. And then again, we may not be able to harmonize.

So, there's reg review. There's the next time the chemical is looked at for new use. That's an opportunity, and you do have to go through the rulemaking. But, retrospectively is much harder than prospectively. That's why we like these joint reviews in the beginning when you can get it all out on the table

and find out why people are thinking what they're thinking.

And even Codex, the problem with Codex is it always comes after because their rules are it has to have a gap, a registered gap, in a country before it can even get on the -- and for another time and place, I'll tell you the story of how we tried to change that and got bashed around for five years.

MR. JONES: Mae.

MS. WU: Thanks. I wanted to just parse that a little bit, what you just said in your answer. So, is that correct, then, to say there are times when, say, the MRL is 4.7 -- and you all have gone up to 5 -- has there ever been a time when you've actually lowed the US one to meet like a lower more stringent Codex thing?

Also, I mean, I was kind of interested when Dave said that you can provide kind of all the numbers. I'd also be interested in seeing, like, for the other countries whether that has caused them to have to make their MRLs less higher -- basically, what the trend is of how the numbers are going everywhere.

MS. ROSSI: Sure. Again, if we have the same

data, okay, and we have a similar gap, and there are new active ingredients that have been coming in with global gaps, that's the best situation. There's no reason why we all shouldn't come out with the same MRL.

The US oftentimes has a gap that is higher. It's a higher use rate. It's a shorter PHI, something that our data bring us to a different conclusion. So, sometimes we do have a higher MRL than other countries. As I said, national authorities have their own decision, so they don't have to come out and harmonize with us.

If it's a trade thing, sometimes we will go back to the registrant and say, can we reduce this MRL, can we get a lower rate or a longer PHI or something like that. So, we do go through those discussions. If the data will support it, and our residue chemists are pretty convinced that if we went with a lower MRL we wouldn't have a violation, we will do that.

We're pretty much open on that. All those factors are routinely considered in the discussions when you're trying to harmonize these MRLs. We can go up down. I don't really have the data for the other countries. I could probably look at the joint reviews,

though, and see if they were coming out.

But, quite frankly, because of the harmonized guidelines and because we're all getting the same data, we are coming more to the same conclusion more and more. If the same data is submitted to Codex and they use the Codex calculator, they should come out to the same reason. That's why the building blocks are so important.

MR. JONES: The final two, Mark and then Cynthia.

CYNTHIA: Thank you. Just following up on what you were just saying, it seems that once you have an MRL harmonized, it's quite difficult to amend. I mean, it's not carved in stone, but it's a lot easier to sort of come at it from the front end with the new data. But once you already have it in place, you have a challenging time or it takes quite some time. But you can correct me if I'm wrong.

Secondly, you mentioned pollinator protection. I'm just wondering, in your work on science, Cyantraniliprole and Sulfoxaflor, or any others that affect the pollinators, what has been your experience and has there been a lot of coordination with EU and others?

MS. ROSSI: I mean, it's rulemaking, so, I mean, it's not impossible. The problem is that we have our new uses and our new chemicals and our reg review. It has to kind of fit into one of those processes. We don't have another pathway that just amends MRLs. So, we incorporate it into our work.

For those of you who went to NAFTA meetings for a long time, we dealt with lists of trade irritants. It was very, very costly to go through and deal with a trade irritant one by one. So, it's just a resource to do that. It can be done and we have done it, but it's not something that is -- we're rather incorporate it into our main regulatory engines of new uses, new chemicals, and reg review.

As far as Cyantraniliprole and Sulfoxaflor, the EU was not a primary or even a secondary. They were kind of like a coordinator on Cyantraniliprole and Sulfoxaflor. But our other regulatory partners, Australia and Canada, reviewed the same data we did and made regulatory decisions on those. We were either in line or more stringent than what they ultimately registered those chemicals on.

MARK: Thanks for the opportunity to speak again. One of the things that I was surprised didn't come up in the conversation, and that's why I put my card up again, is that the reality of MRLs, once set, are hard and fast in a way. The disruptor of that, the card that throws the whole game into the ditch, is invasive species.

Right now, I would think in especially crops across the whole United States, that most growers would be able to point to spiked wing dipetala and the brown marmarated stink bug (phonetic) as tremendous examples of disruption. In most instances, their problems are at the very end of production, not during the season. They're there at the end. So, people are having to put sprays on in order to prevent contamination.

So, the big issue I think in front of us long term is going to be how do we deal with invasives because of our trade and travel, and how is the agency going to facilitate that kind of dramatic overnight change for us to really key ingredients in the future of our especially crops, especially agriculture?

MR. JONES: Okay, thank you, Lois.

The next session is pollinator protection. So, we've got four presenters here. Don Brady with Environmental Fate and Effects Division, Richard Keigwin with Pesticide Re-evaluation Division, Lois with Registration Division, and Sheryl Kunickis from USDA. So, take it away.

UNIDENTIFIED MALE: Okay, thanks, everybody.

So, what we thought we would do first is go through just to bring everybody up to speed -- I think there are a few new people around the table as well -- some of the advice that we've already received through the PPDC as it relates to pollinator protection and some of the initial actions that the agency has taken in response to that.

Then we'll transition into a summary of yesterday's very lively workgroup meeting and some recommendations that we have for your consideration in terms of a reorganization of the committee, the workgroup, to a certain extent, and then some ideas that the workgroup discussed yesterday morning in terms of areas for new work that they think would be fruitful areas for additional advice to ultimately bring forward

to the committee.

So, the committee is organized currently with four subgroups. There's a labeling subgroup that's chaired by Marylou Verder-Carlos from Cal DPR, as well as Dave Epstein from USDA. There's an enforcement subgroup that's chaired by Gabrielle Ludwig from the Almond Board, as well as Jeff Anderson who is a beekeeper. There is a best management practices subgroup that is chaired by Rich Bierly (phonetic) from Cal DPR and Brett Adee (phonetic) who is a beekeeper. And then, the training education and communication subgroup is chaired by Wayne Buehler from NC State, as well as Ray McAllister from CropLife. So, we'll go through the recommendations and advice that we've received thus far and the steps that the agency has taken in response.

So, the first area was recommending that labels be clearer as it relates to the use of the term visiting versus foraging. The advice was that we should discontinue the use of the term visiting on labels and instead use the term foraging. We have begun to implement that.

At first, it was noted in the new labeling

requirements that went out for the neonicotinoid insecticides last August. It's also begun to be adopted as part of new registrations that RD issues, as well as it's been incorporated into label considerations in registration review.

The second area was having harmonized protecting labeling across all products. You know, we had done an analysis that showed that with the same active ingredient across multiple products, even if the active ingredient was at the same percentage, there would be different bee protection statements on them. That wasn't making a lot of sense to the workgroup. It wasn't making a lot of sense to EPA staff as well. So, we've begun a process again. It started with the neonicotinoid products last August.

We also announced at the December PPDC meeting that we were working on developing a pesticide registration notice that will go out for public comment once it's completed for broader consideration that would extend that to other types of products that are acutely toxic to bees.

The labeling subgroup, and there's a carryover

with this with the best management practices subgroup as well, recommended that while it was premature to include this information on labels right now, that it would be helpful for the agency to compile information regarding residual toxicity of pesticides and make that available for growers to make in decisionmaking -- tool and communication between growers and beekeepers.

So, we have compiled that information. We had some discussions within the workgroup and with individual companies about how that information would be utilized and how it would be characterized. We're now in the process of publishing that information on our website. We hope that that will happen late this year.

Now we're transitioning to the BMP group. So, the workgroup also recommended that BMPs for crops be compile and posted in a single web site in a centralized way. This piece of advice was something that in working with our colleagues at USDA, they agreed to take on. They are in the process of figuring out the best way to do this. Is that a fair way to characterize it, Sheryl? The IPM centers would play an important role in helping to compile and make this information available more

broadly.

In the area of communications and training, they identified a variety of applicator training programs around the country. These could be opportunities to increase awareness about pollinator protection. The workgroup has begun to compile these different types of training programs and materials.

Wayne Buehler, I think, has demo'd for us at previous meetings a web site that he has really helped pull together, and Pollinator Partnership, I think, has also played an important role in that as well, that houses all this information. In past meetings, Wayne has also mentioned if there are other materials, I think you said get them to Wayne and he'll try to get them onto that web site as well. So, that's become a very good clearinghouse for all of this type of information.

Then, in the last area, the workgroup recommended that there be a more uniform and transparent approach to how EPA and our state lead agency partners who have primacy for enforcement conduct bee kill investigations. So, in response to that, last year our regional office out of Chicago took the lead on behalf of

the agency of developing some guidance for states on how to do these investigations in response to bee kill incidents.

I should note that that was an EPA state product that was not a product that was reviewed by the workgroup, per se. Several stakeholder groups have provided us with comments about that document. We are looking at these comments right now. So, I want to make sure I don't leave anyone with the impression that there was consensus around the EPA document that was developed. The consensus was that we should develop a more uniform approach to how we conduct these investigations.

This is where we're going to ask the co-chairs to walk through our discussions from yesterday. So, first would be the labeling subgroup. Marylou, if you could just help us with some of the ideas that the labeling subgroup brought forward in terms of future work.

MS. VERDER-CARLOS: Okay. For the labeling subgroup, we kind of started small a couple of years ago and then our group got bigger and bigger. So, we were going to make a recommendation to have smaller subgroups

to be formed to ensure better balance and representation from all stakeholder groups. And then, to possibly meet more regularly, possibly every month. This is a big workload. So, that's one of the things because labeling is such an important issue for the pollinator protection.

And then, once the draft PRN on label language for all products that are acutely toxic to bees -- there's an effort right now by USEPA. And apparently it's going to go out for public comment. The subgroup will discuss it and submit recommendations to agency.

And then, also, we were going to look at existing state programs. I'm thinking this would probably be in collaboration with enforcement subgroup, to improve the intersection of state programs and labeling and focus on advice that the agency can implement.

And then, we also wanted to explore available information, additional data needs to inform whether and how EPA should address labeling for tank mixes because that's one of the things that the bee keepers and industry has been talking about on the tank mixes and the application of those during bloom and even post bloom.

So, that's it for the labeling subgroup.

UNIDENTIFIED MALE: Thanks, Marylou.

One of the next areas, and I'll ask Wayne if he can help out with the next piece, but a recommendation that we had in terms of restructuring is the BMP group and the training and education communication group oftentimes was finding that they were working quite closely together on their products and in their discussions. So, we are making the recommendation that we actually combine these groups, noting that there is a need across all of the various subgroups to have communication issues associated with them.

Wayne, could you help us with this group's recommendation?

MR. BUEHLER: No, thank you. Kudos to you, Rick, for coordinating and directing a great discussion yesterday morning and also to Mary Clock-Rust (phonetic), wherever she may be. She deserves credit for putting together these slides.

I have been part of -- that being pretty much on the bench -- with the BMP group, just listening in to a lot of the telecons that we've had. I think there's

been great progress in terms of airing out concerns. We do want to make sure that growers are aware that BMP should be practiced not only for crop dependent or bee dependent crops but also for non-bee dependent crops.

So, here we have the first bullet to help somehow forge an incentive plan for growers to be more aware, to increase their stewardship practices. Many of them that grow field crops don't even know that bees are nearby or that bees can't even visit their crop or that bees perhaps can even provide a yield bump to them in some cases. So, somehow or another, that needs to finger out and we need to have a greater impact in providing incentives to growers that aren't reliant on bees.

Bullet two, I'm reading this as fast as you are, we're combining our efforts. The education training and communication group, as Rick has already alluded to, found that we have a lot of things in common, so it makes sense for us to join forces and try to work at those overlaps together.

Explore knowledge gaps, this is a difficult situation because there's a lot of competing interests. Obviously, farmers, to be productive, are having to

manage a lot of pests. So, their incentives are to increase their production or perhaps prevent pest damage from occurring. So, they're looking at, obviously, the production of the crop in relation to the proper pesticides to use. Many times there's not much credence given to the bees that may be foraging in those crops.

The crop specific BMPs are not all that well developed, with the exception of almonds. I think the BMPs that I found on the web are very, for almonds anyway, quite mature, and the almond board deserves credit for developing programs there, which I will allude to in a web site I'll talk about in a little bit. There are some crop specific BMPs as it relates to real crops in citrus. We're increasing our awareness of those and hope to post those on line.

The other aspect of this is really to try to bridge those gaps by having greater communication with researchers in the area that may work with apple crops, for example. Perhaps the information that we lack in terms of potential interactions or the effect of certain pesticides like IGRs can bubble up to the awareness of EPA. And then, perhaps more can be done to note this on

labels.

We do have a lot of programs that are available. Bullet item number four -- resources, conservation service, cooperative extension, which I represent, we're all stretched. We all mentioned that this morning at 9:00. But, in essence, there is a lot of corroboration, there is a lot of contact, there's tremendous face-to-face opportunities with these programs.

Growers, for the most part, those that are certified to apply pesticides, are a very captive audience for us because they need to take our sessions and attend our training programs in order to remain recertified. As I mentioned to someone the other day, a grower would just rather trade in their pickup truck rather than having to take the test again. So, that's why we can have a great, I think, exposure and create learning moments for these growers as they participate in recertification programs or have visits from folks within extension or NRCS.

The last bullet, we do have a program that's available, or right now it's being beta tested, but it

will be available by late summer/early fall that is kind of a pseudo-certification program, if you will, for bees, protecting bees on crops. It's an effort that has been put forth by the pollinator partnership group, but it has a wide consensus of supporting organizations and folks that have vetted the information.

There's a training manual. There's a workbook. There's a DVD where growers are speaking about their experiences and providing best management practices in a variety of crops. There's probably no better way to talk to another grower than from a grower's perspective. So, I think this will have a tremendous impact. I'm looking forward to using it in North Carolina. I think that covers the BMPs, Rick, if that's fair.

MR. ADEE: This is Brett Adee. May I make a comment? I was also on the BMP group. Wayne did a wonderful job. I'd like to thank him for that. There's a couple of things that I'd just like to add to it. One is we haven't come up with a solution, but I think the registrants in industry can help us in the need to communicate with growers and PCA either via the label or BMPs about how tank mixing can change the toxicity of

crop protection products and how that can be harmful to bees and other beneficials. So, we're going to need some help bringing that message out, because everybody in the room is well aware of what happened in California this year. So, we need help in communicating that. I think it's a good stewardship opportunity for the registrants and the rest of industry.

Then, I'd like to make a comment that most of the BMPs is for the growers, applicators, the PCAs, and the beekeepers. I would like to suggest that the EPA begin a tiered review or the Pelston reviews on products that have the most exposure to the bees by crop and then by after crop, perhaps almonds, since we have almost 100 percent of the bee supply there and the chemicals that are used to protect that crop.

Review them on the tiered review first by the crops (inaudible) and forage crops and then maybe by the tons and the toxicity ratio that they're marketed into the environment. So, that would be another comment we'd like to make.

UNIDENTIFIED MALE: Thank you for that. Then, the last workgroup or subgroup is the enforcement group.

Gabrielle is here.

MS. LUDWIG: A couple things. One is I just wanted to highlight one thing that didn't make it on the things that EPA has done in response to the enforcement workgroups' recommendations previously. That is, one, in terms of getting state-lead agencies more aware of how to deal with potential bee kill situations. One is they've taken some of the -- added bee kill investigations to the priorities for the little bit of grant money that EPA has to give to states on enforcement.

The other thing that EPA has done is use the SFYREG, the State Federal -- where the state lead agencies and EPA, OPP, sit down on an every two or three months basis to talk about regulatory issues, label enforcement, how to do things. In that SFYREG group, raising the issue of how do we best manage potential bee kill situations or pollinator issues in general.

So, I just want to say EPA has done more follow up on the enforcement side than shows up here on the piece of paper. Having said that, where we are now is we're still struggling with the really fundamental disconnect between the experience of beekeepers and the

experience of EPA, if I can put it that way. The disconnect is that beekeepers feel like they have been having bee kill situations that are attributable to pesticides, and then they're asking EPA to do something about it.

EPA looks at the incident report data and essentially either the data is not there or it's not there in a way that is useable by EPA in any way, form, or manner. So, for a number of years now, there's been this fundamental disconnect between the experience or the purported experience of beekeepers and EPA's ability to do anything, because the information is just not there. Without data, EPA cannot do things.

So, there's been this whole issue about how do we get better incident reporting. EPA has been working on trying to make that easier to do, a variety of ways of doing that, and it's still not happening, as this California situation, which was in almonds. Made very clear was a number of beekeepers did not notify the authorities. So, we're left back to not really knowing what happened, which is a very frustrating place to be.

So, I just provide that as background to

understand where some of the to-dos for the enforcement workgroup are coming from. One is that EPA will take the time to explain a bit more about what data they need for an enforcement or an incident report to be usable to them, the data quality, the kind of information that needs to be included.

Then, the other issue that became very clear yesterday in the workgroup, at least I hadn't heard articulative clarity, is part of the reason why beekeepers are hesitant to go to the state lead agency is when the term enforcement happens, it's not just an investigation of what might have happened in that hive, but every aspect of the grower's pest management gets reviewed and, to some extent, every aspect of the beekeeper's pest management gets reviewed.

Anything can become a source for a citation, something that has nothing to do with the actual incident that's being investigated. There's a lot of hesitancy then because there is a relationship between the beekeeper and the grower, and both are using pesticides, and both don't necessarily always want someone looking over their shoulder at everything they're doing. So,

there's a hesitancy there.

So, the homework now to the enforcement subgroup is to start exploring what are ways to get the needed data to fill this fundamental data gap that exists in ways that might not be as scary, let's put it that way. So, try to figure out what options we have to get the data needed without necessarily triggering fines and so forth just because of something other T not being crossed that has nothing to do with the bee kill.

Then, I will add, since we're then moving on into other additional areas to explore and in some way that ties in with the BMP, this is just a thought that crossed my mind, since we're getting rid of one workgroup, maybe we add another workgroup to talk about research needs. That came up yesterday in the workgroup on the BMP side, what are the gaps, what are the research needs.

But the other issue is just simply from EPA's perspective, a better understanding of what the research needs are and what kind of quality that data needs to have. I just kind of feel like there's a lot of research going on. The way I put it is 95 percent of the research

being done on pesticides and bees (inaudible) is useless from a regulatory perspective at the moment. So, another one of these fundamental discrepancies between what people think is going on and what's useable and can we find ways to bridge that. So, that's tying into the next slide, Rick.

MR. KEIGWIN: The last slide is really not an area that the group is embarking on in terms of developing new advice. But near the end of the meeting, there was a brief discussion about what are some other areas that EPA is involved in right now as it relates to either pollinator protection directly or other aspects of the regulatory program.

So, EPA did agree to provide the workgroup at the next meeting with some updates in these areas. One is foliar use of pesticides. EPA and USDA have been working very closely with the Feed Trade Association to put in place best management practices. I note a number of chemical companies have been involved in developing new technologies to reduce exposures from feed treatments during the planting process. So, we committed to providing the workgroup with an update on that.

Also, another area is that a lot of the workgroups' activities have been focused specifically on honeybees. So, there was an interest in finding out about efforts that we have underway related to non-honeybee pollinators and monarch butterflies. There is actually a North American initiative right now as it relates to conservation programs and rehabilitation programs for monarch butterflies. So, we said we would do an update for the workgroup at one of our next meetings.

Then, finally, there was a discussion about finding out what and how EPA goes about collecting water quality monitoring data and utilizing it in our assessments. I actually think that there's a one-pager in the PPDC members' handouts that we did on a new water quality standard operating procedure that we developed with the states on how to get that type of information in. But we agreed that we would do an update for the workgroup on that part of our regulatory program.

Margie corrected me. It was e-mailed to PPDC members, and it will be posted on the PPDC website shortly.

So, with that, that's our report.

MR. JONES: Mark.

MARK: Thank you. I think the workgroup has done an outstanding job. The recommendations really make a lot of sense to me, and I hope they work. I'm certain that they will have an affect. Again, I hope they work, you know, really well.

However, it appears that the US is taking one approach and then there's another approach that the EU has taken. I think that a recommendation that should be added, and we would be remiss in not doing so, is to track the results of the EU moratorium on the neonics with regard to their effects and how it works over there.

I'm not recommending that that's the way we go, but as a scientist, I certainly would say that we need to look and see what the results are. If necessary, go to plan B.

MR. JONES: Dawn.

MS. GOUGE: Thank you. Dawn Gouge from the University of Arizona. I just have a question regarding states. Are any states requiring pollinators -- specific information in either licensing, trainings, and

certification processes or continuing education units?

UNIDENTIFIED MALE: I can address that by saying yes and no. I think we're addressing it as one of 174 competency areas that applicators need to know for core knowledge. Recertification is really dependent upon the state. In North Carolina, we will be having that for our private applicator program using this particular package that the pollinator protection group has put together. Other states may have that developed to a point where they have programs through their state apiarists.

I just learned through Tom Dulaney, in fact, that New Jersey has legislation or at least proposed legislation to require it as part of the initial certification face-to-face training.

MR. JONES: Dave.

DAVE: Thanks. It might be helpful to go back to the enforcement subgroup slide. I don't think that it quite captures the part about not triggering an investigation and enforcement action. I don't think that's quite accurate as to what the workgroup was saying. I think it was more about concern about not

triggering unnecessary or enforcement.

But it sounded like there was a lot of support for reporting that lead to thorough investigation. I think there was concern about maybe decoupling the investigation from the people who have authority to do enforcement.

So, I'm not a member of that workgroup, but I did attend yesterday. I really think that this doesn't accurately reflect -- it's just a small wording thing, but I think it doesn't do service to the -- better investigations.

The other thing related to this, and even Stephen Coy made a really good point that's reflected in this, the beekeepers are reluctant to do or to report things. But I'm reminded of -- but I think it's really important to address that on both ends, both the enforcement agency's but also the relationship or the willingness of the beekeepers to do the reporting, because that really hampers the efforts.

I think it's pretty clear that the enforcement agencies need to be educated on the need to take a graduated response in any enforcement that's necessary.

I can't see how it would be sustainable to maintain sort of a parallel investigation arm that maybe is centered with EPA when they're not in that state. They're not in that county. They're not familiar with the players.

I think even just timeliness of being able to get the type of information that you need to really dig out what was the underlying or what where the several underlying issues that occurred in this incident or that incident. So, I think the state enforcement agencies to maybe tone it down a little bit and work something out so that fear of enforcement doesn't hamper the gathering of information.

I don't see how we can get to a really good solution without really thorough information. I understand that's not a trivial or an unreal issue, but I think it's something that creating that parallel thing doesn't really lead to a long term sustainable system. At some point you need to get the states or whatever -- maybe it's your local bodies in some states -- they need to be part of the solution and not putting up barriers. I think their local knowledge is going to be really important.

Then, finally, just a little bit to step beyond how Wayne talked about the certification. You mentioned that you have something that's almost like a certification. It was reflected on the slide, but I just wanted to reiterate my suggestion yesterday of looking to actually have a certification program. I think there could be some real value to having a real certification program that means something across the country. It's probably based on the training that you've already developed. Thank you.

MR. JONES: Thank you. Sheryl?

SHERYL: Can we go back to the labeling next steps? This is just clarification, please. I don't understand how breaking into smaller subgroups is going to ensure better balance in representation. If you break off to smaller groups, what are you trying to achieve?

Is it that each one of these groups is going to then tick off some of these other -- you want to meet more, have smaller groups, and then you've got a whole bunch of things. Are they going to each tackle a different thing/bullet or are they all going to do it simultaneously? I'm just kind of confused.

UNIDENTIFIED MALE: So, a little bit of background, because I agree with you, Sheryl, that seems confusing on the surface. So, bear in mind that workgroup is 80 plus members. The PPDC pollinator workgroup itself is about 80 people. The labeling group is over 50. So, bigger than this group here. So, part of the idea was that with a group that large, it can be difficult at times for everyone to be able to provide input.

So, by breaking initially into some smaller groups to work through issues and then coming back together once all those issues have had a chance to be aired, it would give more people an opportunity to have a voice in the deliberations. That was something that came out of the group itself.

SHERYL: So, again, then, are those groups going to break off and simultaneously try to tackle the rest of the group's work or are they going to be assigned subpieces of all this work?

UNIDENTIFIED MALE: I think that's something that we'll figure out as we go. It was a concept that came up in yesterday's meeting. There were a number of

people that wanted to explore that as a different way than how we've been operating. I think one of the recommendations that we brought forward at the last PPDC meeting is it took about five or six multi-hour conference calls to get to resolution on an issue. So, the idea was maybe experiment this with one issue and see if we could get to resolution on it a little bit faster.

MR. JONES: Tom?

MR. DELANEY: Tom Delaney from Professional Landcare Network, the landscape industry. Our industry is a little different than a lot of the others when it comes to pollinator protection and protecting bees. We're out in the residential backyards where there's a lot of different kinds of plants. They're all flowering at some same times, different times. We're out there trying to protect the ornamentals from pest attacks.

So, this is sort of from the enforcement side and the labeling side. I didn't see in my first meeting with the pollinator group any discussion about the new labeling requirements and what the results has been found since then with some of the possibly unintended circumstances that may arise from that. With the pending

of a new one to add more products, I'm wondering how different that can be from the first one where we're understanding trying to level the playing field between neonics and the other products.

I understand that this group can't make any comments before it's released, but is there any way to characterize that, how different it may be from the first one in how more comprehensive or whatever and then whether this group can be dealing with that as sort of something that was planned to fix what some of all these problems are?

UNIDENTIFIED MALE: So, the draft PR notice is still in the developmental stage. So, I think it's just premature to go into much detail on that. As we mentioned, we are getting some experience with the new neonicotinoid labels. They're in the marketplace now. As we've been developing the draft PR notice, we've been mindful of the types of feedback that we've been receiving. So, we are hoping that as we draft this revised PR notice, that we are taking those types of considerations into account.

Then, during the public comment period, we will

provide an opportunity for the workgroup to weigh in on that PR notice. So, we can have that input as we move forward on the finalization of that notice.

UNIDENTIFIED MALE: I'm hoping that enforcement will be involved that can evaluate it beforehand, because we found out after it was -- the last one was introduced I enforcement, had different comments of what the language actually meant beforehand. So, if we're going back to issuing the same language or changing something, I hope the Enforcement Division plays a better role in making everybody understand what the results may be, because that's always been a problem in my experience for 30 years; enforcement gets in on the end or after and not beforehand.

MR. JONES: Okay, Cynthia.

CYNTHIA: Thank you. I'm wondering to what extent the lack of a specific category for bees or pollinators in FIFRA 682 contributes to or hinders EPA's data collection efforts on bee kills?

For those who are not familiar, over the years, ABC has raised a lot of issues with the 682 aggregate reporting categories. We've expressed a lot of

frustration about the thresholds. For example, for flocking species of birds, the reporting threshold is 200, flocking species for raptors is 5 raptors, for mammals it's 50 or more of a herding species, for fish, it's 1000 or more of a schooling species, and so on. These are the sort of reporting thresholds required of registrants. For pollinators, they are just grouped under other non-target organisms.

I'm wondering as EPA thinks about revamping the 682 reporting rules, what would be the ideal for pollinators? Could the pollinator workgroup maybe assist in making recommendations for that rulemaking?

UNIDENTIFIED MALE: We'll treat that as a comment. Thank you.

Steve?

STEVE: I would like to make a few comments, basically just go back through all the slides. First of all, the workgroup recommended that the RT-25 data be put on the website. I'd like to know if there's a mechanism for evaluating how useful that information -- how much of that is going to be used. Is there some way to see after it's been on the web for three months, six months, is it

being utilized like it's intended to?

There's been a lot of focus and emphasis on BMPs. I know the BMP workgroup spent a lot of time discussing things. I'd just like to point out that for the past two years, BMPs in almonds have been promoted by both the bee industry and the almond board. Still, in January, we had more than 80,000 colonies damaged because BMPs were not followed. While BMPs are good practices, they are not the solution; they're just enhancements for how to farm your crop.

The training and communication subgroup, training and education is good. There's never too much training and education, but it needs to be backed up by enforcement, just as Tom said. If the labeling and the training don't have some enforcement behind it, then it's not going to be very useful to protecting the pollinators.

EPA's region 5 development guidance as far as beekeepers view that -- it's not what we would call beekeeper friendly once an incident investigation starts. We'd like to see some changes made to that so that it focuses more on the incident at hand instead of the extra

things. In fact, I think that in some states, once they start an investigation, OSHA rules fall under their purview of what they can cite, write citations for. So, nobody wants to deal with OSHA, I don't think.

On one of the points from the labeling group, the state programs have also been -- I think four states within the last 8 to 12 months have been initiated state bee protection programs of some sort or the other. It was mentioned yesterday, and I'd just like to reiterate, that these state programs cannot be less restrictive than federal protection, either the label or federal regulations. So, if state programs are enacted, they must be equal to or more restrictive than the federal regulations.

That's my comments.

UNIDENTIFIED MALE: So, just a point of clarification on the RT-25. Your question is how will we know it's -- we can tell how many times it's accessed or looked at on a web page. How that information is utilized once someone accesses it, I'm not sure. Is that your question?

STEVE: Yes.

UNIDENTIFIED MALE: I mean, simple access is one way to gauge who's looking at it, how many people are looking at it. But then there needs to be some way to verify if it's being used. I don't know. Probably through extension or something. I'm not sure how they can do that. But just because it's there and people look at it doesn't mean that it's really serving a useful purpose.

MR. JONES: Okay, Mike.

MR. WILLETT: Mike Willett, Northwest Horticultural Council.

Rick, first of all, I apologize. I wasn't able to be at the pollinator meeting yesterday. But I do have another follow-up question about this RT-25. Has there been some consideration about how that might be expressed? I mean, is it going to be expressed as just the RT-25 value on the website or in another way? You know, some states have represented that information in different ways in terms of when applications can be made or when they can't be made, like in the evening or before dawn, that kind of thing.

Has there been any thought given to how that's

going to be viewed in terms of what the range of how that kind of information is already represented across the country?

UNIDENTIFIED MALE: So, the answer is yes, be expressed as the RT-25 value. But there will be a description, which we passed out in draft to the workgroup yesterday, and we can get you a copy of that, that will describe sort of the uses and the limitations, if you will, of the data so that people don't misinterpret it.

MR. WILLETT: I think that would be great, because what I've seen is that a lot of that information -- there used to be an awful lot more folks following bee toxicity issues in the states. I can see people might link to your information in any number of states. I think you want to find some way to tie it back to maybe the same metrics they had been using previously.

UNIDENTIFIED MALE: Yes. Well, we're aware of some of the issues around the use of that data.

MR. WILLETT: Okay, perfect. Thank you.

MR. JONES: Ray?

RAY: There's a number of points and comments I

wanted to make. We discussed briefly yesterday in the workgroup meeting a number of the state efforts which are underway to develop BMPs. On one point, I disagree with a minor point that Steve Coy made. There are circumstances where those BMPs do need to be less restrictive. That's one of the reasons we have section 18 exemptions, because they have the ability to control a very focused situation.

There's a lot of good work going on there that can help to guide EPA's efforts in the pollinator protection arena. The folks on the state level are closest to the problems, closest to the concerns, and closest to the needs of both their growers and their beekeepers.

I want to agree with a point I think Dave Tamayo made with respect to the information needs, the investigation, and the enforcement. The slide up there says we don't want to trigger an investigation, but I think we do need to trigger an investigation to explore all the factors that could be involved in a reported incident. But we do need to find a neutral ground or framework so that it is not going to scare people away

from reporting the incident so that they can be investigated.

I applaud your attempts to explain the RT-25 data. I think I missed the description. It was distributed yesterday. I'll watch for that. There are a number of shortcomings and use of that data for decision making in pesticide application. I think all the folks who will have access to that information need to be aware of those limitations.

We're concerned that in some circumstances, policy on pollinator protection has been driven or is being driven by highly publicized incident reports, possibly even before the full story is known, before the incidents are verified and the causes can be determined. So, w e would urge that that policy be based on evidence-based investigation and development of appropriate mitigations rather than knee-jerk reaction.

The last point I wanted to make is on the over-wintering surveys which are done by the Be Informed Partnership. They provide a lot of useful information for everyone involved. We think they could benefit considerably by involving the National Ag Statistic

Service. They have a lot of expertise in this area. They already do work with respect to honey production, so they have the contacts that could help contribute to the over-wintering law surveys and make them more rigorous.

UNIDENTIFIED MALE: I have a couple comments on this. First off, Ray's comments on investigation situations. I mean, it really does need to be thorough. I don't believe a myopic style investigation would tend to uncover all the factors (inaudible) in a situation.

But the other couple of concerns I do have in this subject is we do still need viable crop protection products, even during that time. As these new labels expand, obviously there does need to be some sort of risk benefit analysis, even on this, of what is the protection that would be lost.

And also, to the comment of the large workgroup on this, there is still a shortcoming, even though there's lots of people on it, for very many of the actual commodity groups to be on it. I mean, obviously, almonds and cotton are on it, but they're sort of the exceptions because they have such a huge apparent stake. But as this expands by your stated direction to additional

products, obviously the risk is much greater to other crops of the lack of viable protection labeling.

So, thank you.

MR. JONES: Mae?

MS. WU: I know that EPA is looking a lot at the neonics, but I'm wondering whether there are any efforts underway or even questions about whether there are other chemicals that EPA should also be looking at, like the pyrethroids and the fungicides, as well as the inerts and their impacts on the pollinators, and whether there's anybody in the workgroup that's discussing that.

MR. KEIGWIN: If I can start, and then Don can probably fill in some details, but a couple of falls ago we did bring out risk assessment framework for pollinators to the FIFRA Scientific Advisory Panel. That was a framework that was developed in collaboration with California as well as the Best Management Regulatory Agency in Canada.

We are in the process of adopting that, not just for the neonicotinoids but across all pesticides. So, as chemicals, for example, go into registration review, every quarter when we're opening up new dockets

for older chemicals, Don's group is applying that framework to how we would scope that review and what data we would need to evaluate potential pollinator risks in light of that framework. So, I think we've been doing that rather systematically now since we received the FAP's advice.

MR. BRADY: Yes, I think that's a good summary. I would point out that because we had the question yesterday that it's very consistent with the C-TEC work that was done, going back a couple of years now, that made some recommendations, that was the basis of what we brought to the SAP. So, it's very consistent with that.

So, there won't be surprises there. The document right now, the risk assessment guidance, is in the final clearance process amongst the agencies that Rick mentioned.

MR. JONES: Ray, are you a rerun?

RAY: No.

MR. JONES: Good, good. Tom?

TOM: As I observed some more of the conversations, every time enforcement is mentioned, it's sort of like this is Office of Pesticide Programs and

Office of Registration. How does it get to the compliance folks? Why maybe even, Jeff, for this session that the compliance folks should be in the room.

MR. KEIGWIN: I mean, we do stay engaged with enforcement, but I think that is a good take away from yesterday's discussion as well as that. We will reach out to our colleagues in the enforcement group and invite them more routinely to be part of the meetings. What I will say, though, is that we have a number of state lead agencies on the workgroup and they have primacy for enforcement. So, we do get a lot of insight from our state partners as part of that.

But the point that you've raised is a good one, and we will redouble our efforts with our enforcement colleagues to have them be part of the workgroup more routinely.

MR. JONES: Okay, if there are no more questions --

MR. SANCHEZ: Yes, this is Valentin. I have a comment to make if we still have a couple minutes.

MR. JONES: Yes.

MR. SANCHEZ: I was going to say that going

back to the training and education part of it, we have talked about beekeepers, farmers, applicators. I think we should also throw into the extent possible farmworkers because I think that since 2004, I have talked to hundreds of farmworkers who oftentimes tell me that they have never received (audio trouble) -- can you guys hear me?

MR. JONES: Yes.

MR. SANCHEZ: That's some background music.

MR. JONES: We figured that.

MR. SANCHEZ: I thought you guys were partying or something. If you guys can hear me, I'd like to continue. I was saying that since 2004, I have been talking to hundreds of farmworkers. A lot of the complaints I hear are many of them do not receive training. Of those who do receive training probably see training inadequate.

So, I think it's important to train farmworkers because sometimes they're asked to apply pesticides when they have never received any training or received the certification to apply pesticides. So, I think it's important to (inaudible) training and education part of

it, because I think it's important, especially for Spanish people farmworkers out in Oregon, California, who oftentimes are asked to apply pesticides to know about (inaudible) as part of their job.

MR. JONES: We had a request, which I granted. We have one more comment on pollinator protection. Steve.

STEVE: These acronyms, I still don't have all of them. The B E A D, we think that there needs to be a more accurate assessment -- let me see if I can read this here -- an economic evaluation of honeybees hired for one crop does not take into account their value across the neighboring farmland or wild land or the next crops that those colonies will pollinate. The current way that the evaluation is done does not accurately reflect the total value of the bees.

MR. JONES: Okay, thanks.

Now, on to IT. To lead off this session is Phil Villaneuva. Phil, take it away.

MR. VILLANEUVA: All right. Thanks a lot for this opportunity to be able to address the PPDC. The IT initiatives that I'm going to be covering today primarily

focus on the PRIA set-aside money (interruption to audio) particularly by our IT Division that is currently being headed by Mike Hardy. He's offered to provide any help on any additional questions, answering questions you folks might have. There's a large amount of working going on in his branch.

One of the first projects that we will cover, though, actually relates to some workgroup one efforts. You folks probably haven't heard of workgroup one very much, but it's basically a workgroup that has been charged with providing and making sure that our office, especially during these times of limited resources, has access to instantaneous information, quality information to make sound decisions. So, that's kind of our vision statement. That is an internal workgroup. We have representatives from our regulatory division as well, their science divisions, and our IT division.

So, that brings us to our very first project here, smart labels. This one, the genesis is from workgroup one. It's related to the electronic submission of label content. So, right now our label submission process is very manual. Electronic documents do come in,

but once the review starts, our hard work here, it actually is something that's quite manual.

What we're working towards is receiving, validating, and reviewing label content information, including the bits and pieces of the information (audio trouble) important to our science division to do the risk assessments that our risk management decisions are made on.

So, what we plan to do is issue decisions and make that information available also on the web. So, kind of from soup to nuts, being able to have an electronic process for capturing this information. It focuses on what we term structured content rather than format. Really, that's the whole purpose of getting this information, so that once it comes to the door, it's not just in a PDF file, but we're actually able (audio trouble) bits of qualitative and quantitative information that's important for our label reviewers and also our science division.

There will be some formatting aspects that we will continue to look at, although we're primarily focused on the structured data as it comes in. For

instance, any time we have requirements for visual or graphical reasons, like the bee box, we will be continuing to review that information.

We're very excited about this project. It has a lot of folks behind it. We're working with our partners in FDA who currently have a structured product label process that has worked quite well for them very successfully where they also get content information. So, we're partnering with them, hoping to build on their successes.

We actually have a federal partner that comes in here on a weekly basis working with our smart label team. It's a large group of scientists and risk managers and IT folks working all the time to identify the critical bits of information.

They're in the process of drafting what's called an XML specification. So, that is a term that you'll hear a lot within the IT developments. XML is the standard, so that when information comes to the door, it's tagged in such a way that you can ingest it, consume it into your existing IT systems.

They are also working on developing

vocabularies that are important for us as far as making sure that we have quality information that comes through the door. So, any time you have, say, for instance, a use site or a pass, that there's a drop down menu that you would select exactly what those values are.

We will be conducting an internal pilot shortly so that we can start working on what we're calling validation rules to make sure that when information comes in, again that it is quality information, that there's certain criteria that are set as far as what type of information is submitted in this label submission, smart labels.

We're targeting a pilot in late summer where we'll actually open it up on a voluntary basis to some registrants so they can provide labels to make sure that they actually fit into our format specifications. We see an iterative process where we continue to refine our specifications so that we're capturing information that the registrant can easily input into the system and also that will be useful for our reviewers.

We are actively seeking input from stakeholders and our regulatory partners, so we have a number of

meetings that are going on so that we can really understand what their current process is for developing label information, or with the states, how they review that label information. So, we want to collect it in such a way that it's important or improves the way that they're able to do this type of work.

The next project is electronic CSPS. That's a confidential statement of product specification. You heard that earlier in the day, so this is going to replace our CSF, confidential statement of formulation. I start off with a consolidated form so that if a submission comes in, that it will actually be compatible with the requirements by our partners in Canada, PMRA, and also meets the requirements that we have for the CSF now.

It was originally identified as a need at a 2011 product chemistry workshop. That it would be very useful for the Canadian and US regulators to get together to come up with a form that really helps us get quality information through the door. So, again, there were lots of errors being seen with these submissions. It was actually developed as an action item under the RCC, which

was also mentioned earlier, related to our NAFTA agreement.

It's a harmonized process again that allows registrants to submit the form once. There's going to be work to develop an electronic tool. So, right now there's an existing draft form that is available. We're checking with OMB right now to make sure that it's okay that we have a voluntary submission of an electronic form, because this is a modification to that form.

EPA is conducting an internal pilot to make sure that all the bits of information that are entered into that form make sense, that it works well. Where we really want to be, though, is to have an electronic wizard that will kind of guide the registrant to how they fill out these forms, depending on if they want to do a joint submission or if they only wanted to go to PMRA or just to OPP.

So, there's quite a bit of work that's involved with that. I'm just kind of harmonizing the fields that are important to both of our regulatory agencies. But, kind of a trickier piece is making sure that our security requirements are the same on both sides of the border.

So, this would be an electronic submission. It's a joint portal.

There's some more going on right now to satisfy Canada's requirements to make sure the information is transmitted in a confidential and secure way. So, you can imagine, there's lot of legal and technical hurdles to make sure that that information is safe and secure once it comes through our portal and we're able to share it between the two regulatory bodies.

Another important project that is being funded in part by the PRIA set-asides, the endangered species assessment knowledge base. So, that is a database that has search capabilities for collecting biological information for the listed endangered species.

So, that's been quite a bit of work being spearheaded by our environmental fate and affects division to identify various sources of information about these endangered species. Collecting information like body weight, diet, obligate relationships, habitat descriptions, elevation restrictions, all that information is being documented in a searchable database.

It also has the ability to link directly to the

publication or literature that that information is based on. Currently, all that information is available for the listed terrestrial animals. For plants, the initial data collection is about 90 percent complete. You can see the numbers up there. That work is currently underway.

There's the idea of combining the information that so far has been collected in the knowledge base with information that the Fish and Wildlife Service collects on species location. So, there's a pilot collaboration that's going to start with roughly 50 species in Arizona to kind of link the more refined species location with this biological information.

Next we have our registration submission milestone tracker. So, this is one of the projects that is working with our current IT system, so mostly open. Lots of information is collected about where submission is and open already. The idea was that we were going to work with the existing systems to generate these automated e-mails that allow registrants to kind of keep track of seven kind of critical milestones that are important to know where their submission package is in the process.

Obviously, the registrant has to supply an e-mail address so they can get these frequent updates. Our phase one implementation was actually January 1st, 2014, so we just started this year. It's been working, based on some of the initial feedback that we were getting. We've incorporated the ability to kind of bundle some related packages together so that they're not receiving multiple e-mails for related decisions.

Phase 2 implementation will be coming. We're going to be working with stakeholders to figure out how that implementation is going to work, as far as if there's going to be need for more detail. We're very excited about that.

We are in the process, though, of modernizing our IT systems, so there's a lot of work that's going on as far as how we track work from the very first time that it hits our doors when we have our electronic submissions all the way through our work flow process and then when it goes out for us to put it up on the web.

So, we're looking to modernize those systems now. There's a lot of work that's going on internally for us to figure that out. So, phase 2 obviously will

take into account any changes that we make in our tracking system.

The last one is the conditional registration tracking system. So, again, right now, this takes advantage of what technology we have available to us. It was quite a bit of work for us to consolidate a table of existing conditional registrations for our AIs since 1999.

What it does, in this table -- it's available on the web right now -- is identifies all of the data requirements that are conditioned for registration, including the due dates, the day that it was received, and the status of the agency's review.

We'll be using this to monitor the timely submission of data, making sure that we're actually getting the additional information that we've required as part of that conditional registration. A potential phase 2 implementation is under consideration.

Again, we are currently looking at modernizing the way that we track our work, the way we do our entire work flow within the program. So, we haven't determined quite yet if phase 2 implementation will work with the

current open tracking system or if our newly developed system is going to be what embodies phase 2 of this conditional registration tracking system.

So, those are a couple of efforts. There are other things that are internal that we've been working on. You heard mentioned earlier with acute toxicity data that there's quite a bit of work going on to actually collect the information that goes into those analyses. We have some other subgroups under this internal workgroup that are determining the best ways for us to get that information from studies that are submitted.

There was a pretty successful way of doing that. It was found with the EDSP program where we're able to develop what are called composers, which allows someone to generate like a Word document of a study summary. But at the same time those summaries are being developed, there are key fields of information that are recorded. For example, with acute tox data it would be something like DLD 50s or the associated doses from that study.

Once that information is recorded in these composers, what we can do is actually pull it into

internal data tables so that we have access to that quantitative information if we want to do an analysis such as what was mentioned earlier with the ICCVAM analysis or for doing our regular risk assessment work.

so, that's currently underway. There's a lot of work that's going on internationally, too, as far as OECD in Lois's slides earlier where it was talking about the global harmonization transport standard. So, that has a tie in as well with kind of getting these bits of important information from our studies so that they kind of seamlessly come into a science data warehouse, if you will, so we're not spending tremendous amounts of resources manually extracting that information.

But these are some of our IT efforts right now that are really moving quite fast. Some of the other things we talked about, updating our internal tracking systems and some of these composure efforts. Those are coming along, maybe not as quickly. But these are the ones that we focused on for today's presentation.

I'm happy to take any questions.

MR. JONES: Sheryl?

SHERYL: A couple of questions and a couple of

comments. You mentioned other databases. A while back I heard that there was something being developed to track metabolism and the results of metabolism studies. I haven't heard much about that recently. I'll stop and ask you to respond to that.

MR. VILLANEUVA: Okay. Are you talking about Metapath (phonetic) perhaps?

SHERYL: Yes.

MR. VILLANEUVA: Okay. So, that's the model, the composer, that they use for Metapath. That was the model for EDSP. We actually worked with the same folks that developed that composer. That work is currently being done primarily by our ORD partners for collecting that information. I know they've been adding various study types. There's a rat metabolism. I'm not going to know all of them off the top of my head. But our folks over in Duluth are working primarily with that.

We do have some kind of what we would term, I guess, as our Metapath gurus that are in HED that deal with that interface as well. But yes, that's an example of being able to collect that information kind of the first time that you even look at the study summaries.

That's what we're trying to work towards.

SHERYL: So, the question is always going to be is that public or is it held in EPA? I think that that one is still just within EPA?

MR. VILLANEUVA: As far as I know, it is. It's not something that I would term like an enterprise solution. That is something that we've been trying to move towards. Right now, that database is kind of located in one area. So, the person who maintains it has access to the most current version of that information.

So, as far as I know, that's not posted anywhere publicly, but it is something that I believe is shared on a regular basis. I'm not sure as far as external, but I can find out more about that.

SHERYL: Okay, that would be great. This idea about the smart labels, overall it's a great idea. I know that it was floated here maybe three years ago and there was some reaction to the way it was being presented. So, it looks like you've gone back and refocused the effort a little bit. So, that's really good to see.

There is always some concern because the label

is legally binding. Then the registrants are always concerned that you're going to add yet another step to the laborious process of checking the labels. This is going to add resources instead of actually making it better. So, I just wanted to throw that out there. Continue to keep the stakeholders and all those people that are going to use the system well involved so that it actually gets (inaudible) for everybody.

Do you anticipate having an electronics stamped accepted label? How are you collecting your volunteers for your pilot?

MR. VILLANEUVA: Okay. So, we do believe that it is going to result in greater efficiencies. We're actually working with stakeholders, states, and registrants to find out what they currently do, what type of information would be useful for them. We believe it's going to save quite a bit of effort, especially with our review process, being able to collect this information in electronic format.

The way that FDA uses it, once you enter the data into this X amount specification, you have access to these files. They're made kind of publicly available and

so that's kind of the official copy. And any time there's any modifications to the labels, so think of new uses, that specification is modified and resubmitted, it becomes very easy to identify what those changes are.

So, for one, we won't be spending as much time reviewing that label information. Also, for some companies they already have electronic systems for managing that content. What we're looking to do is making sure that the way that we identify that information and store it, that it's going to be useful for them as well. So, we are outreaching to them.

As far as collecting volunteers for that, we did want to keep it to a reasonable number. But with a variety of labels, the plan currently is to work with the PRIA coalition to identify volunteers for that pilot.

Did I hit all your questions? Okay.

MR. JONES: Ray.

RAY: I think we already helped you identify some volunteers for that pilot, but I may be getting pilot programs mixed up here.

On your slide regarding the submission milestone tracking, you mentioned the phase 2. Is there

a time line for phase 2?

MR. VILLANEUVA: That's a good question. I will ask Mike.

MIKE: Hey, Ray. The quick response is no, there isn't a time line for phase 2. At one point, we started discussions about perhaps having even dashboards where a company could go online, log in through the agency portal and actually see the status of their actions and know where they are. That's more along the lines of phase 2.

If we want to actually add some of the milestones to the existing seven, because then they come back and say we thought these seven were the ones we wanted but in fact we need two or three more, that's not a full blown phase 2. That would be a minor tweak to what we currently have.

But anything that's dashboard related and more automation, we don't have a time line for that because the existing systems we have probably wouldn't be able to sustain that type of a need. So, we'd have to build something else.

So, that's part of our longer IT vision that

workgroup one is trying to point us toward. So, that is a goal but no time line yet for that.

RAY: I just didn't want to overlook an opportunity for input into phase 2.

I've got another couple of quick questions, which may not be appropriate for this discussion. If so, just tell me and we can address them differently.

Web labeling, web-based labeling, is there any experience or progress to report?

MR. JORDAN: Ray, this is Bill Jordan. Several companies have approached EPA but no company, to my knowledge, has submitted an application to implement the PR notice that explains how we would like to address web-based labeling.

RAY: Thanks.

MR. JONES: My depth perception leaves after about 100 feet, so I'm not sure whose card that is.

MS. FULKERSON: Laurele Fulkerson. I just had a quick question about the endangered species database. I was wondering if you're going to include any information on the effects of particular pesticides on ESA listed species, in particular like jeopardy

determination or protection measures that are being put in place related to those ESA populations?

MR. VILLANEUVA: My understanding for that knowledge base is that it's not really there to capture that level of information. It's really the biological information that's going to feed the models. And we have Don here.

DON: I was actually just going to confirm what you're saying.

UNIDENTIFIED MALE: I just want to add one thought, as well. clearly, this database that we just heard about is something specific that will help inform models. But I want to make sure that everybody remembers that over a year ago, I think it was March 2013, we agreed to a new and open and transparent process that really is unprecedented for Endangered Species Act consultation.

So, not only will EPA make available draft biological assessments, but at the same time draft biological opinions will be available. We fully expect that that will be followed all the way to completion. So, that information, those analyses, will be available

to you.

UNIDENTIFIED MALE: One last contribution here. To the extent that we have (audio problems) issued biological evaluations or received biological opinions, they are available on our website.

MR. JONES: Cynthia?

CYNTHIA: Thank you. I think it's great that you're working on the endangered species database. That will be a huge contribution, and it's great to be working together with Fish and Wildlife and bring all that data together.

I was just wondering to what extent the data would become geographically available so that then in the future if we had pesticide use data, we could superimpose the databases and look some more at the potential correlations and vulnerabilities.

UNIDENTIFIED MALE: You going to be here tomorrow? We're going to talk about this issue a lot tomorrow morning, but I will just say I hear you. We all hear you. This was also a key recommendation from the National Academy of Sciences. We have a plan to move in that direction. It's not a simple snap the fingers and

you have a solution, but it's something we're committed to achieving. It will take time, and we've got a game plan we'll describe in the morning.

UNIDENTIFIED MALE: I would just add one thing. On the knowledge base that Phil presented, that database is actually been under development for a number of years and predates the sort of work that we've been doing with the services coming out of the National Academy of Sciences' report.

So, one of the tasks that the workgroup has taken on is to look not only at that database but other data that all the agencies sold and think about the best ways to be efficient in the use of our IT resources as well as our information of that species.

We have presented on that database probably two years ago to this group. So, anyway, it's part of the ongoing discussion between the agencies.

MR. JONES: Jerry?

JERRY: Phil, I've got a bunch of nuts and bolts questions, but I won't bog this group down. I'll speak offline with you. But I have one question, and that is, with your pilot, would you want to include a

tenth group, a publicly sectored group, that submits an awful lot of data to EPA?

MR. VILLANEUVA: I think that's a little bit different from our label submission, but I'd be happy to talk with you about some of the work that we've done so far.

MR. JONES: Okay. If there's no more questions, we'll move on to IPM. So, Bob McNally, the Director of the Biopesticides and Pollution Prevention Division, will chair this session.

MR. McNALLY: Jack, are you sending me a message? I don't have a name card.

MR. JONES: I think everybody knows you.

MR. McNALLY: Thank you. I want to do three things. The first thing we want to have is Thomas Cooke (phonetic) who heads up our Center of Expertise give you an overview of the activities of the Center of Expertise. Then we'll turn to the state pilot. That's the second part of the presentation. So, let me have Thomas give you an overview.

MR. COOKE: Thank you. Good afternoon. What I wanted to do is pretty much give everybody here a quick

glimpse of our past year and activities we've been able to accomplish with the Center of Expertise. Let me figure out how to work this.

So, over the past year, we've been working hard to help create a demand for school IPM. With that demand, we're also working to empower schools. We've been able to enhance the involvement in coordinating with some of the national and regional school IPM working groups.

We worked diligently to formalize a lot of existing networks, as well as form some new networks that we can pursue. Also, recently we've been able to align some of the agency-wide school-related programs to make sure we're all sort of thinking from the same page and working together internally.

So, how are we creating that demand? Over the past year or so, we've been able to partner up with some of the large national organizations. For example, we worked with the National Parent Teachers Association. We've been able to create some articles and blog materials and disseminate that information through these organizations. We've had an opportunity to partner up

with the School Nurses Association. So, we're pretty excited to work and build on these large national groups.

We're also working to create a mass outreach. I'll go into it a little further a couple slides later on how we're actually performing our outreach efforts. We've also been able to create a series of webinars that we're going to roll out in the future to really work hand in hand with both state and local officials and really pushing the school IPM message.

Also, as far as continued efforts as far as creating demand, as I just mentioned, we have publications we've been able to create within the Center. We've created a business case to be able to aid and assist school officials in showing the great examples of how school IPM can affect their overall programs.

I think I just mentioned, as far as the blog material, we're working with some of the great partners we have here within the PPDC on creating a lot of the blogging and pushing that mass messaging out.

Outreach efforts, we've been pretty excited as well to have our AA Jim Jones. He's had an opportunity to actually go out and visit a couple schools throughout

the country and see how the implementation is going on the ground. So, Jim has been able to visit a school in New Orleans, as well as participate in a couple big check events, most recently in the University of Arizona. So, these outreach efforts are really helping to create that excitement on the ground.

So, now, how are we empowering schools and (inaudible) change agents and IPM champions on the ground? As I mentioned, we've been able to create a model policy, pesticide policy, for school districts to actually use and help them on a lot of the implementation.

We've created a series of stock power points that are readily available for both internal partners, as well as external stakeholders. We've created a national school IPM expert list, as well as our most recent action we're working on, updating the Rat Book. So, we're excited to continue that effort.

Providing additional information, what we've found is that we've heard a lot of feedback from the community, and a lot of it seems like individuals would like to have that on hand in person training. So, we had

an opportunity to pilot an actual school IPM effort in region 10 with the Environment of Health Officers. It was well received, and we're looking to disseminate the information across the entire country to the other regions as well.

As I mentioned, providing additional information. We've scheduled a series of webinars that we're going to roll out over the next year or so reaching the on-the-ground stakeholders. Of course, we're working within our strategic plan or coordinating and collaborating our efforts with both our regions as well as our team members within the PPDC. I mentioned already that we're aligning our school related programs together.

MR. McNALLY: Let me just stop there. Are there any questions about the program in terms of the Center of Expertise? It's been up and running I think about a year now, so we wanted to give you a flavor of what we've done the first year and what the plans are coming up to get the message out to help change agents at the state and local level, the school level, take the information we've developed, and use it to try to instill the school IPM philosophy within the school community.

So, that's sort of the goal of what Thomas and his group are up to.

With that, the second part is Julienne Barta (phonetic) from region 10 is going to talk about the state pilot. This is the pilot for school IPM tat the PPDC commissioned about a year ago. So, we wanted to give you an update on the status of that. So, Juliann.

MS. BARTA: Thank you. I'm Juliann Barta from region 10. I'm from the other Washington. I work with a lot of different state partners in my region. One of them is Carrie Foss from Washington State University Extension. She's not going to be here today, but she was at the IPM workgroup yesterday and helped present with me on this topic.

But the goal of this whole pilot project in Washington State is we really want to create a model that other states can use and try to diffuse a school IPM statewide model for school districts within the state. Our objectives include increasing our school IPM partnerships.

We have a number of great partnerships currently in Washington State, including the state

agencies, the Indian Health Service in the Portland area, our extension, and, of course, the school districts themselves. So, we want to keep the program sustainable by continuing to strengthen those partnerships and also trying to find new partnerships in our state.

We want to definitely document what works and what doesn't work over the next 18 months of this project so that it will be a successful model for other states to use. Of course, our ultimate goals is to increase IPM implementation in K through 12 public schools.

Some of the resources that we will have is a staff, including the expertise from the Center of Expertise. We also have a group called the UPEST, Urban Pesticide Education Strategy Team. There's representatives from different Washington state agencies. We have an information clearinghouse on line. If you Google UPEST, it should come up. It's talking about urban pesticide safety and IPM.

Of course, the PPM IPM workgroup is a great resource. There also is going to be some funding for this project from EPA headquarters. The money is going towards our cooperative agreement with the Washington

State Department of Agriculture. It's going to fund a number of coalition events and walkthroughs over the next year. WSDA is going to contract with WSU for this work, Washington State University.

So, some of the outputs or the mechanisms we're going to use for this pilot project, we're going to put together some school district focus groups. We want to organize a core of champions. So, this would be between 6 and 10 school districts who already have a pretty robust school IPM program.

It would be bringing them together, having them provide peer-to-peer mentoring to other school districts, also providing us with input and what are the needed resources and incentives for schools to implement IPMs, and also to possibly pilot different tools that are created throughout the year.

We also want to hold a focus group at the Washington Association of Maintenance and Operation Administrators Conference this fall. Again, at that conference, we hope to get district input on needed resources and incentives.

We want to start looking into a recognition

program and starting to answer the question how can we best recognize school districts. This recognition program still needs to be developed. We're working hard on figuring out how it would best be designed. And then, like I said earlier, having partnerships. One idea we had was to create a letter of support from multiple state agencies to send out to administrators and the school board to support these efforts.

That's a quick summary of this. I'll turn the tables, I think, to Dawn Gouge to talk about sustainability in school IPMs.

MR. McNALLY: Any basic questions from folks before we turn it over to Dawn in terms of what the pilot is about, what it's seeking to do in terms of its mission and mandate?

MS. GOUGE: I'm going to stand up because I don't think I can talk when I'm sitting down. But if you can't hear me, let me know.

So, the rest of the time our workgroup spent trying to figure out how we're going to make this sustainable, how are we going to embed school IPM into the very infrastructure of our public schools. But I

wanted, before I move on, everybody in the workgroup who is here right now to just raise their hands so that those people who are sitting around you know exactly who you are. Thank you.

So, if you have any questions and we don't have time to address them today, those are the folks you can ask. I want to say thank you to Janet Hurley, Mark Lame and Carrie Foss for sending slides and contents that you'll get to see now. We have about 96 slides, I think. Only kidding.

I want to start by referencing Mr. Dave Tamayo He is right there. He quoted some physicist and I couldn't remember which one, chose I chose one of my favorite ones and that was Newton. Is this the correct one you referenced?

Yesterday, I swear he referenced a law of physics in support of this idea of sustaining school IPM in schools. What stuck in my brain is the second law of motion being the idea that you have to give something a shove. Depending on how much energy is required to keep it going in a particular direction depends on how much resistence comes back in the opposite direction.

This fits directly with the notion of behavioral momentum. If you're not familiar with that term, it is just that. If you are trying to cause a change in people's behavior or an adoption of an innovation by a society or community, then it takes energy input into the system in order to get things going in a different direction. You need to keep the pressure on depending on how much resistence you get.

I want to say that having been doing this for 15 years, 15 years ago I felt like I was running uphill. Maybe about eight or nine years ago I felt like I was running on the flats. At this point, I feel like I'm hurdling downhill at great speed. Something phenomenal has changed. We have school districts requesting more of our time than we have available. They want us to facilitate the implementation of school IPM.

So, the magic S word for us is sustainability. So, I'm going to give you some of the ideas that we came up with as a group on how best to build sustainability and institutionalize school IPM practices.

The first bullet point there is building the change agent core. Probably everybody in this room is

fairly familiar with the concept of using change agents to alter things in society. I want to say at this point that we probably have about 15 to 20 raving fanatical school IPM people who have the badge and the tee shirt and everything else.

We probably have about -- well, I can tell you exactly. We have 47 nationally who respond to represent their state or territory when it comes to request for information about school IPM in the state or territory. We have several thousand stakeholders that that core group of us interface with constantly. So, this has really built in the number of people involved and the impacts of the results.

So, yesterday we were talking about why some school systems adopt school IPM only to abandon it years later. Changes in personnel being one of those challenges that we deal with. Other school districts, it doesn't matter how many people leave, they are bound and determined to demand high quality school integrated pest management at their facilities.

We came to somewhat of a consensus that the more of the school community that you can engage from the

onset -- and that is all of the stakeholders, not just the school site people themselves, but all of the stakeholders that are associated with the school system. The more that you can engage from the onset, the better, the more sustainable a program is.

We talked about marketing and brand recognition and the fact that IPM, for whatever reason -- I like it. I love it. I know what it means. But the general public doesn't seem to like it very much. It's really hard to stick an IPM label on something and get it to stick. So, we decided to call our particular initiative Stop School Pests as a result.

We talked a little bit about EPA's approach at wholesaling school IPMs. We talked about the difference between wholesale and retail efforts. Really, what we see that's being presented to you hear today is both. It's the top down, the bottom up. We're really doing it from both sides. I think that's a really good way to go.

We're building new partnerships with stakeholder associations. Some of them it takes more than one try. But eventually we find the right people and we get engaged. We feel that those stakeholder

associations are terrible important. So, if you're here and you represent one of those and you're not involved in school IPM, please let us know that you want to be involved.

So, Stop School Pests, Juliann referenced in her presentation that Carrie Foss and Juliann are a team in Washington. They will be developing a Stop School Pests recognition program. I can't emphasize how terribly important this is and what great ramifications come from these recognition programs of various kinds that are around the country.

But we talked at length as a team, as a group, yesterday on the benefits. It's a modest investment in energy to run some of these programs, considering the great benefits that they return to us. Juliann and Carrie will have a tiered approach. So, everybody can get involved right from the onset.

We talked about procurement contracts and model policy and how very powerful having the model policy that is endorsed by a significant agency, and of course collaborative agencies and organizations, could be for us at this moment in time. Everybody wants to do the right

thing.

Having a definitive document to place in front of them that really means something that commits the school to partnering with the pest management professionals, whether they're in house or external, and forces the pest management professional, whether he's in house or external, to partner with the school staff will have great effects.

We talked about having environmental health committees at our schools. This is a very helpful way to institutionalize school IPMs in a district. It really has to be district by district, and we know that some districts have got small numbers of schools and others have many, many schools. But irrespective, having an environmental health committee has been enormously helpful. Those districts that have one, IPM is a part of that health committee.

In many ways, it connects them with the Public Health Department, which is next on the list. The Public Health Department, I have a slide on that. I'm just going to talk about that in a minute.

Statewide enhancement projects, like Juliann

and Carrie Foss from Washington State University, will be profoundly helpful to the rest of us. This is the very first time we have had an experiment like this, a pilot program, where we're aiming at statewide implementation and diffusion of the IMP innovation. So, it's superbly exciting.

So, here's my go public health people slide. I have this in animated form, but I didn't have 15 slides to show you the animated form today. So, here's the abbreviated version. Lots of people think that the reason why we don't die in our 20s and 30s and we live longer, we don't lose our children, is because of antibiotics, various things.

As you see there, the state health departments undoubtedly played a pivotal role in declining mortality rates over the last century. So, clearly, they couldn't do anything about flu in the 1920s, but we won't hold that against them at this point.

So, we discussed some of the tools for sustaining school IPMs. I would like to invite anybody from the team that has anything to add to anything that I talk about in the next couple of slides to just please

chime in.

Demand side IPM messaging, I wasn't entirely clear on this. It took several conversations for me to really get it. But the idea of having consumers be receiving IPM messaging is credibly important. Who recalls the days when your mom would smack you if you didn't put your hands over your mouth when you coughed? Okay, nobody's mother hit them over the head? I guess not. Things where I come from are a little different.

Those days are gone now, right? Anybody do the whole vampire cough? So, somebody decided that perhaps it wasn't a good idea to cough into your hand and then touch everything. It can spread the flu. It could have been avoided that 1920s disaster if we'd only known how to do the vampire cough.

But overnight, when H1N1 arrived, we were messaged to heck and back with the do not put your hands over your mouth. After years of belt with my mom, we completely eliminated by a mass media event that successfully gets me to do this 99 percent of the time.

So, Environmental Health and Safety Committees we've talked about. I just want to ask the team if

there's anything that anybody wants to add, any examples specifically of instances when they've been incredibly helpful.

UNIDENTIFIED MALE: Just the idea of the makeup of the team is not just internal as far as the school nurse, the nutritionist, the IPM coordinator, who may or may not be the pest management professional, and then the pest management professional, principals, teachers, head custodians, but also some of the internal people like athletic directors are also part of it, and then using external people, someone from the county health department and from the hospital as far as the community person that all hospitals basically have to have. So, you have external people that are also part of this.

The reason for these kind of committees is it's a sustainability tool in that it provides cover for the IPM coordinator when they need to make a decision that might be slightly unpopular, like we're going to have a different threshold for dandelions or for lice. But even more important is the idea when that IPM coordinator leaves or the pest management professional leaves and the contract changes, this committee provides continuity.

That's what we're really looking at is how do we keep IPM in schools continuing.

MS. GOUGE: Thank you. We talked a little bit about pest presses. I just grabbed a couple of pictures, one of ours. We learned a few things about pest presses. It's a good way to connect with your stakeholders en masse regularly. I mean, probably twice a month I interface in electronics form with every school district in my state and many, many more in other states.

We've really got rather good at this. In fact, we have run workshops asking our school folks what do you want in a pest press and how do you want it delivered. And so, several of them now are specifically tailored to exactly what they told us they wanted. That really helps with the distribution.

Having pest management professionals partner through thoughtful procurement, having meaningful high quality integrated pest management contracts that make it crystal clear for everybody involved, who is responsible for what, what everybody's expectations are is enormously helpful.

Does anybody want to add anything to that?

We didn't talk about this, actually. This was something that I added. That is, I wanted to emphasize the importance of being genuine and caring about the stakeholder's priorities. That's not just the school staff or one particular parent or a concerned parent or a student, but actually having genuine, genuine consideration for all stakeholders involved in the community.

Really, I love this. I think he was an American author and a pastor, John Maxwell. Quite interesting. He had some interesting public books that he's written. He coined the phrase, people don't care about how much you know until they know how much you care. It really couldn't be any clearer working in school environments, childcare environments, public housing environments, those kinds of situations.

So, I think we sometimes do an awful lot more listening and we respond to the priorities that are relevant for those particular situations. As an academic, I have this great plan for school IPM. I want to do this, this, this, and this. You know what, maybe two things will resonate with the staff at that site. I

have to focus on those first. I mean, usually, anything public health related comes first, but that's usually their priority as well.

So, I think that that's critically important as we build sustainability, to make sure that those change agents are out there and do address the school's priorities first.

Area-wide coalitions, I think one of the reasons why Washington State was considered so seriously -- and we had lots of discussion on the phone on this topic -- was the fact that they had one of the largest, longest running state coalitions for school IPM called UPEST. It's currently run by Carrie Foss from Washington State University. It's just the longest in existence and has a very broad stakeholder's team associated with it.

So, it has proven to be extraordinarily helpful. I think, with the exception of Texas and perhaps one or two others, they have a very, very high rate of numbers of students already in attending public schools at some level implementing IPM to some extent.

So, that's actually an Arizona picture. You might recognize a few of those people in there. But the

gentleman that is talking is the school IPM coordinator. He is an expert in many things. So, when we visited his school, he did most of the talking and the other school guys listened.

Again, we talked a bit about the recognition programs. We ran our own certificate system just recently where we recognized people who had engaged in school IPM, education efforts specifically. So, on their certificate it says thanks for being a great educator. As a result of those nine individuals who got those certificates, we expanded our stakeholder teams significantly. We expanded the number of change agents involved in the Arizona effort.

There's just been great impact for the individuals who received the certificates, that they've given me feedback. They feel that their school is looking at them with a whole different level of credibility and professionalism. So, that was wonderful to hear.

This was a mock slide, get dirty, mostly because it's fun, but it does make a difference. It really does, actually, make a difference. I've cleaned

drains. I've been in dumpsters. I've done pretty much everything you can possibly think of. I've cleaned tons of rodent poop correctly, using 10 percent bleach and waiting for it to soak and all of that. The great thing is that you get to demo and everybody gets to watch. Having your stakeholders see something demonstrated in front of their eyes, it really does work. But it's lots of fun.

Then, finally, having some non-pesticide rules and regs. I didn't put legislation because I thought I'd be like instantly burst into flames or something saying that in here in this building. So, I'm not going to say that. But rules and regs can come in many forms. Schools can institute their own rules and regs and policies. Quite often, that is where they start.

Focusing on pest resource reduction has been phenomenally effective. Who is going to argue with you when you say your sanitation standards need improving. Your clutter needs reduction. Your waste management program is generating problems with rats and flies, et cetera, et cetera. Nobody argues with those things. They're such common sense. I haven't had anybody argue

so far.

I'm going to ask Mark to cover this particular slide. This is one of the things that he teachers, so he's better qualified than I.

MARK: Well, it's just what it says. What we want to do as change agents is work out way out of a job. Basically, we want to reach a point of critical mass, which is the point that individuals in a system have adopted an innovation so that the innovation's further rate of adoption becomes self-sustaining.

It actually goes back to what Dawn was talking about earlier with behavior. Once the resources are out there to get that momentum going, then you have to spend more resources to keep that momentum going. But, at some point, it will continue. So, how do we do that is the question. There are ways of doing it. That's what the workgroup hopefully will be working on in the future.

MS. GOUGE: This is just a final reminder. People are motivated by perceived threat. They're motivated to change their behavior based on perceived, being the important word, threat. All of this change is made individual by individual.

I'm going to just ask, who is more terrified of sharks than mosquitos? Come on. Sharks, put your hands up. Come on, people. Be honest. Okay, mosquitos. Oh, you guys, seriously. You know, mosquitos are way more deadly. But I still stand by the fact that for those five people who are eaten by sharks every year, it's going to be a bad day for them.

And one final thought, individuals are motivated. They take action based on perceived ease and efficacy. How easy is it to make this change and how effective is it going to be if I put the effort in? So, I got on a website, the American College of (inaudible) Medicine.

They recommend that if you want to reduce your blood pressure, so you're a little hypertensive, you can do it this way. You could engage in 30 minutes of exercise 5 times a week. You also need to be doing some strength training at least twice a week. You can park your car away so you have to walk, take the steps, take your kid out to the park. Oh, yeah, you can't eat anything either.

So, then again, you could take some pills.

What's easier? Who wants to go for the walking and all of that? Good man. So far, one person in the entire room. So, we have to make sure that we really can motivate people and give them something that is relatively easy. We cannot make it too complicated as we continue to expand this across the country.

We have to stay focused on making is simple, easy, and with huge benefits at the end of the process. I think as a group, we realize we've been doing a lot of that already, and we're just going to continue on.

So, with that, any questions?

MR. JONES: Jimmy?

DR. ROBERTS: Nice presentation. Jimmy Roberts from MUSC. I wanted to point out one thing. You had mentioned partnerships. The American Academy of Pediatrics, which represents 60,000 pediatricians, has come out with a policy statement on pesticide exposure in kids. In that, they strongly recommend the use of IPMs. So, that might be, number one, useful for you as your group, but also your local pediatricians might be a great partner in every place that you go to.

MR. JONES: Mark.

MARK: Yes, thank you. By the way, we have two pediatricians in the room that I know of. One is Jimmy Roberts and the other one is Geoff Calvert. Between the two of them, they wrote, probably, the articles that I use the most in trying to diffuse IPM out there.

Geoff did an article five years ago now, five or six years ago, with regard to pesticides and children and exposures with schools. It wasn't just children; it was the school community. Then, what Jimmy is talking about, I actually just found out that he was the author of that American Academy of Pediatrics paper. I use that all the time.

It's quite valuable in that people don't have to believe me when I stand up in front of them as an entomologist or whatever they want to think of me. But when I say this is something that is recommended to you by the doctors of your children, that is very powerful. So, I want to thank him and the Academy for doing that.

What is really nice, and it's part of what Dawn was talking about, is finally feeling like we're not climbing uphill all the time. We have pediatricians that are also coming to us and willing to help implement

integrated pest management. That's a powerful tool out there both with schools but also with agriculture, I'm sure.

First, I want to say how impressed I've been in the past couple years with the agencies, particularly this office's commitment to school integrated pest management. I've been doing this for 20 years or more and it's been a long slog. It's really been good and it's really reaching that critical mass slide that Dawn put up there. As far as I know, other offices in the agency and some other agencies are getting on the bandwagon and partnering up with this office.

So, that said, I would like to ask a few questions, which I know I had that opportunity earlier, but I wanted you guys to get through your slide show. Probably one is to Thomas. In slide 9, there was a reference to one of the major activities of the offices to provide technical assistance. Could you give some examples of that? Then I have a few other questions.

THOMAS: Sure. So, a level of technical assistance we've been able to provide as we're working hand in hand with our regional coordinators, obviously,

is either outreach efforts or connecting them with partners or external partners. But to the level of actual on the ground technical, we're looking to utilize the existing partnerships we have through the PPDC and subject matter experts on the ground. So, no, we haven't had that degree of assistance reach out to us yet to this date.

MARK: Well, in a sense, you're brokering with the change agent core that you have out there, so that works better anyways, the leverage of resources.

THOMAS: Correct.

MARK: That's good. I wasn't quite sure if you guys were on the ground doing that or if you were acting as brokers.

THOMAS: We're utilizing all the existing resources we have.

MARK: Okay. Then, I guess this one is going to Frank. I think one of the drastic differences out there that have changed things is the idea that we've gone from grants to cooperative agreements. So, that's where there's a substantial federal involvement. So, could you give us some examples of what that means and

what the difference is?

FRANK: Sure. The last round of grants that were issued prior to the three that we just awarded were initially set up as grants. As Mark said, the key difference between a grant and a cooperative agreement is the term substantial federal involvement. We converted several of those initial grants to cooperatives agreements kind of midstream.

With these three that we just awarded, we felt that it was important at first to set those up as cooperatives. That does allow EPA folks to be more involved in the projects. We don't get to help with the initial project proposals or those types of things. The ideas are generated by the applicants. But we are allowed to participate in the project's implementation.

So, we can have EPA folks participate in meetings, provide webinars, provide information as far as ideas and guidance on how the project may be steered in different directions. So, it provides a more collaborative environment for the project as it goes forward.

So, we think that this is a better mechanism.

We think that it can get us working more collaboratively with the recipients. It will, in the end, result in better outcomes of the projects than we could achieve with just awarding money through a grant process.

MARK: Thank you. I see that, and I'm learning about it in that it's a work in progress. When I work with folks in the states that have these cooperative agreements, I think it will behoove us to try to come up with a list of ways that they can work with the agency. This has lots of benefits, tangible ones, for the diffusion of IPM on the ground, but it also would for future projects that, in fact, don't entail money but partnership.

MR. JONES: Thanks, Mark. Good point.

Fawn, go ahead.

MS. PATTISON: Thanks. I want to commend you all on the great work. Dr. Gouge, thanks for your great presentation. It's nice having educators give power points.

I have worked on school IPM a fair bit in North Carolina. Now we're doing a lot of work on childcare IPM. I'm curious about -- and I think I've asked about

this before -- but I'm curious about whether the Center for Expertise or the workgroup have talked about doing more work in the childcare arena. You all have referenced in several ways how important it is to have an authoritative agency, an authoritative source speak to why this is a good idea.

It seems so intuitive that if it's good for schools, it would be good for childcares. It is, but the folks who work in that completely different arena look to different sources, use different lingo. I would love to have more of those authoritative reference points saying yes, this is great for childcare.

Once we get over that initial hurdle with them, they're so receptive and so much less red tape than in a school environment that the ball rolls downhill a lost faster. But getting over that initial hump, especially once you get into the for profit childcare networks that serve a lot of vulnerable kids, it's been very, very challenging.

So, we would love to have more to be able to point to to say not just that it's a great idea but we're not the only ones who think that.

MR. JONES: Dave.

DAVE: Thank you, Dawn. That was actually a very good presentation, although I looked puzzled. I must have been asleep when I made that quote. I'm not in the habit of quoting physicists, but I'll take your word for it.

I wanted to thank EPA for actually moving on the recommendations. It took us a while to get to them. I think once we sort of landed on some more specific recommendations of direction, I think you guys have done a good job of moving forward with that.

In the discussion yesterday, one of the things that we landed on was well, what's next. I mean, I think we kind of landed on a lot of the sustainability things that Dawn touched on. But we also wanted to talk about, what is the role of the workgroup and what would we recommend to EPA to do.

I think that as a group we decided that we would continue to advise EPA on what is its ongoing role or what is its role, at least for the time being, in promoting sustainability out in the very large country and getting it to the points that it's not so much EPA's

initiative or any one person's initiative, but we get to the point where these systems are in place and sustainable on a statewide and regional and district level, and looking for whatever it takes.

I know that there's going to be some trial and error. Obviously, there's some good information on what really does work. But focus on what EPA's role can most constructively be in getting that fully sustainable throughout the country so that it just takes on a life of its own and it becomes the way people do pest management in schools.

My vision is it's been 20 years and people think well, you mean you used to do it a different way? So, anyway, I'm looking forward to the workgroup moving in that direction.

MR. JONES: Ray.

MR. McALLISTER: We'd like to encourage the workgroup and the various projects coming out of that workgroup to adhere in their efforts to the IPM definition that's codified in FIFRA, which states that IPM is a sustainable approach to managing pests by combining biological, cultural, physical, and chemical

tools in ways that minimize economic health and environmental risks. If you leave out some of the tools, you may hamper your efforts to minimize those risks across the board.

MR. JONES: Mark

MARK: First of all, Ray, I certainly agree. You want to be able to use all tools, as long as they're safe. That's the important thing, with our children in particular.

By the way, thank you for allowing me to talk about. I wanted to mention something that I was talking to some of the other offices to the other day about what are the advantages of setting up an IPM program in a school besides reducing the risks from pest and pesticides.

What I have seen over the years and what I think is really valuable for taxpayers to think about is that schools have an infrastructure in place for children's health. That infrastructure, whether it's with regard to pests or pesticides, that same infrastructure deals with nutrition. It deals with athletic injuries. It deals with indoor air quality.

So, once these infrastructures are set up and have had some success to where they become part of the institution, you have a more efficient system.

So, this is something that is, for me, an unanticipated consequence, because when I just started this it was about pests and pesticides. So, this is what I see now, that availability. Then, that same model can be moved to childcare facilities, elderly care facilities, hospitals, public housing, et cetera. That is what is happening. So, it's not just their bed bug management; then it goes to nutrition and indoor air quality as well. Thank you.

MR. JONES: Tom.

TOM: I think that the group would like to know, because I'm not sure myself on the committee, how long is the pilot project supposed to go? Is there a plan for another pilot project? It may be based on your funding or whatever, but other than us working on the sustainability, what are the plans, so that the group would know, of how you're gong to bring it forward? Would another group get a small grant to implement what's already been done in Washington?

UNIDENTIFIED FEMALE: Sure. So, the pilot project is supposed to be 18 months long, starting just recently. We are definitely going to document everything that goes into this project, the outputs and outcomes. We hope to do a webinar at the end of the project to the other regions and states really being honest about what worked and what didn't and how we were able to strengthen the program statewide.

I don't know if you wanted to add anything else about diffusion.

UNIDENTIFIED MALE: I think, Tom, we're looking to see how well the pilot is. We assume it's going to be successful. We anticipate it will be. If it is, then the idea is to take it and work with other states, maybe not on a one-on-one basis like we did with Washington, but maybe get a couple of states, two or three or four states, onboard with the same kind of model and work it from there.

We haven't thought as far as funding or anything like that I think we want to look to see how much we can do with the resources we have with this project. Then, like Juliann said, do a good

documentation so that it is a well-documented model that is applicable to other places. So, I think we see that as the next step a couple years down the road.

UNIDENTIFIED MALE: Dawn, I wanted to compliment you on a great presentation. I know yesterday you were a little hesitant, but you did a superb job. So did Tom and Juliann as well.

I know looking down the road, it appears you have a really school IPM program overall. One of the things, and I think you had it on one of your slides, is to be able to show the benefits of impact as we go along. Sometimes there are unintended impacts or benefits, one of which I think would be to determine how (inaudible) school IPM, the kids or other folks who are involved in it.

Has there been or do you know (inaudible) spill over into their homes as a result of the knowledge that is acquired from (inaudible) from the school IPM? That would be really a big deal if we can document that as a result of school IPM other things that are happening.

DR. GOUGE: Thank you very much for that comment. It brings up a really good point. Yes, we have

had spillover in two particular kinds of situations, the first and most obvious being when we're training in a school environment, the staff and the faculty are engaged. They receive the pest presses. They get topical information constantly. They are involved sometimes in inspections but always in the training aspect. Teachers are by far the most hostile audience I ever engage with. Within the first few minutes of explaining that everything that I'm going to explain to them about the school pest environment is applicable in their home environment, they are, like, oh, okay, all right, because they don't necessarily initially see pest management in their school as their job. It's somebody else's. Little by little, they get on board with the whole pest management is everybody's job in a school or a childcare facility.

So, first of all, faculty take it home. We've had great impacts from that. There are a number of states and some great advocates for teaching students IPM as part of IPM in schools programs. That also has had some follow-on effects where the kids take the message home to parents and then parents get more involved.

MR. JONES: Jerry.

JERRY: I want to congratulate the team on what a great job you've done. I was involved in this issue many, many moons ago when Bob's predecessor's predecessor, Janet Anderson, convened a workshop and I was asked to facilitate it. I've just seen this come light years from where we were 12 or 14 years ago to where we are today. So, congratulations and Kudos.

The question I have for the team is are there necessary biopesticides and conventional chemical pesticides needed to sustain this IPM system that are difficult to obtain and retain due to data requirements and how are you going to get around that issue?

DR. GOUGE: I have not been aware of any, but I'm based in Arizona. So, I can't speak for all parts of the country. I would like to open it up to anybody on the team or anybody that's aware of a situation where that's occurred.

UNIDENTIFIED MALE: In my experience, I have not seen that as a problem. We get into situations on who can apply some emergency stuff occasionally, but it's not too big of a problem. With my research on looking at

the efficacy of IPM in schools as far as the amount of pesticides that are used and the pests, I measure all pesticide applications no matter.

I don't take into consideration toxicity because I don't want to get into that. So, if it's boric acid, if it's diatomaceous earth, if it's fipronyl (phonetic) on the outside, I measure it all the same. But as far as availability, I've never run into any problems. Obviously, it's nice to have alternative, but from my point of view, I look at IPM as pollution prevention.

So, if you look at pesticides as a potential pollutant, then what is the source reduction for that, and that's not having pests. So, I always hesitate to provide more of those pills for people who need exercise.

UNIDENTIFIED MALE: I guess the only warning is to learn a lesson from what's occurred in the agriculture IPM where a lot of the fruit crops had tremendous IPM systems. Then comes the brown marmalade stink bug and it's all gone in one quick swoop. So, you don't want those kids or that spike going back to the 1920s with the flu. So, you have to be prepared.

MR. JONES: Dave, do you have another comment?

DAVE: Yes. It's sort of reflecting on what Ray commented on. I'd say that the discussion in the committee isn't really centered on oh, okay -- I haven't heard any move towards defining IPM as the goal is to reduce pesticides and focus on good pesticides versus bad pesticides. Really, I think it is consistent with the definition that considers the use of all tools and really focusing on overall and long term effectiveness.

I haven't really heard any effort of let's try and measure this by how much did we reduce the use of this pesticide or that pesticide. So, I'd say we sort of started from a standpoint of an understanding of it, using all the tools.

I don't think this is explicitly stated, but I think we all recognize that pesticide reduction can be one of the benefits, if you will, of having a system that really focuses on what is the whole system that reduces the pests.

So, I think we've kind of accepted that definition and sort of moved on from there in trying to get people to understand it's not a trivial or

uncomplicated concept.

DR. GOUGE: I did want to just qualify that. Thank you, Dave, for putting that so succinctly. There are situations when I prohibit the use of a chemical approach in certain instances. I say that unapologetically to each and every one of you. I'll give you some examples. I could go on and on for hours, but I'm just going to keep it to a few.

Many of us dealing with school situations or dealing with roving bed bugs, the initial reaction to a single bed bug in a classroom is to want to evacuate the classroom, to spray it down with as many different things as they have on hand at any given time for the one roving bed bug that's being caught, squashed onto tape or mashed into the desk. Those very, very few instances that I've ever come across amongst many, many situations where I would ever think that anything beyond cleaning, vacuuming and monitoring for additional bed bugs was the correct response.

So, I recognize that Ray referenced the definition of FIFRA, but by no means are we required to use all of those tools to respond to any one particular

pest. On occasions, we're faced with a pest where the knee jerk reaction is not the correct choice. So, there are situations where I absolutely go insane. We're going to deep clean, we're going to monitor, and we're not going to send any kids home today.

Then, another situation that we come across, this is special ed rooms where we have a lot of kids who are disabled either physically or mentally or both, that are particularly vulnerable to chemical sensitivities. I will get very animated when people are using strong cleaning chemicals or anything that's going to agitate and adversely affect those kids who are in that room and sometimes in a particular location in the room for an extended period of time.

I could go on, but I'm just going to stop there.

MR. JONES: Any other comments? Okay, thank you very much. I've never seen anyone so excited about cleaning rodent poop.

So, we don't have any public comments. Is there anyone on the phone who wants to make a comment?

MS. DUKE: Hi, I'm Marcia Duke with the

National Pest Management Association. We represent the structural pest control industry. We are excited about talking about school IPM on a lot of levels. Some of the things that are being talked about are things that we have tried to get happen, not only in schools but in food plants and other very sensitive locations for a very long time. So, we hope this is successful and from a big picture perspective, we can get schools to do all of these things through a health committee or something along those lines.

We play a small role in what has been described. But not very long ago, typically, a school IPM was very focused on the person doing the pest management. This is a bigger picture perspective. I'm sort of taking it away from the traditional definition of what one would consider IPM. So, I'm sort of glad we're moving a little bit away from that talking about this is school IPM and some different circles, maybe not here.

That all being said, I think there is one thing that maybe is missing from this discussion. Maybe it isn't and maybe I just missed it. One of the reasons that we haven't been successful in different places of

actually getting these things to happen is the money behind it. Getting a school to make these changes, even with a core of change agents and other people, and diffusing that out, I do believe will be difficult, although I am very hopeful that this will be successful in the end. And that somehow we're reaching that critical mass and we can push this forward over the hump and it catches on.

But I just want to state that I'm a little worried about where the money -- I think we're at the 50,000 level. If you take it back to we're on the ground and we're at the 1,000 foot and we're implementing this program, who pays for all of the components that have to be put in place to keep the pests out in the beginning, if that's where we're going. I think that's where we're going and I think it's the best place to go.

And then, we need to keep in mind that not only does my group use pesticides in schools, but there are a lot of antimicrobials being used as well. So, we have to keep that in our school and greater pest management minds that we're not just talking about those pests. We're talking about the antimicrobial pests as well and

bringing that all in together.

I thank you for allowing me to make a public comment.

MR. JONES: Okay, thank you. Anybody else?

MS. HURLEY: Hello, this is Janet Hurley. Can I comment?

MR. JONES: Go ahead.

MS. HURLEY: The fact that what Marcia just brought us is extremely true, but this is where I'm going to put a plea out to the PPDC committee and every parent and every person out there. The problem with that cost has to do with schools not keeping up with their infrastructure. I don't know how many people have watched the news, but I've seen things on schools that don't keep up. That's our biggest hurdle when we're doing this. When you walk into a school that will not put money into infrastructure to fix things, that's when we have pest problems. We can do everything we can, but when a school district doesn't want to put money into an old building but wants to build a brand new building -- we're working very hard on changing things.

But I am applauding everything that I've heard

today because I, like everybody else, remember when we sat around and told everybody what we were doing but we weren't doing it. We're now doing it and we've got lots of people helping us. We're welcoming more.

So, understand that we understand these hurdles. It's just not always easy, depending on the school system.

MR. JONES: Thank you. All right, where has the time gone? It seems like we just started. So, we'll meet back at 9:00 tomorrow. We'll do endangered species, endocrine disruption, screening program, and comparative safety claims.

So, have a good night and we'll see everybody bright and early tomorrow. Thank you. I just want to thank everybody for making my first PPDC chair and first day so easy. It's nice to see everybody have a constructive discussion without letting everyone's personal emotions get involved. Thank you.

(Whereupon, the meeting was adjourned.)

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UNITED STATES

ENVIRONMENTAL PROTECTION AGENCY

PESTICIDE PROGRAM DIALOGUE COMMITTEE MEETING

June 5-6,2014

Conference Center - Lobby Level

2777 Crystal Drive

One Potomac Yard South

Arlington, VA 22202

P R O C E E D I N G S

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MR. HOUSENGER: Good morning. Welcome back to day two. We have a short day today. I think there are a couple new people sitting in for people who had to leave. If those people could identify themselves.

MS. : (Inaudible) USA. I'm sitting in for Scott Schertz.

MR. WHITE: Mike White, Council of Producers and Distributors of Agrotechnology, sitting in for Dr. Susan Ferenc.

MR. CHEN: I'm Teung Chin, USDA Office of Pest Management Policy, sitting in for Dr. Sheryl Kunickis.

MR. HOUSENGER: Okay. I know that people probably will, at some point in the day, leave early, at least some of you. Before that happens, I wanted to thank Margie Fehrenbach who is responsible for getting a lot of people here. So, blame her or congratulate her on doing that. But it is a lot of work. It's a lot of work for a lot of staff here, actually. I want to thank everybody for all the work they put into it, and to you guys as well. I know it's not easy to get to Washington

from where everybody is coming from, so we appreciate it.

We had a good day yesterday. Let's continue today with endangered species. The people leading off the discussion are Rick Keigwin, Don Brady, and Lois Rossi. Don is going first.

MR. BRADY: So, welcome. It's a good topic to take up first thing in the morning. I'd like to also acknowledge Paul Sousa (phonetic) from the Fish and Wildlife Service who, in addition to being a member of the PPDC, is the senior manager in the Fish and Wildlife Service that's helping with the implementations of the National Academy of Science's report.

So, today -- oh, and I would like to point out that I got projected, at least on some of the screens. One of them is flipping on and off over there, the web site where people can find the materials that describe the interim approaches that the agencies have adopted and are working through right now to implement the National Academy of Sciences.

You'll find a white paper. You'll find a fairly involved Power Point. I would remind people that these are evolving approaches. We've had one workshop

with CropLife and Defenders of Wildlife. We expect that there will be some additional workshops as we go down this road jointly with Fish and Wildlife, NOAA, and USDA to implement the NAS recommendations. We anticipate that we'll learn and adjust as we go.

But having said that and encouraging everyone to pull down that material and take a look at it, we wanted to do three things in this morning's session. The first was to share some information on some of the litigation that's confronted the agencies around endangered species. Then, we wanted to share with you an approach that we are thinking about, really.

It's a conceptual approach at this time to dealing with consultations in the future. This is primarily from EPA's viewpoint, but we're very interested in hearing reactions from the committee to this outline. We're going to actually stop after the second point and ask the committee for thoughts and comments.

Then, finally, we'll get an update on the interim agreements, and there's two key things that the agencies have agreed on. One will be what Paul alluded to yesterday in terms of the approach for producing range

maps of endangered species for use in the interagency work. Then, hopefully, we'll have time for Steve Leonard's (phonetic) from EFED to share some of the work around use data based on USDA's geographic data.

So, that will be a busy session. I'll be joined at various points. Paul will chip in, and Lois will chip in, and I know that Rick will, too.

So, the first thing we wanted to talk about is that there is a stipulated injunction. It's scheduled to be published for comment today. The injunction would settle litigation against EPA by Northwest Center for Alternatives to Pesticides, or NCAP, and others in the district court in Washington State.

The injunction in big picture terms does three things. It reinstates the stream side buffer zones established in the prior Washington toxic litigation and applies to carbaryl, chlorpyrifos, diazinon, Malathion, and methanyl (phonetic). It will remain in place until EPA implements necessary protections for salmon and steel head based on reinitiated consultation with National Marine and Fisheries.

It provides notice to certified applicators,

state and local governments, federal agencies, land grant universities, and extension organizations of the settlement, and it provides for an updated EPA web site. There will be a 30-day comment period, and EPA will review all comments to determine whether the proposed injunction should go forward or whether we should reconsider or revise it based on the comments.

In separate litigation, the National Marine and Fisheries has agreed to complete consultations, any consultations that EPA reinitiates on chlorpyrifos, diazinon, and Malathion by December 2017, and on carbaryl and methanyl by December 2018. These consultations or the work that EPA does will be done in connection with the National FIFRA registration review work plan.

Fish and Wildlife also has comments (tape malfunction).

PAUL: I think it’s safe to say it’s an exciting time for consultations with registrations. As we’ve talked about the last few PPDC meetings, we’re trying to figure out how we create this fully unified approach to consultations.

So, what Don mentioned previously is really

important to us as well, because, again, a year ago we had the National Academy of Sciences report come forward to give us recommendations for how we complete consultations, how we move beyond some of the scientific disagreements that we've had in the past.

Before that, we had the public engagement strategy that I (tape malfunction) to providing draft biological opinions along with draft biological (tape malfunction) transparency in an effort to really make these consultations work.

So, what we are really interested in doing is figuring out how we align all of our workload. Clearly, litigation has a way of helping identify your priorities. So, as Don mentioned, we have a situation now where we've got three chemicals where consultations would be completed by the end of 2017. That's chlorpyrifos, Malathion and diazinon, with a couple of other consultations a year after. We are very interested in finding a way to ensure that we can bring our full capacity to those consultations as well.

The real value in this would be our scientists would be sitting down working together as we implement

for the first time in real consultations the National Academy of Science's recommendations. We would, for the first time, be able to use this full public engagement process on some chemicals that historically have raised a lot of concerns in the public.

So, we are trying through our litigation and through our staff capability, more broadly, to be able to bring to bear the kind of commitment that is going to be necessary to move through these consultations. 2017 might sound a long way off, but to meet that kind of deadline with the registration review process, with the public engagement strategy that we have previously agreed to, we're looking at biological assessments as early as a year from now in draft form, obviously.

So, our teams have already started working through this issue. We've outlined a rather ambitious plan to work through the details of the Academy's recommendations. It might seem a bit odd that it takes a lot of time and energy to work through recommendations that were produced a year ago, but the reality is when you apply these kinds of recommendations in a specific context at a nationwide level, you find there are lots of

questions that reflect important details that were not apparent as we were developing the interim approaches available at that web site.

So, that's really where we stand now. We're still working through this issue. Clearly, there's a public comment period in place, as Don mentioned, for the next 30 days. We are, in the Fish and Wildlife Service, doing our best to figure out if we can bring the capacity necessary to be a full partner in these consultations as they move forward. It's our sincere hope that we'll be able to, because I really see that shared workload moving forward together as the federal family with these chemicals.

It's very important for us being able to get the longer term efficiencies that we've talked about. Once we have a number of these consultations under our belt and this new day of National Academy of Science recommendations, we're really hopeful that we're going to be able to expedite the consultation process dramatically. So, this initial kind of go slow to go fast approach is really important.

MR. BRADY: Thanks, Paul. I think that it's

important to emphasize one of the things that Paul said, which is that this work around the litigation represents a real effort amongst the agencies to align and focus our available resources so that we can demonstrate the utility of our process for implementing the NAS report and start to move through a more concerted implementation process.

So, with that in mind, we wanted to share sort of our concept. I think it will generate some interested discussion. I hope it generates some interesting discussion around the table. Basically, given that we can't do everything, and neither can the Services because of the resources that we all are working with currently, we need to focus and put our energy where we think that we'll get the most protection for endangered species.

So, we sort of have a three-legged approach here. I'll introduce the first point, and then Lois will pick up on the second two legs. Our main focus will continue to be registration review. That's where the vast majority of our consultation activity will occur. It will remain the primary way in which we accomplish our consultation obligations.

We believe strongly that by consulting during registration review, we will be working with the greatest potential impacts to species. And consistent with the interagency shared scientific approaches, principles, and the day forward approach that the agencies have adopted as part of the NAS implementation, we will phase in the National Academy of Science's measures over time.

So, the first consultations that we've given you the hard dates for will be the first place where we'll see those NAS measures start to be implemented and jointly used by the agencies. As we said before, we expect that we'll learn from the application of these interim approaches, and that the teams, the science teams that are already working together on these five chemicals, will be providing back to the senior managers and the agencies adjustments or revisions or refinements of those interim approaches that have been identified so far by the agencies.

So, registration review will continue to be our primary focus. We will, however, do a couple of additional things in response to some of the concerns we've heard from stakeholders. I'll ask Lois to pick up

there.

MS. ROSSI: So, in the registration world, we'll have two approaches, and these are basically in response to concerns that we have heard. One is we will complete endangered species assessments for the new herbicide tolerant crop uses that are currently in house. We'll affect determinations as resources allow. It is likely that these registrations will not be nationwide but targeted states, and they'll be focused on situations where EPA can make no effect determination decisions.

The second in the registration world concerns new active ingredients. For these, EPA will provide information in the proposed decision document that goes out for a 30-day comment period that compares potential hazards of the new active to already registered pesticides with similar modes of action and use patterns. This will allow stakeholders, when they have the opportunity to comment, to compare the relative toxicity hazards of the proposed registration to the available alternative.

Again, following up on Don's remarks, we believe the greatest potential threat to species is from

older currently registered chemicals, and that hazard information will illustrate this to stakeholders and allow them to comment. That's it from the registration point of view.

MR. BRADY: Okay, anybody else from -- all right, so I think we've tried to share with you sort of our conceptual model here. There's obviously lots of details that we need to work out and continue to think through. But we are interested in hearing remarks from the committee here today on this approach, or at least the umbrella of this approach.

MR. HOUSENGER: Well, that's good. Everybody agrees with our approach. We'll take the agreement from you. Mark, go ahead.

MARK: Well, as long as I've sat here and listened to endangered species talks, I haven't been as encouraged as I am today about progress. So, love to hear it; want to see it.

UNIDENTIFIED MALE: This may be a question that's a little early, but have you contemplated how 21st century toxicology will be integrating into this new approach?

MR. BRADY: We expect that it will at some point, but we haven't done a lot of thinking, honestly, about sort of where it starts to come into the play. Right now, we're interested in the kinds of things that were more immediate in the NAS report, starting to develop some of the data and processes around the probabilistic modeling approaches, develop or move into developing some population model work that the agencies can share. That will come at some point.

Remember, given the way that we're working and given the bodies available to all the agencies, these NAS measures are going to roll out over time. So, not every immediate action is going to show the impact of every part of the NAS implementation. So, it's a phase-in process, and we hope to keep up with the science as we go.

I think the thing that's really encouraging from my standpoint is that even now, as the interagency science teams who are responsible for producing these initial biological evaluations and consultation packages, they're meeting very frequently. They're talking to each other. A little personal marker that I have in my head,

quite honestly, is when rather than sitting around the table and having agency scientists say, well, Fish and Wildlife does it this way or EPA scientists say, well, EPA does it that way, come at it from the science, regardless of which agency you represent.

So, we're working real hard that way. Eventually it will come, but we haven't had an explicit conversation.

MR. KEIGWIN: When I think about the 21st century toxicology model, that outer ring, in the case of endangered species, is, in fact, populated by individuals who will be counting the impact on endangered species and assessing what did it. Again, you'll be faced with the same question we faced in human issues, which is how do we determine what did it.

UNIDENTIFIED MALE: Fair enough.

MR. HOUSENGER: Ray.

RAY: I want to make sure I understood the details. You would be using the new NAS recommendations for the first time in these assessments or consultations on compounds to come out in 2017-2018?

MR. BRADY: The consultation, the completed

consultation, is scheduled to be completed by NIMS in 2017 and 2018, depending on the compound. But there are interim steps that obviously EPA has to go through to do the work necessary to trigger the consultation.

RAY: Are those NAS recommendations to be used in the assessments for the herbicide (inaudible) uses that Lois mentioned?

MR. KEIGWIN: Probably not initially.

RAY: But you are limiting those ESA assessments -- are you limiting the assessments or are you limiting the registrations to the targeted states where you have a no effect determination?

MS. ROSSI: Both. I mean, the assessments will be for the states, and then that will equate to where the registrations will be.

RAY: How does all of this interact with the reduced risk process for new uses and new active ingredients?

MS. ROSSI: Well, for new active ingredients, obviously, the reduced risk -- the reduced risk process will still go on. In that reduced risk process, as part of the rationale and the document that you do to get the

reduced risk classification, there actually are a lot of comparative data. That would definitely factor into the decision, as I said. These decisions will have a comparison to alternatives. So, it will actually work very well.

MR. HOUSENGER: Gabrielle.

GABRIELLE: I'm just trying to understand, and I realize this (tape malfunction). I'm just trying to figure out how does this work in a couple different scenarios. One is, what happens if -- I couldn't be heard again.

The question I have, for the new AIs, I'm just trying to figure out how this is going to work in the future in terms of relative toxicities, because I can envision a couple of the following scenarios. One is, let's say for fish it's less toxic but for bees it's more toxic. I mean, I'm just making this up.

We definitely have situations now where for humans it's a lot less toxic and for mammals it's a lot less toxic but for aquatic species it's more toxic. How is this supposed to be helpful, because there's always these tradeoffs? So, what does this mean if something is

not necessarily less toxic in all scenarios? I'm just trying to figure out what this is going to mean.

MS. ROSSI: Well, that's exactly what the risk manager has to do. I mean, each case that you do presents a different risk scenario and a different picture. In this case, you're only even looking at hazard. I mean, that's exactly what the risk manager has to do to figure out what the registration is going to be like.

I mean, we have one out there already, a decision that's in the public domain, (inaudible) medicine, which has this comparison and a little bit of the discussion. I think you'll see as we do more, there will be more discussions. But, I mean, that's exactly our job and what we have to do. I mean, we welcome thoughts on that because it isn't easy and it isn't obvious. Some of these, though, it's very obvious that they have a lower hazard profile than their alternative. Some are easy.

MR. HOUSENGER: Andy.

ANDY: I would just like to make a request, that the PPDC consider forming an ESA workgroup. I think

it would be very helpful if that workgroup had representation from Fish and Wildlife Services and USDA at those meetings as well. Thank you.

MR. HOUSENGER: Dave.

MR. TAMAYO: Thank you. Dave Tamayo. Don, I applied what you said about trying to get it so that the Services and EPA really use the same science and it's not a question of, okay, our science is better than yours. What I wanted to say is that in support of that, I'd like to see a little faster progress in working on the common effects methodology so that the Office of Water evaluations for what's a water quality impact and OPP's evaluations are much more compatible. I think that will be part of avoiding conflicts between the service's evaluations and OPP's evaluations. Thank you.

MR. BRADY: Okay, noted.

MR. HOUSENGER: Cheryl.

DR. CLEVELAND: So, I guess I'm responding to, again, the promulgation of hazards, especially in the context of yesterday's conversation where we're really concerned about the EU's approach overall to hazard cutoff. The answer to Gabrielle's question is it's the

risk assessment not the hazard. So, I know you're aware of this and you're trying to do your best to try to put as much information out to move things forward.

But I guess, again, my kind of radar went up when you started talking hazard. I think it's going to have to be communicated very well if you back off and don't do a full risk assessment and only do a hazard communication. I was obligated to say that.

MR. HOUSENGER: Mark.

MARK: So, at the risk of looking ignorant on this, it's because I am, and I need a little bit of education. So, this question goes to Fish and Wildlife Service. With the understanding, or my understanding, that in a registration process, we look at the environmental fate of pesticides and we review environmental fate of pesticides that have been out there. Correct me if I'm wrong, but this has come about because of groups who have brought suit with regard to endangered species and specific chemicals.

Could you tell me what the service is doing or the agency, but I think this is a service question, with regard to once these products hit the field, sometimes

they perform differently. There are unanticipated things that happen. We know that that is the case. So, what is in place to proactively deal with this to where the service can deal with this before it comes to a lawsuit?

MR. KEIGWIN: That's a great question. Let me try to explain a little bit of context about the consultation process. I think that the lawsuits, by and large, have focused on the process required by law more so than the actual after effects of a chemical that's been used on the ground for a long period of time.

For a long time, probably as long as ESA has been around, and FIFRA as well, there's been a real challenge between linking these two statutes. We had, really, different cultures within EPA, the Fish and Wildlife Service, and also the National Marine Fishery Service. We had different needs regarding the scientific assessments that we complete.

By law, if a federal action proposed by EPA, any other federal agency as well, the Corps of Engineers, for example, the Federal Department of Transportation, if they propose an action that may affect a listed species, they have to consult with us.

Truthfully, for many, many years, decades even, we did not have a very effective engagement on these consultations. The kinds of analyses that we do were different than the common risk assessment policies used by EPA. So, because we had not created an effective merger, if you will, of the FIFRA and ESA process, we started to see the lawsuits. The courts, I think, encouraged us to figure it out.

It must be three or four years ago now we recognized that we were still having scientific challenges in terms of the disconnect on the processes that we have to follow separately. So, we commissioned the National Academy of Sciences to look into this issue, unpack all the details, and help us figure out a model for moving forward.

That report was finalized about a year ago. The interim approaches that Don mentioned, represent the agency's best attempt to translate those recommendations into a process that we could use for consultations. So, the way that we avoid lawsuits is by effectively marrying the FIFRA and ESA requirements.

Another point I mentioned that's really

important, the public engagement strategy we finalized, even before the National Academy of Sciences report was issued about a year ago, allows us to try to recast how the consultation occurs so that we've got early engagement with the registrants, this notion of focus meetings where we sit down with the registrants early on.

We bring scientific information about wildlife to those conversations. When appropriate, we discuss whether or not mitigation could be brought to bear in a way that would avoid or eliminate all together effects. So, we don't have what, truthfully, we had for too long. That's a situation where we tried in the 11th hour to complete a consultation on a risk assessment and a registration review process that had been undertaken for a long time. We identified issues of concern, and we had conflict with those 11th hour questions.

So, really, that early engagement plus the shared scientific methodologies is, I think, the path forward for completing consultations that will avoid litigation in the future. In the end, we all want the same three things. We want to have effective registrations. We know EPA has a registration review

process with very specific time lines. We want to have a transparent process. Lots of people raise questions about what was perceived to be the black box of the analyses behind the endangered species consultation process. And, of course we want to have effective conservation from periled species.

So, the implementation and in the path forward that Don described for bringing the agencies together basically from the beginning to the end, working through these issues, I think is the way that we avoid litigation in the future and achieve those three goals.

MR. JORDAN: This is Bill Jordan. I wanted to add a couple of other thoughts prompted in some part by what Cheryl Cleveland said in her comments. We, in EPA, absolutely agree with what Paul has been saying about the importance of getting the science right, of doing it in a transparent process, and moving ahead as efficiently as possible.

We would all love to be able to snap our fingers and make that happen right away and put it in place and do it for all of the many, many decisions that EPA makes both in registration review and on the

registration side. Unfortunately, that's not possible.

We have finite resources at EPA. We have finite resources at the Services and USDA. We can't make all of that take effect right away. So, we have to pick and choose where we're going to put our energies and make sure that we are directionally correct in dealing with what are the most important things first.

The most important thing first is to get science right. The next thing is to apply that science where we think it will do the most good for protecting species. As Lois and Don have said, we think that the chemistries that are being brought to us as part of the application process for registration, new active ingredients, are, as a general matter, safer than the chemistries that are in the marketplace and being used today. That's a good thing, and we are really pleased to encourage that process.

But folks might ask, well, how's that going to be transparent? How are we sure that new active ingredients that EPA approves are indeed better for the environment, better for human health, and not going to do unacceptable things for protected species? That's why

the hazard assessment, the hazard comparison, is going to be part of our path going forward for new active ingredients.

We don't have the resources to do a full ESA analysis for every new active ingredient right now. We don't even actually know the science about how to do that. We're working through that. We're getting our arms around that. But we think that the hazard comparison will give people a basis for understanding that yes, indeed, our assertion, our general proposition that new active ingredients are better is a valid conclusion.

By the same token, we're not going to be able to do everything right away on re-registration, registration review front. We're focusing in on the five active ingredients that are identified in the proposed settlement agreement and stipulated injunction. As those evaluations proceed and as we move closer to biological opinions, the science teams will work out a lot of the details that Paul talked about, and we'll begin applying them. But we don't yet have all those in effect.

So, it means that some of our registration

review decisions will go out with only some elements reflecting the NAS understandings, other registration review decisions will go out with full NAS type compliant analysis, and some won't have all of the NAS.

The last thing to say is that even though we may not have all of the NAS elements implemented in all of our registration review decisions, we are doing, as you will see on some preliminary risk assessments that have come out and proposed decisions, we are applying our standard ecological risk assessment methods to the review of individual active ingredients.

When we make those assessments, sometimes they identify issues/risks that we need to address. We are implementing risk mitigation measures for those chemicals that we think will lessen the ecological risks for all wildlife, not just threatening endangered species.

So, as we move forward on the registration review front, we will be seeing progress that we think will provide protections for species in scientifically defensible ways, even though we may not have done all of the NAS compliant analyses that we hope eventually to make as the standard for our registration review work.

MR. HOUSENGER: Ray.

RAY: Bill, your repetition of hazard assessment or hazard comparison in the context of new product registration raises more alarms. As Cheryl mentioned earlier, we feel it's the obligation of the agency to do a risk assessment and risk comparison. In the context of new product registration, how is all of this going to fit into PRIA obligations and time lines?

MS. ROSSI: Actually, Ray, we've started on the pending. We have about 14, maybe, new active ingredients right now pending. We are starting with our Benefits and Economic Analysis Division to do that work as the other divisions are doing the EFED analysis and the HED. So, it's incorporated. It's not added on to; it's incorporated into the review in the PRIA time line.

MR. KEIGWIN: So, just one thought. I know the hazard raises an issue, but that's kind of a 50,000 foot look at it. If we were to do more than that, I think then we're talking about a lot more resources. Obviously, if we see something with the initial screen, we'd have to do more work. But we think that we can get away with doing this and showing that the new AIs are

better for the environment.

MR. BRADY: Okay. It looks like we've had the questions here, so we'll take back what we heard. We'll think about our model a little more.

Having said that, there's sort of two topics that we'd like to share with you, the progress that we've made on the interagency level on two key questions that relate to the completion of the biological effects documents and the, ultimately, biological opinions by the Services.

So, the first topic we'd like to talk about is to have Paul share with the group the approach that the interagency team has adopting or is adopting in working through for developing endangered species range maps.

PAUL: First, let me characterize the problem here for those folks that might not be intimately aware of it. We've got about 1,500 federally threatened and endangered species across the country. The way that our organization is set up, we have 80-plus field offices that work very closely with private land owners, with federal agencies, to evaluate the effects of proposed actions at the local level.

As we talk about national consultations of pesticide registrations, that model that we have as an agency has posed a challenge. We really rely on our field offices to be the holders of the best available science to be able to analyze in specific details what the effects of a proposed action would be on the ground. With a pesticide registration, we need to be able to work at a much broader scale.

One of the things that's become very clear to us as we have tried to figure out how to most effectively complete these consultations is we need the most refined species range maps that we can get. Right now, sort of our default model, we have species maps at the county level. So, we can tell you if a species is found within a specific county.

When it comes, however, to being able to provide meaningful information to EPA and to a registrant, to environmental organizations and other interest groups that are interested in really understanding the details, we need more refinement so that we can have a conversation that would allow us to have an early dialogue with registrants about the degree

to which --

In this specific sensitive area for threatened and endangered species, could the application of the pesticide be modified in some way to avoid impacts all together, in which case, ESA obligations would be met in full or, if not to avoid them, to minimize them in a way that's consistent with their business model and also protective of the species?

So, we're in the process now of trying to figure out a method for how we drill down to those county level maps, to that level of specificity. Where is the species found? What's the occupied range? We've had, I think, really fruitful discussions since the Academy of Sciences reported a year ago to think about how we complete this effort.

Some of you might be aware of the group FESTF, the Federal Endangered Species Task Force, that is a composite of a number of the registrants. They have already created a data base that includes the county level maps that we have. It also reached out to many of our field offices across the country and attempted to get more refined maps when they're available.

It also has a contract with an organization called Nature Serve that has element occurrences, essentially data from states that show where endangered species have been identified in the past. Working with them, they are looking into a way through which we can organize this information that would be useful for our field structure.

We have a plan in place now that essentially will use this information coupled with what I'm hopeful we'll get to if we have time today for the first time providing our field offices with a very clear footprint of the application areas for these chemicals, including the off site transport from wind and water flow.

So, for the first time, our field offices are going to have those two important pieces of information. We're going to request our field offices to provide a more refined species range map, when possible, that will be, essentially with that application use footprint, the action area for the analysis of these consultations.

I want to make it clear it's not as easy as it sounds to put together a species range map. We have, in many cases, just holes in the data. We don't know what

the full occupied range is. We have to make assumptions based upon habitat where we think they might be. There hasn't been, in many cases, comprehensive surveys for species. So, we've got to use our best professional judgement. That is our job as the Fish and Wildlife Service and the National Marine Fishery Service to use the best available science to come up with the range that makes most sense.

I don't expect, and I don't want to set an expectation that through this process, which will unfold over the next three months, we're going to have a refined species range map for 1,500 species. But I think we're going to be able to move the ball down the field. It's very clear to us that in the mid to longer term, this is a real need that will make national consultations more effective.

We need to find a way where we've got a data base that is available to people, including the EPA, and registrants, and environmental organizations, the public more broadly, that helps them understand where the species are found. That will go a long way to speeding up the process for consultations. We won't have to reach

out to 80-plus field offices to get that data. It will also make it more transparent, again one of the major goals that we have.

I think from a conservation perspective, what's most exciting about it is we will have in our hands information that will allow us to implement conservation measures through conversations early in the registration review process.

MR. BRADY: Thanks, Paul.

Steve Leonard will provide the other half of the picture here, and then we can take additional questions.

MR. LEONARD: Thanks. I'm Steve Leonard. I'm a GIS analyst here at EPA. Paul sort of set up the first half of the equation, which is to say, okay, where are the species in question and where do they co-occur with where pesticides are being applied. So, that's the half that I'm looking at.

What we're trying to do is find the best available data that shows where different agricultural crops are grown on a nationwide level. What we've come up with is using the USDA's crop land data lair, or CDL,

land cover data that they produce annually, the remote sensing techniques for over 100 crops. Every year, they show where on the landscape these crops are grown.

What we can do with that is instead of looking at all 100-plus crops, we can aggregate those different classes into 11 very general crop groups. What that does is it helps improve the accuracy in which the different crops are mapped, and it helps us account year after year where the crops are rotated and where they could be in the landscape at any given time.

So, another thing we look at for best available data is we combine the crop land data lair with the national agricultural statistics services census of agriculture county-based statistics for acreage for any given crop, and we compare the crop land data lair to that on a county by county basis. We're able to improve the land cover data using those statistics.

Once that's in place, we can then take the registered label uses for each one of these pesticides and cross walk that into our categories, our crop categories, to say if a registered use is for corn, we can say where is corn grown in the United States and add

that to a potential application footprint for that given species. So, we do that for all the different agricultural registered label uses.

We also do it for the non-agricultural registered label uses. So, through conversations with the Services, we've come to agreement on the method that we would use for the agricultural crop types and the way we would leverage the crop land data lair from the USDA to establish that footprint.

What's ongoing right now and that we're still in discussions with is what is the best available data for the nonagricultural registered uses. There are a couple different options for that that we're working through the national (inaudible) dataset. It's a great resource that we plan on leveraging, but there are several other details that we're working through, as far as different registered label uses.

Once we establish a footprint of where all the different label uses are in the landscape, where a pesticide could be applied, then we can say depending on the application method, whether it's crop dusting or on the ground, how will that application be carried off

site, whether it be through spray drift or from water. We have models to take those scenarios and expand the footprint out to account for those types of off site transfers.

That's essentially how we're leveraging the CDL and establishing a footprint.

MR. BRADY: Okay. Does anybody have questions for Paul or Steve? Matt.

MATT: In light of changing weather patterns, both with an increase in -- a change in water distribution across the country, as we saw in Wisconsin with the huge rains. Runoff was much greater than it has been in the past -- and the changes in temperature/weather.

How accurate are those two sources in terms of what might come? How often is NAS updating that crop information and keeping it current? How are you accounting for changes in, say, water distribution throughout the country?

MR. LEONARD: Well, the USDA updates the crop land data lair every year. What we do is we take each vintage that comes out and aggregate it to the current

model. So, if corn was grown in a field last year, now it's soybeans, that field could either be a potential application site for any registered use for corn or soybeans.

So, over time, we can see in the landscape any given spot in the landscape isn't just one crop or another; it's any crop that's been grown there for as long as the crop land data lair has been produced. So, since we aggregate over time, we're accounting for these different scenarios for a given crop.

As far as water is concerned, we use a downstream pollution model that leverages the national hydrography dataset -- the NHD Plus is what we're using -- and that's the best available data for the different streams.

MR. BRADY: I would also add that generally in EFED, we update the MET files, the weather files that we use to feed our models. Most of our models will work within certain parameters of variations in climate and water flow.

Gabrielle.

GABRIELLE: I've got a couple questions and a

comment. So, similar to what Matt was just asking, how does seasonality of pesticide applications tie into this database? I mean, are you accounting for either what the label says or based on actual data when these compounds are really being used? Is that being accounted for in the GIS system?

MR. LEONARD: In the first phase, we're just looking at proximity, step one. But then, as we move into the more detailed analysis in step two, we start to look at actual application. The trick here is to balance the label use with the typical use. That's a conversation that is going on amongst the agencies right now.

Just to re-emphasize, this is why it's important to us to have the focus meetings and get as much information up front about what the actual use of the pesticide will be.

UNIDENTIFIED MALE: If I could just add one thought on that, I think your point is extremely important because the original footprint is just the first question. It could very well be that because of the seasonality of the application, there are no issues,

even if that first step showed an overlap.

GABRIELLE: So, my other comment/question is, nowhere was it mentioned that California, the other country of California, does things differently. We have pesticide use reporting, at least from the ag sector. There's a lot of detail there as to where and so forth that is. Where is that information going into this whole system?

UNIDENTIFIED MALE: So, we're aware of that information. We've been in the interagency sort of discussion. We've been through a series of workshops on that use reporting data. I think the challenge for the agencies is that that is specific to California. You have to think about whether it can be used in other parts of the country.

So, I think you might have different scales of analysis at some point based on the data that's available. But that is honestly something that we're still trying to work through.

GABRIELLE: So, I would like to have credit for it.

The other thing I wanted to mention, and this

is just an FYI. I'm trying to figure out how it fits into it. But the almond board funds research. Over the years, we've been approached at different times by companies who said, oh, we can remote sensing, we can tell you where the almonds are, blah, blah, blah. Most of the time we looked at it and we said, not really very good. You've got five or six different pruna (phonetic) species going on in California. How do you differentiate them, plus all the other trees.

In a project that we funded that actually was about greenhouse gas and sequestration, we realized that we needed better mapping. We're actually working with a private company on this. They developed a remote sensing combined with pattern recognition software. So, really looking at it with ground (inaudible). So, we now have a system where they can differentiate between almonds, pistachios and walnuts in the 95 to 98 percent range.

We are hopeful to actually get a grant to get that totally mapped for the central valley in the next year or two. We're co-funding it. It's going to be moving forward. It's a question of whether it goes forward more slowly if it's just us funding it versus

getting some grant funding.

The reason I asked that is, our experience with a lot of the NAS data, the almonds are getting big enough that we're on the map. But for specialty crops, especially the short term specialty crops that you have a lot, how well does currently the NAS data even capture those crops and map them?

So, if it's not that good, then I really suggest you sit down with this company and explore what they're doing, because what we have seen -- I have a committee chair who is, like, we're going to spend the money even though we have drought and we're going to be getting less money this year. We're going to spend the money on this, which is pretty rare for them to jump on new technology that adamantly.

MR. LEONARD: That's a good question as far as the accuracy is concerned with any given crop. As I mentioned with the crop land data lair, there's over 100 categories, including various orchard species, whether it be almonds or peaches, you name it, apples.

So, in an effort to look at the different accuracy levels, major commodity crops have very high

accuracy, whereas some of these specialty crops that you mentioned have lower accuracy. So, in order to improve the accuracy overall, we have grouped the different classes into both phrenological and, what makes sense in accuracy terms, aggregated these into broader groups. We went from 111 categories of crops down to 11 categories of crops.

So, in your example, almonds would be lumped into a category we called orchards and vineyards. So, from a remote sensing perspective, the way that's handled from a physionomic perspective would be trees, right, the architecture of these agricultural trees in rows, and vineyards, which would generally be these rows of trellises as well. So, it fit nicely and it also worked out in terms of the way that the original CDL produced errors of commission and omission between the multiple categories. It just lumped them into the one orchards and vineyards class.

So, for example, if there is a registered use for almonds for a specific chemical, the footprint of almonds would be lumped into the greater footprint of orchards and vineyards.

UNIDENTIFIED FEMALE: I could see from a planting perspective or potential planting, there is overlap there. I think what I'm also worried about is just you take Philaenus Valley and all these different crops and some of them are there only for eight weeks. I mean, the multiple plantings and so forth, you have a temporal spacial variability. Tree crops, (inaudible), they stay put for a while.

MR. LEONARD: Right. And I think a lot of those minor specialty crops that are only there for a few weeks are generally lumped into another one of those 11 categories. We look at the National Agricultural Statistic Services Census of Agriculture, which gives us county level acreage statistics, which are considered the gold standard of on-the-ground numbers. We compare those numbers with the CDL, and we're able to refine the CDL based on those values.

You had mentioned some of the pattern recognition work that the consulting firm is doing. My experience with that is it's great for the smaller projects, but we haven't really seen the national level effort that's produced annually to really get that into

production level work yet. I hope to see that in the future. But right now, it's not part of the best available data conversation.

MR. BRADY: I mean, I think it's important if that information is out there that we -- going back to sort of the focus on early awareness on the agency's part of any information that's out there that may influence our work. I think we all realize that there may be certain industries or certain parts of the landscape where there may be information we're not aware of which may be relevant to our analysis. But it's much better to have it come in early in the process than later on in the process.

MR. HOUSENGER: Was Ray next? Ray.

RAY: Well, in addition to the seasonality question that Gabrielle raised, there are multiple other factors ultimately affecting whether a pesticide is even used on those acres where the crop is planted. How and in what state do you take into account those factors, for example, the pest profile that that pest treats, when that pest occurs in the crop, what other competing products might be used? There's lots of layers here.

How do you take them into account and at what stage?

MR. BRADY: I think that some of those questions will come to bear initially in the step two analysis where we actually start to try to move beyond simple proximity of the pesticide application and the use and start to get a better picture of what the use profile really looks like. So, I would assume that some of the information about pest pressure and when it occurs would be related to application. That would be something that we'd be wanting to look at.

But I caution you that the answers today -- we're giving hypothetical answers to your first set of questions. Again, the teams are working through this on these first five as we go. We fully expect that we'll learn as we go and refine our approach.

MR. KEIGWIN: If I could add a thought as well, we've been living and breathing the National Academy of Sciences report for the last year and the process that led up to it for about three. So, the NAS came up with this three-step process in an effort to try to marry the ESA and the FIFRA approaches.

From the Endangered Species Act review, step

one, as Don said, is just a simple first cut might there be an effect. It's that's simple. So, the easy screen for that is overlay the sort of maximum footprint of the application use with its off-site transport with the species. If there's no overlap, you're done. You don't go any further.

Step two, if there is an overlap, you sit down with smart, informed people that actually are registering the pesticide, that know about the potential seasonality and the impacts to species potentially, and you determine whether or not there may be an adverse effect. If the answer is no, then you're done. ESA consultation is complete.

If we think there may be an adverse effect, then we go to step three, and we determine how big that effect is. In most cases, even if there is an adverse effect, you measure it, you quantify it, you exempt it. Endangered species consultation is done. If there is a really significant population level effect that could jeopardize the very existence of the species, then you have more conversations about how you avoid that level of impact.

MR. HOUSENGER: I think Dawn, you were next.

DAWN: Just really a comment. When it comes to the tier where you are actually looking at actual use data, Arizona, along with California, we have at least 10 years of historical data in a use database that we gather in collaboration with Arizona Department of Ag. I'm sure there are other states as well, but certainly not only what's going on now, but the historical data might be of great value.

MR. HOUSENGER: Thank you.

Patricia.

PATRICIA: Hi. I was just curious to know if you're using any of the water quality monitoring data either from the GS, the states, or the feds on more or less pinpointing maybe where pesticides are showing up in the aquatic environment.

MR. BRADY: We do have approaches. We've described how we're going to use monitoring data in the analysis. The challenge here is to distinguish what the appropriate use of general water quality monitoring data is in the assessment from targeted monitoring data that's designed to specifically tie a use to a condition in the

water or a concentration in the water. So, we're aware of it. We're considering it.

The pesticide program in other ways -- I think we talked about this yesterday a little bit -- is making a concerted effort to ask all stakeholders if they have water quality data that may be relevant to our analyses.

Jerry.

JERRY: Just a suggestion that when you're bringing these crop groups down, that you use the existing crop groups. There are 20 and you're targeting 11. A lot of those crop groups are redundant. (Inaudible). It's redundant, so you're not going to be much more. but probably the benefit would be that then you could back it into where the labels are. If you go different crop groups and make your own, you're going to have a hard time backing into the labels.

MR. BRADY: Okay, thank you. That's a good suggestion. We'll look at it.

Mark, I think you were next.

MARK: My question or thought or comment kind of follows through on what the folks are talking about in terms of how you actually implement something (tape

malfunction) process. So, I was thinking that if you establish thresholds much like any IPM kind of approach, as you've suggested, and you begin to arrive at decisions based on the three-step process that Paul was talking about, and you begin to move into a regulatory mode or action mode, then the kind of thresholds that you'd need would, in some instances, be very crude and in other instances where you've got good overlap data and good precision. You've got to (inaudible) or better process.

So, understanding that, the question I had was, how is the agency and the Services going to arrive at those threshold processes?

MR. BRADY: Are you talking about when we determine that there's an effect? We actually have set out that in these interim approaches for each step one/step two part of the process, we've described exactly how we're going to determine when there is an effect that we need to be concerned about.

So, I think we've got a good outline there and some very clear points of where we think we have a problem that we need to be concerned about and when we don't have a problem. To be honest, I can't pull one out

of my head.

MARK: It's very hard to define now because it's so nebulous. But I guess the thing I think that many, particularly from the grower perspective, would want to know, what kind of probability. Are you going to take a 96 or a 99 or are you going to take .9999 probability.

MR. BRADY: Anita is much more adept at the memory on these things. Let her give you an example. She may kill me later.

ANITA: So, if you look at the agreements, we are trying to move towards more of a probabilistic approach. So, one of our thresholds is based on species (tape malfunction). In the past, what we would do is we would take the most sensitive value from a particular (inaudible) group.

But now what we're doing is we're looking at all of the available data and developing a distribution and then taking the fifth percentile of that distribution for acute mortality. That would be one of the thresholds that we would use as we move through the process for chemicals that have robust data sets, which the chemicals

in these pilots do. That's just one example.

UNIDENTIFIED MALE: (Inaudible)?

ANITA: That would be something we would look at in step two as part of the species biology. Right now we have an ES knowledge base. We're gathering information on enlisted species, including not only where they are in the landscape but where they are temporally in the landscape. So, migration patterns would be considered as part of that step two analysis.

UNIDENTIFIED MALE: (Inaudible) around water potentially?

ANITA: That could be part of the mitigation, yes.

MR. BRADY: Jack, are we about out of time? Before we close, I want to acknowledge one thing. Folks who have heard various reports over at these meetings in the past years know that Rick and Kathy Eiden (phonetic) from PRD and Anita Peas (phonetic) from EFED in our organization have done a lot of work on this.

But in addition to that, I want to publicly acknowledge the work of the scientists on the interagency teams. We come to these meetings and we're the sort of

talking heads, but they're the folks who have actually worked through the Academy recommendations and are working collaboratively now to get us to a successful process.

So, let the record show that we understand the stress we're putting them under, and we appreciate their work.

MR. HOUSENGER: Okay. I guess like ESA, EDSP is one of those activities within our program that requires a lot of our resources to do. So, we have today David Dix who is the director of the Office of Science Coordination Policy here to talk about our efforts and kind of again some of the early thinking about how we're approaching EDSP screening programs, as you've heard with the ESA approach. These are our initial thoughts. We're still kind of tweaking it as we go along, but we thought it was useful for everybody to hear what we're doing.

MR. DIX: Thanks, Jack, and good morning. I'm getting set up here with the clicker and with the slides. I think we all have paper copies, if we want it, of the slides. I don't have a lot of slides to go through.

As Jack mentioned, we're at a very pivotal

point in the program. There's a lot of plasticity and a lot of change going on within the program. I wanted to leave plenty of time for discussion with this FACA on some of the new science that we're bringing to bear.

For those of you who don't know me, I've been with the agency for about 20 years. Up until last year, it was all with the Office of Research and Development. When I left there, I was the acting director of the National Center for Computational Toxicology.

As you know, the agency has invested deeply in computational toxicology over the past 10 years with an eye towards bringing it to bear on just this topic, the topic of potential endocrine disruption and the program that addresses that, the endocrine disruptor screening program.

So, I guess in some ways, it's not a surprise that I've ended up in this position. But some days, it's a little bit more of a surprise than others. It's been a good year. I've worked with Jack at OPP, with Wendy Clalin-Hammett (phonetic) in OPPT (tape malfunction) in the Office of Water, and with Tina Bahadori (phonetic) in the Office of Research and Development. I think we have

matured the science and prepared it for translation and putting it into practice first in the endocrine disruptor screening program and then, as it applies, across our other chemical programs.

So, I'll start with the legislative mandate that established the program in 1996. I'm sure many of you are quite familiar with the FFDCA and Safe Drinking Water Act amendments that basically charged the agency with establishing a program on endocrine disruption and led to the establishment of the endocrine disruptor screening program under these two separate authorities, one relevant to pesticidal chemicals, actives and inerts, and the other relevant to drinking water contaminants, pesticidal or otherwise.

In response to that legislative mandate, the agency established a FACA, the EDSTAC, the Endocrine Disruptor Screening and Testing Advisory Committee. The produced a report in 1998 that (inaudible) legislative mandate to include both human health and (inaudible) to include the estrogen and androgen and thyroid pathways, again a bit of an expansion because the legislative mandate only mentioned the estrogen pathway. And as far

as implementation, a plan to develop a two-tiered screening and testing program.

So, since that conceptual framework has been put into practice with the tier-one screening for potential for chemicals to interact with the biology to demonstrate activity and then a second tier of testing, it determined the dose response of that interaction with the endocrine system and to link it to adversity.

So, since that time, since the late 1990s, EDSP has implemented that two-tiered screening and testing approach. At this point in time, we've had the first list of chemicals, list one, which started at 67 chemicals (inaudible) out and have test orders issued for tier one screening.

Fifty-two of those chemicals were supported for moving forward, and test orders were responded to either with other scientifically relevant information, which was accepted by the agency as a satisfaction of the test order requirement for some of the assays in the tier one, or, in other cases, the testing of the compounds in those tier one assays following established guidelines and the submission of those data to EPA. So, we now have a

complete data set, or close to complete data set, for screening for these first 52 list one chemicals of about 500 different studies.

The agency is in, I would say, the outer stage of the process of reviewing these data and making a weight of evidence determination for these 52 chemicals of whether we see estrogen, androgen, or thyroid activity, evidence of estrogen, androgen, or thyroid related activity.

I apologize in a sense. I may have lost a few of you (inaudible) one screening assay slide next. This is slide 5, by the way, for those on the telephone, if you're not tapped into -- I don't know if we're doing a webinar.

So, this lays out the 11 tier one screening assays in the current battery. But you need to be open to the concept as we apply it that the screening and testing assays and tests are open to change over time as the science develops. We're open to other scientifically relevant information as we apply it to the list one chemicals.

They are a series of in vitro and in vivo

assays ranging from low throughput cell, or cell free based assays, to in tact animal assays, such as the pubertal male and female and rat, that address the three pathways that are relevant to the program, the estrogen pathway, the androgen pathway, and the thyroid pathway, EA and T in this diagram. This is a diagram that lays out the 11 different assays in the first round of tier one testing and how they address either the estrogen minus estrogen antagonists. So, you can think of estrogen agonists as the first column, estrogen antagonists as the second, androgen activity, androgen antagonist activity, A minus, thyroid activity or estrogen activity, again --

On the far right -- and this is a table that's been presented many, many times and used in a variety of different scientific advisory panels, et cetera. On the far right, HPG and HPT refer to hypothalamic pituitary (inaudible) and hypothalamic pituitary thyroid networks or pathways, systems that are interrogated by these more in tact in vivo systems. So, that's the assays for which test orders went out on tier one, and those are the 500 studies that are referred to in the previous slide.

The next slide, slide 6, is labeled EDSP implementation. Here I've added in EDSP list two, which was published last year. In fact, I had the pleasure of being able to sign off on the revised list two being published my first week in the role of office director.

This 109 chemical list, in combination with list one, represents these two small spots you see on this universe of chemicals. In 2012, the program published the universe of 10,000 chemicals that are relevant to the EDSP. It's a very large universe of chemicals and compounds that are relevant, pesticidal actives and inerts, as well as many different drinking water contaminants.

So, we have the 52 chemicals in this figure at the bottom here for EDSP list one, and the 109 chemicals for EDSP list two. The EDSP list two is comprised of 41 pesticidal chemicals and 68 drinking water contaminants. So, unlike list one, which was predominantly pesticidal actives and inerts, list two is, at least in the majority, drinking water contaminants. So, it's a diverse list.

But the point that I want you to take away from

this slide is that list one and list two are a very small fraction of the EDSP universe. So, our screening program is challenged at this point in the approaches that we've taken to date to properly screen and address this large universe of chemicals.

For that reason, we've been evolving the endocrine disruptor screening program. We realized at some point over the past several years that based on the current pace, it would take literally decades, many, many decades, many millions of dollars, many thousands of animals, to screen all 10,000 chemicals using the current tier one/tier two approach in assays.

At the same time, concurrently with that realization, the computational toxicology research program had made progress and matured to the point where they could provide solutions to that throughput issue to address the thousands of chemicals in that universe, that 10,000 chemical universe that's relevant to the EDSP.

On slide 8, just to emphasize those points, the computational toxicology approach, combinations of encylico (phonetic), so computational and in vitro, non-animal screening approaches offer the ability to rapidly

screen chemicals and to take those data together to -- to rapidly screen these thousands of chemicals and use predictive models to evaluate them for potential risk to human health and the environment in terms of these three relevant endocrine pathways.

I used the term risk specifically here. Computational toxicology is not only biological assays, not only in vitro assays for biological targets, computational toxicology also includes assessment of potential exposure.

We are very motivated to take a risk-based approach throughout the endocrine disruptor screening program from prioritization to screening to testing. As you know from the pesticidal program, the agency has a commitment to identifying real world risks, quantifying those risks, and managing them appropriately in all of our chemical programs.

So, the computational toxicology research, as we translate it into practice in the EDSP, will increase our capacity to prioritize, screen, and predict chemical toxicity and exposure and to overcome through throughput limitations that I pointed out in the preceding slide

with the current tier one/tier two set of assays and tests.

Moving on to slide 9, this will eventually lead to potential replacement of some of the existing assays and tests in tier one. Tier two continues to evolve as well, especially with a focus on providing non-animal alternatives and reducing the burden of animal use in the program.

We've been partnering not only across EPA in the program, but with other federal agencies, states, industry and non-governmental organizations to continue to evolve these tools and validate them for appropriate use.

We continue across the agency and across the program, and particularly across OSCPP, continue to make our data, underlying data, and scientific decisions more open and transparent to others. So, a good example of that is the can view portal that our sister office of OPPT, the toxic's office, has recently put on line.

All or much of the computational toxicology data that we'll be incorporating in the EDSP is online through Office of Research and Development websites and

portals, particularly the ICSS dashboard. That's the Chemical Safety for Sustainability dashboard that has gone online in the past year.

Within the EDSP, we will continue to make the data available publicly through a series of mechanisms, including what we bring to the scientific advisory panel, which the next one is scheduled for late July, if you haven't heard. We'll be bringing the high throughput exposure prediction models to the SAP for peer review, s well as additional OCSPP web portals and dashboards specifically for the EDSP.

Moving on to slide 10 and the next series of slides, I'll show you some of the new information that we're bringing to bear to the program to help us with this evolution. There's a big emphasis right now on translating data from two research projects from Office of Research and Development, the ToxCast project, which is a high throughput screening project, and the ExpoCast project, which is a high throughput exposure assessment or determination and prediction project, bringing that activity data and that exposure data together to support a high throughput prioritization that approximates or is

associated with potential risks for endocrine disruption in the case of this program.

The next slide, slide 11, shows us, in a broad view, our goals in this prioritization effort, first, to prioritize and target the screening of the list two chemicals, the 109 chemicals of list two that I mentioned before, the 52 list one chemicals, as I said, have complete screening data sets and are going through weight of evidence determinations for activity (inaudible) pathways.

For list two, we have yet to issue any test orders for these compounds. We are actually awaiting Office of Management and Budget approval for those test orders on list two. But, in the meantime, we are translating the science to prioritize and target the screening for the list two chemicals.

Many of the list two chemicals, we have data from computational toxicology that already gives us strong indications of whether we can expect activity in the estrogen or androgen pathways and some indications, though not as much information and data, on the thyroid pathway.

Beyond the current list two, we are also able to address thousands of the universe chemicals, those 10,000 chemicals in the EDSP universe, and to look to that universe of chemicals beyond list one and list two for those compounds that actually do show estrogen activity, androgen activity, or thyroid activity.

One of the lessons we are seeing from our list one experience, whether we're talking about the weight of evidence determinations based on the tier one screening or the ToxCast data, is that certainly for list one chemicals, which I think many people might have predicted, we did not and do not see a lot of estrogen activity. Yet, we've spent quite a few years and quite a few dollars and quite a few animals confirming that negative.

So, we're looking to prioritize and target our screening for list two to be more efficient and to apply the resources where there is actual potential for activity and, ultimately, risk, and also to turn our attention to compounds in the universe where there is actual potential for activity, exposure, and risk.

Slide 12, which is the blank slide on the

screen, and I apologize for that, but it did come out in your printout. What it shows is a ToxCast estrogen activity score. I won't go into any more details on that. That will be presented in a series of scientific publications over the next several months, but a compilation of results for 16 different high throughput screening assays relevant to determining estrogen agonist activity.

For the list one and list two chemicals in the slide that you hopefully have on paper in front of you, you can see that for the majority of compounds that we have these results for, and that's 49 of the 51 list one chemicals and, I believe, 56 of the 109 list two chemicals, the majority of those compounds have a negative result, a zero. They show no evidence of activity.

For those who show a low evidence of activity, they're all below 0.1 on a scale of 0 to 1. To give you some sense of scale, a compound like ethonyl estrodial (phonetic), a very potent, synthetic estrogen agonist, has a score of 1 on this scale. Disphenol A (phonetic), a moderately potent estrogen has a score of 0.8.

Fornonephenol, the branched form, the more active estrogenic form, has a score of 0.4, I believe. And relative to things like ethonyl estrodial or estrodial, I would consider a moderate to weak estrogen.

So, all of the list one/list two chemicals that we have ToxCast estrogen activity scores for don't even approach 0.1. If you look at comparable reference chemicals, those are the types of scores you see for compounds that are commonly referred to as negative for estrogen activity.

This is the driver for us to refocus some of the efforts in EDSP away from confirming negative results for estrogen, androgen, or thyroid activity in some of these compounds, and to focus on other chemicals in the universe -- this is in the third piece of this plot -- that do show appreciable activity.

So, for those of you who have the piece of paper, you can see there is a series of I think it's 78 chemicals from about 1495 chemicals that we have ToxCast data for that are in the EDSP universe. Approximately, 78 of these chemicals have ToxCast estrogen activity scores of 0.1 or above. In fact, those include a variety

of different phenols and parabins (phonetic) and a number of other pharmaceutical and agroceutical agents that are all in the EDSP universe.

So, there are chemicals in the universe that show estrogen activity through not only the ToxCast assays, the 16 assays here and additional ToxCasts in tox 21 assays, but also uniformly across the literature. So, there is evidence of activity. As the program continues to evolve, we want to marry that evidence of activity with strong predictions of exposure from the ExpoCast project and to prioritize these compounds moving forward in a risk-based context.

Moving on to slide 13, this is a figure that was published in our EDSP 21 work plan. It was published in 2011. It shows the staging of the evolution of the EDSP in the near term supplementing data from tier one, the current EDSP tier -- this is the top row of this figure -- supplementing the current EDSP tier one battery with additional data from basically the ToxCast project, the high throughput screening assays.

In the intermediate phase, which is where we are now, we're starting to compare the results from those

ToxCast assays and other sources to the tier one results that we have from the list one chemicals that are already available to us in the literature, to target the screening for list two chemicals, and then also consider additional chemicals for the program.

And then, you see in the bottom row of this diagram the longer term goal of eventually replacing some or much of the tier one battery, which is low throughput and animal intensive, with higher throughput, more quantitative and less animal intensive types of assays, similar to what the ToxCast project brings to us.

Moving on to slide 14, just a quick recap. The 52 list one chemicals with complete tier one data sets are going through their weight of evidence determinations. The 109 list two chemicals are going through OMB review for tier one screening.

The EDSP universe, including list two, is being prioritized for screening using computational toxicology and other tools. And, as I mentioned, we have a series of scientific advisory panels being cued up for the exposure prediction models in late July followed by risk-based prioritization SAP in the coming months.

Now, finally to the 15th and final slide, a topic that I'm happy to discuss if it's relevant; I'm happy not to if it's not. But there is an activity that's been going on over the past several years within the agency. Last year, we published a white paper, a scientific paper on the state of the science around non-monotonic dose response relationships. We charged an NRC panel to provide us comment on that white paper.

In May of this year, we received those comments from the NRC. We are currently looking at those carefully internally and considering next steps from these recommendations to develop a plan of how we might select chemical case studies, the pathways discussed in the EPA and MDR state of the science paper, and how this might be relevant to assessing potential impact to these key findings to regulatory programs such as the EDSP and our other chemical programs.

So, with that, I'll stop. I actually went a little long and didn't leave a lot of time, but, Jack, perhaps we have time for some questions.

MR. HOUSENGER: Yes, thanks, David. Hopefully, that gives you an idea of what we're doing in EDSP.

David could talk all day, believe me. I've heard him on this subject. But we can take questions now.

Fawn, you want to go first?

FAWN: Thanks so much for your presentation. You mentioned in a couple of points OMB approval needing to be obtained for steps moving forward. I apologize if this is in the statute and I should already know it. But I'm curious about OMB's involvement, how many points in your flow chart of your process, do you need to go to OMB for approval, and also, how long does that take? How long have you been waiting, for example, for the example that you gave?

MR. DIX: The example I gave, the reference I was making to was to the list two tier one testing information collection request or ITR approval. I think in that case it's somewhat on the order of about a 12-month process. But I think it's been with OMB for about a total of 12 months, somewhere on that order. Bill might be able to help me out with this one because some of this precedes my tenure.

That will be necessary. That approval will be necessary before we can issue test orders for tier one on

list two chemicals. So, we're in the process of, as I said, continuing to refine the science and refine the plan for list two testing while we await that OMB approval.

MR. JORDAN: This is Bill Jordan. The Paperwork Reduction Act requires an agency any time it tells a member of the public that they have to submit data to the government, information to the government to go through a clearance process, the information collect request and clearance.

David is right that we've been working on this one with OMB for a little over a year. I'm thinking that this one, they want to understand what happened with the list one chemicals and, as David has mentioned, the sciences evolving. So, that's, I think, why it's taking a little longer.

Once we get an information collection request in place, then the process moves ahead without any further OMB engagement. And I expect for future lists, for future test orders, having ironed out the science and established a track record, we'll be in a position to move them more quickly.

MR. DIX: For those that don't know, I'll just mention that the OMB process involves a series of public comment periods. So, it's a very robust process and, I think, a very useful process because, in part, those series of public comments and our responses to those that are built into it. We found that very helpful, I think, in the past and continue to find that helpful with the list two tier one ICR to have those public comments coming in.

MR. HOUSENGER: Patricia.

PATRICIA: Hi, Dave. Thank you so much for the update. It's really exciting to see the progress that's being made with the computational toxicology work. I am just wondering, on list two, do you foresee actually being able to exclude some of the chemicals now based on the results of the high throughput or the comp tox methods for some of the pathways for testing? Do you foresee it being able to actually say we don't need to test for estrogen with this compound or this compound or so forth?

MR. DIX: So, we have to be careful with the words, or I have to be careful with the words we use. I

wouldn't call it exclusion. We are taking a couple of steps, and one of them is relating to exclusion. But that's based on physical chemical properties.

In January 2013 SAP, we took a series of physchem filters -- and I think this was the second go at this -- and asked for feedback from the SAP, who was very encouraging, to use certain physical chemical filters to exclude compounds that were not able to be bioavailable or not stable in the environment and, therefore, had no potential for activity, and then also had a real challenge in terms of any kind of testing.

So, those are being applied, and that's part of the science that's being applied to list two and will impact and potentially could lead to exclusion of some chemicals on list two from testing. But you don't want to call it exclusion; you might want to just think of the competition on toxicology data as similar to any other scientifically relevant information.

If we already know that a compound is or is not estrogen active, we will use that if it's reliable, reputable, repeatable, reproducible type of science. In the case of some of the ToxCast data for some of the list

two chemicals, yes, we feel strongly that that is the case, that we already have an answer and we're moving towards making use of that.

That also played out in the list one chemicals. I think somewhere on the order of about 25 percent -- it might be a little off, but some significant percentage of the test order requirements were met by other scientifically relevant information.

Now, in some cases, and I think maybe many cases, it was other scientifically relevant information coming from results from assays that were either guideline assays or very much like the guideline assays. So, taking other scientifically relevant information that may be high throughput may be a little bit different. But the data and the answers are oftentimes proving themselves to be just as reliable and oftentimes more quantitative as well, which has great value.

For those of you familiar with the current tier one screening assays, they are not going to give us dose responsive information. They don't have enough dose groups, they don't have enough information for us to understand the full dose response.

But for some of the high throughout screening types of assays, many of these are run in 8 point, or 14, or 15 point concentration response formats that allow us to understand the dose response of the activity, which is very useful as we continue to move and put this into a risk based context.

MR. HOUSENGER: Given the time, I'm going to take the remaining cards that are up and then call it a day.

Liz, go ahead.

LIZ: Yes, thank you. It's my understanding that OMB attached some conditions to the first list, one ICR. It sounds like EPA has done a lot of work towards completing or meeting those conditions. But can you maybe comment on where you are on meeting all of the conditions of the first ICR, which will then let us know when to expect the next list to be issued?

MR. DIX: Yes. There were a number of conditions. I'm going to struggle a little bit to remember them all or get this exactly right. Bill might be able to help, but probably not.

One of the requirements was for a report to the

assistant administrator, in this case Jim Jones, an internal review, if you will, of the program. There's also additional cost analysis/burden analysis reports to OMB. Those have all been submitted. The reporting requirement on the cost I think is an annual requirement. And the review of the program to the assistant administrator is also an annual requirement. So, I can't recall if we're in our first or second iteration on both or either of those. But those requirements from the first list one tier one ICR have been met.

MR. HOUSENGER: Mae.

MAE: I hope I don't take up too much of your time, but I have a bunch of questions. First about that OMB part, you said that the tier two list has been in OMB for about 12 months. Then you said that was to incorporate some notice and comments. Have you already taken notice and comment on the tier two list or are you planning to?

Do you want the whole list or one at a time?

MR. DIX: My memory probably would ask for one at a time.

MAE: Okay.

MR. DIX: List two, not tier two.

MAE: Sorry, yes, list two. You're right.

MR. DIX: There is a tier two process as well. My understanding and recollection is that we're waiting for word from OMB for list two tier one. It's gone through the two step public comment phase.

MAE: And then, list one tier two will there be notice and comment period on that or will things just move directly into tier two?

MR. DIX: No, that follows the same process. That is ongoing.

MAE: Same processing meaning like there will be notice and comments and all that going through OMB?

MR. DIX: Correct.

MAE: Do you have a sense about when you may be finishing with the list one tier one and when we might see that?

MR. DIX: So, we expect to be complete with the weight of evidence determinations at the end of the calendar year, which will bring us into FY 2015. With internal reviews, et cetera, we expect to be making these public in FY 2015.

MAE: Sometime in FY 2015, okay. Will you be making the data publicly available from that or just the determination?

MR. DIX: Well, I can say a few things. The determinations will be made public. The determinations are based in a very typical approach to the pesticide program in what are called data evaluation records. They're derived from the test results. At that point, I'll let Bill address the data and the relationship (inaudible).

BILL: As you know under FIFRA, EPA has legal obligations to protect information. Consistent with that, we'll make the data themselves available. But the DERs, stripped of confidential business information, should be available.

MAE: Okay, so just the DERs?

BILL: No. We can make the studies themselves available, provided that people who are requesting it comply with the limitations under FIFRA section 10G.

MAE: Okay. So, when you finish with the tier one and there's a chemical that does not come through as positive through tier one, what happens to that? Then,

kind of the corollary to it is, if at the end of tier two you have this list of chemicals, what is the plans for ones that are positive coming out of tier two?

MR. DIX: So, this will be a general response and then Bill, I think, can put some general nuances relevant to pesticidal chemicals.

Chemicals that don't show activity in tier one screening or perhaps maybe the more important way to put that is in the weight of evidence determination of whether they show activity in the three relevant pathways. So, that won't be dependent on just tier one screening assays; that's including all other scientifically relevant information.

So, if we already have, in the case of a pesticidal active extensive in life testing in multigenerational tests, et cetera, or if we have extensive computational toxicology data and other scientifically relevant information, and we determine that there's no activity for a compound in that pathway, then it would not go forward to tier two screening. If it went forward to tier two screening, the tier two assays, whether it's one or all four of those different

multigenerational assays that are run, they would give us definitive dose response information and linkages to adverse endpoints.

Then, depending on whether the chemical is pesticidal active, it would be involved in a risk assessment process in OPP. If it's a drinking water contaminant, the risk assessment would be handled through the other appropriate offices within EPA, either the Office of Pollution Prevention and Toxics or Office of Water.

You can also imagine -- and if you look at the universe of compounds and chemicals that are part of the EDSP and relevant to the EDSP, there's also probably some shared responsibility for these risk assessments and potential risk management steps with other sister agencies across the U.S. government.

MAE: I guess maybe I was a little unclear. What I was wondering is if something -- I realize you wouldn't go through a tier two if you're a negative. Is there some kind of review of like something that does come out negative on tier one like every blah, blah, blah years you're going to come back and look at it to see if

there's, like, a lot of new stuff out there and whether it would trigger?

MR. DIX: Outside of exclusions for phys chem properties that make a compound not possibly be available or et cetera, a compound is never excluded from the potential for further screening and testing. In the case of a pesticide, I would imagine with registration review, it would be a proactive process following a prescribed cycle over the years. In a nonpesticidal chemical, it would still remain relevant to the EDSP as the science evolves.

So, I speak to these three pathways, estrogen, androgen, and thyroid. My guess is that you're implying or referring to the possibility for continued development of our scientific understanding of biological activity that's relevant to those pathways. Certainly, we'll be open to that.

That's one of the reasons I put that last slide on the presentation. If you look at a lot of the science that's currently in the research and the very active state of development around nonmonotonic dose response, a fair amount of it is speaking to the potential for

nonreceptor mediated estrogen activities, et cetera, et cetera.

MAE: So, I guess aside from registration review, which is like every 15 years, it doesn't sound like right now there's anything in place either beyond like that review of these chemicals. And then, outside of OPP, I guess, it would be up to the other offices how they would be reviewed?

MR. DIX: Yes, to a point. The EDSP is an integrated program. So, I wouldn't say it's up to the other offices. The program is a partnership between the three offices of OCSPP, the Office of Water, and the Office of Research and Development. So, it's a little more -- I would characterize it in a more proactive kind of state with ongoing development of the program and incorporation of data for all the relevant chemicals on a consistent and repeated process.

MAE: Okay. That's good for now.

MR. HOUSENGER: Now Ray.

RAY: Can I yield to Cheryl Cleveland? She can probably ask the question better than I can.

MR. HOUSENGER: Yes. We like it when you put

your card down.

MS. CLEVELAND: So, first of all, I want to support the approach, the care that you've taken, the SAPs, the broad science-based approach, especially when we see this contrasted to what Europe is doing. We appreciate the way that you're working through a risk-based framework.

I also wanted to commend you as I listened so carefully for how you're framing the communication on this. I think using the term screening and prioritization and against potential risk is exactly the right way to go. We don't want lists that come out as oh, these are confirmed risks. You're prioritizing based on risk, potential risk, and continuing to be very careful about how you communicate it.

Apparently, list three will eventually come out on this broader prioritization scheme, continuing to tease out screening, potential risk versus confirmed risk. That's really important for industry as a whole.

My question is, I'm surprised that you said there was 25 percent use of the OSRI data. I did not believe that was true when things first came through. Is

that a post mortem look at what turned out to be in the weight of evidence? More importantly, going forward through the next round when we hit list two, do you anticipate a stronger use of the existing data?

MR. DIX: I think that's high, but we can get the actual number. We just don't have that information in front of us.

DR. CLEVELAND: You know, at this point, forget the past, just going forward, maybe is there a better way to use some of that existing data, especially in the pesticide realm where it's data rich. Can you take some learnings from this round and make better use going forward?

MR. DIX: Yes. I definitely think we've learned a lot with these 52. Going forward, we'll apply that to the other ones. As far as the percentage, I apologize. I may well have misspoken. But we presented that at several of the scientific advisory panels last year when we were asking for peer review on performance of the tier one assays as well as our strategy for the weight of evidence determination. It was somewhere in the 10 to 25 percent range. I just don't recall. That

percentage was published, though.

Moving forward, I second what Jack said. We now have a very, very valuable dataset from list one tier one. In combination with the computational toxicology data and probably more significantly the part 158 existing data, which is part of the (inaudible), I think we can continue to improve the science underlying the program.

MR. HOUSENGER: Wayne.

WAYNE: Thank you, David. So, maybe I should be listening to the full day seminar. But what are thoughts on interactions of two or more chemicals or are you there? I know the challenge has been huge just for the single product, but I do hear discussions or concerns rather about interactions of two or more chemicals as being endocrinic?

MR. DIX: That’s a cumulative risk, which is one way to phrase what you’re referring to. It’s certainly an important issue and been a challenge for the agency on the regulatory side, as well as on the research side. I think the broader research community continues to struggle with that issue.

I think it's still a research issue primarily. I don't see the science to provide us a clear path forward, at least in most cases and in the broader range of combinations that might be considered. We'll continue to move forward with our research partners, both inside and outside the agency on this issue.

I do refer back to the NMDR topic. That's not necessarily addressed in the current white paper, but that could be some type of a follow-on product. But I emphasize, consistent with what I just said, that at that point, topics like key motive risk and NMDR are being addressed and handled primarily by our Office of Research and Development.

We're looking to that continued development of science to the point where we can translate it into practice. But I don't think it's there right now for us. But I don't know if -- that's for EDSP, for sure. There might be some other follow ups from Jack or Bill.

MR. HOUSENGER: And Gabrielle.

GABRIELLE: Yesterday we heard quite a bit from the 21st century about interactions, international interactions, and then also from the (inaudible). I know

that Europe is also working hard at trying to figure out this whole --

MR. HOUSENGER: We can't hear you again. I don't know if it's you or your mic.

GABRIELLE: So, my question is about interactions on the international level. We heard about it for the 21st century toxicology. I know that EU is also working on trying to figure out endocrine disruptors both for pesticides and more broadly. So, what kind of interactions are going on between all these efforts to understand the science and figure out how to do it more efficiently? Where is that?

MR. DIX: Well, one thing I'm somewhat hopeful about is our engagement through the Organization of Economic Cooperation and Development with our European and other international partners. There's a variety of mechanisms or forums for that. As we get on line, and I got on line over this past year, I've been engaging more broadly with a variety of different OECD task forces and groups that will be starting to address how we harmonize between the US and the EU on the issue of endocrine disruption.

One of the more hopeful veins or threads for that is in the development and application of adverse outcome pathways. If you've been paying attention to a couple of the different groups in OECD that are developing those and considering their application in association with test guidelines, we have proposed a potential application of estrogen, androgen, thyroid AOPs, similar to what we presented at the Scientific Advisory Panel in the draft or the preliminary weight of evidence determinations for five case study chemicals in 2013.

MR. HOUSENGER: Okay, thank you, David. I told you he could talk. Now we're late, but I think we're fine. Let's take a 10-minute break and come back, and we can do comparative --

(Whereupon, a brief recess was taken.)

MS. MONELL: Okay, everyone, if you'd please take a seat. I am standing between you and lunch. No slides, so you have to listen. I'm here to give you an update on the comparative safety statements workgroup under PPDC. Some of you may recall our berth in 2010,

January of 2010, when this committee recommended and moved forward to creating this committee. Basically, it was to acknowledge an interest, widely known interest in the consumer community and all things green and wanting information about the greenness of pesticide products and, of course, industry's interest in scratching that itch, if you will, by being allowed to make certain statements or use certain logos regarding greenness or environmental considerations on their pesticide product labels. Obviously, EPA's interest is in preserving the sanctity of the legal label, such that any statements on it are not false or misleading.

So, those were the underpinnings of the work that we began. We came up with a program that allows for the use of the DFE, design for the environment, logo on pesticide products. That DFE, by the way, that program is run out of our sister office in the Office of Toxics and Pollution Prevention. That process involves a screening by a third party screener.

There are many different kinds of screens that relate to the industrial chemical community, if you will. Our products, our AIs, actually go through the general

screen, so it's very difficult for a pesticide AI to get through the screen as it is currently constructed by the DFE program.

Therefore, we have very few products that have made it through the DFE program with approved DFE logos on the pesticide labels. These generally relate to citric acid, lactic acid. Most recently, we've been able to have a hydrogen peroxide containing product that made it through the DFE screen and will be allowed to use the DFE logo after our review.

So, it's somewhat limited, but we're hopeful that the result of our working closely with the DFE program will result in a pesticide sector being developed, so that the recognition of the kinds of chemistries that are utilized in the pesticide products that go through our rigorous risk assessment process will somehow be able to develop a sector to recognize those products. We're just beginning those efforts now and more to come probably in a year.

We have another part of this comparative safety statement work which involves what we used to call factual statements. Now we just refer to them as label

statements. That evolved because everything we say and put on a label is factual. So, we shouldn't be making those kinds of distinctions in a pilot or otherwise.

So, the label statement pilot program was initiated to recognize -- we agreed upon recognition for dye free, fragrance free, corporate commitments on the environment or sustainability so we would allow the link between -- web link to be placed on the label so that a consumer could go to the web site and see what the company's environmental ethic or sustainability commitments would be.

Of course, when you do something like that, when industry does something like that, the whole web site becomes subject, is part of the label. So, it really involves a solo review of the web site in that regard.

So, we have about 30 label statements that have been approved, mostly in the dye free and fragrance free arena. Those are easily ascertained by checking out the CSF and other data that's submitted to us. We also last year added claims regarding or statements regarding biodegradability.

In this case, if your product is 100 percent biodegradable, you can make that claim. You have to submit a paper to us to prove that, but we will allow that claim. We also will allow a claim for the biodegradability of the surfactant in your product. Thus far, we do not have any 100 percent biodegradable claims allowed, but we do have a few surfactants, 100 percent biodegradable surfactant claims that have been allowed to be on product labels.

If you recall, last year in recognition of USDA's program regarding on biobased products, they have developed a -- so that green purchasing statutory authorization -- they have a program by which they will provide a certification and an official mark for a product's label that indicates the percentage of the product that is biobased. So, we will allow that label to be used on pesticide products if there is --

In other words, if you go through the USDA process of obtaining the mark, the certification mark, and then they come to us and they can put it on their pesticide label if there's also a disclaimer that this mark does not mean that the product is necessarily safe

and that the user should follow the label directions. So, it's to get around the concern that perhaps having this mark on a pesticide product label might be perceived to be an endorsement of its safety as opposed to what it actually is.

The other thing that we mentioned last time was a new claim, a new label statement that was being proposed. This is something that apparently has several year's history in this program, and that is a statement about the safety of the product for the hard surface on which it's intended to be used.

So, if you've got granite, let's say, the product, they would like to put a statement on the product label that says this product is safe for use on granite or safe to use on formica or safe to use on whatever. So, historically we've said no, using the word safe on the label in that context could be construed to mean something safe beyond just for application on the surface. In other words, there might be some implication that it would be safe for public health purposes or for the environment beyond the regular FIFRA finding.

So, we actually have been pretty consistent in

saying no to that. This time, however, the groups representing those types of consumer products came to us and said well, we're willing to do a survey, to construct a survey to really find out how consumers would react to that kind of label language. So, we thought, well, you know, that might be interesting, because certainly, if the survey is designed appropriately, you could get a lot of very useful information out of it. So, we said, sure, we will review what you've come up with.

That's an important aspect of our ability to participate in this, because under the ICR rules, information collection rules, we really can't be part of a survey unless we get an ICR for it. So, we're going to review what they're putting together, what their consultants have put together. They're willing to take the risk that they're going to be provided with sufficient information from consumers that will allay our concerns about allowing the use of the term safe for this surface on the pesticide product label. So, that's just an update on where we're at with that.

Two other updates, one you heard here a couple of times about the programs repellency graphic mark. We

can't call it a logo. We've gone round and round with the legal folks about the appropriate naming for this. But essentially, it's a good thing because it's to put on repellency products a mark that will indicate its effectiveness as a repellant against mosquitos or ticks and then for how long. Rose is here to give us an update on that effort.

ROSE: Hi, everybody. I'm Rose Cipriano (phonetic), and I'm with Field and External Affairs Division here in OPP. For those of you who have never heard too much about it, as Marty said, the repellency awareness graphic, as we now like to refer to it, it's similar in concept like putting an SPF on sunscreen. But this would be a graphic that would convey information about an insect repellant.

We work extensively with PPDC and discussing this with them over the last couple years. So, hopefully, most of you are familiar with this. We recently, the end of last year, put out the program to public comment. So, what I'm here to give you an update about is that we've gone through the comments.

We had about 60 of them. Most of them were

from the general public. Overall, they were very supportive of the effort, which is what we were hoping to see. They would love to see this on products. So, we've completed our review of the comments, both of the general public and some of the more technical comments. We're not planning to make changes to the graphic or to the guidance.

We are ready to accept applications. We're planning some more communications to that effect, maybe through an OPP update and through the website through the coming months, but did want to come here and let everybody know that we're open for business.

Also, if a need or interest exists, we're considering holding a webinar for industry sometime this summer about the process to apply and about data that we'd like to see to support the claim. So, I don't know if there's a couple minutes for people to raise their hands or to say yes or no or if you would just like to get back to me or to my colleague, Ryan Yager (phonetic), if you're familiar with him, just to kind of give a yes, please, or no, thank you for something like that. But please let us know if you'd be interested in having a

webinar with us about this program.

MS. MONELL: And the last item on which we wanted to give you an update is related to a topic that was discussed yesterday, science related, 21st century toxicology and the use of that tool. Kristie Sullivan (phonetic), a former member of the PPDC, actually came to the comparative safety workgroup and wanted to have some discussion about the possibility of using statements on pesticide product labels related to the lack of animal testing that resulted in the formulation of the product or sort of minimal animal testing.

So, we've been working very hard, actually, because we see this as an opportunity to promote an interest that the program has at the same time perhaps giving a little competitive edge to those that would be willing to use these tools.

So, Jennifer McLain is going to give you an update on where that effort is at and some of the issues that have arisen.

MS. McLAIN: Good morning. This is Jennifer. When Kristie brought this idea to the workgroup, she said there was a lot of common interest in trying to make

something work and really viewing it as an incentive to reducing animal testing. So, this would be one way to, for example, encourage registrants to use in vitro tests in their acute tox testing for a product, unless they could get the special label claim. That was the concept that was brought forward.

So, I think that was over a year of discussion on various ways to make this work. Through the reduced version of the conversation is that the idea was to have two different types of claims, one claim that would state something like no animal testing for this product.

The concerns that were raised with that was that, first of all, the science for the acute tox testing isn't quite there to -- as we talked about yesterday, there's a lot of really exciting work going on right now. It seems like it's not far away from being in reach, but at this time it's not there. So, it would take a while for folks to be able to qualify for such a claim.

Then, there was a concern, well, how do you put that on a product when there's other testing that's gone on for the active ingredients, for example. Most of the conversation surrounded the potential for having a claim

that would be something like a minimal animal testing to approve this product.

There's still that underlying concern about the testing that happened for the active ingredient. There was a lot of discussion about how to set criteria for what would count for that claim, which was pretty difficult in actually trying to segregate where we would say yes versus no.

There was a significant legal issue that was brought up during the course of the conversation that would apply to both of these, where there was no way to restrict its use. So, initially, the concept was if your company put the work in to doing these in vitro tests and reducing the animal for their product that you would be able to restrict the use of that claim to your product. But in talking to our legal counsel, we found that there's no way to not allow me (inaudible) that product to happen and for that claim to go on any (inaudible) that came in. So, that was a concern.

One of the biggest concerns, particularly with the reduced animal testing, was a concern that having the wording on the label at all would raise the issue that

there was animal testing. So, if you say this is minimal animal testing that went into this product, then the consumer is potentially reacting in a negative way, what, there's animal testing going on for this product?

So, at that time, after having over a year conversation about it, we thought well, maybe we should set that to the side because it seems like there's so many barriers to a successful implementation. We started to pursue another avenue of providing an incentive for reduced animal testing. That would be to develop some sort of award that EPA would give annually or something to one or more companies that were making an effort to reduce animal testing. This would be something that's not product specific; it would be for the company. It would be something that they could put on their website. We, already through the workgroup, have allowed addition of the website that can provide information about good work the company is doing on the label.

So, there were similar concerns about this. Well, first o fall, there was one concern that it may not be too much of an incentive because it's not label based. There are some companies that said they were not quite

interested in it because of that. Then there was a similar concern that it would again be calling attention to the fact that there was animal testing going on for the product.

Not every discussion we had on these was negative, because, like I said, there is a common interest in trying to make it happen. It was just we could never quite figure out a way for either of these ideas to be something that industry folks felt would truly be an incentive and would be providing them with something that they thought would be appealing to customers.

That was just a conversation we had. I think that Marty just wanted to let you all know where we are. We thought I wouldn't say that either idea is dead in the water at this point, but we haven't figured out a way to make it work.

MS. MONELL: Thanks, Jennifer.

Any questions on any of this that we've rattled off for the past 20 minutes? Ray and then Jerry.

RAY: I have three or four questions on different aspects. On the insect repellency graphic, is

this graphic going to state that repellency is good for a number of hours?

MS. McLAIN: Yes. It's specifically either for mosquito or tick repellency, and then it will give the number of hours that a tick is repelled or a mosquito would be repelled.

RAY: And what type of data will demonstrate that time period?

MS. McLAIN: The efficacy data that is provided to support the registration for the product.

RAY: Does that involve human testing?

MS. McLAIN: Yes, it does.

RAY: So, this could encourage additional human testing?

MS. McLAIN: Yes. We've actually spoken recently with the HSRB to bring this to their attention and also to ask them if they are open to receiving different ways of doing protocols that may involve grouping things together instead of doing each product individually. So, they indicated that they would be open to discussing that with anyone who wants to bring in that type of scenario.

RAY: And with respect to the animal testing question, did I understand you say this is probably dead in the water?

MS. McLAIN: I said it wasn't necessarily dead in the water. We just haven't figured out a good way to move it forward. So, if you have an idea, we would love to hear it.

RAY: Well, I'd be surprised if you can find a registration eligibility document that does not depend somewhere on animal testing and making that decision. So, to grant no animal testing on the label, it's disingenuous at best.

One other point, the agricultural pesticide market has largely stayed out of this discussion and just observed it from a distance. But one aspect I'd like to raise as a possibility is the reduced risk program. It's been in place for more than 20 years. It's met its incentive to develop and register products which have reduced risks. But we haven't been able to use them on labels or in advertising programs. There might be some possibilities here.

MS. MONELL: We will definitely put that on the

agenda for a next workgroup meeting discussion.

Others? Oh, I'm sorry, Jerry.

JERRY: Actually, I was going to say the same comment about reduced risk. I'll just add one thing different. A lot of our stakeholders, especially crop growers, we go to great pains trying to make sure that the products we use when there's choices, we pick out reduced risk products.

So, the comments come back. How come this isn't notified or how come we don't see this one? So, I think there's a desire out there to see that.

MS. MONELL: Great.

Dave.

DAVE: With the repellants, I was wondering how you're dealing with interspecies differences and efficacy?

MS McLAIN: In the guidance that we have, we have specific species that we would like for tick studies. Then, for mosquitos, since they're field tested, we want to ensure that there's a certain variety of genre that are covered during those tests. Does that answer your question, generally?

DAVE: Well, it sounds like at least you're gathering information to identify interspecies differences, but then once they're identified, how do you deal with it? To what extent have you looked at if there's a particular species of tick in a particular region that wasn't tested and then people are relying on the number, how is that dealt with? How are you dealing with that?

MS. McLAIN: Okay. So, I think I understand a little bit better. So, the three tick species that we've chosen were based, one, on public health significance of carrying disease. Then, two, are they hovering, kind of that difference between species? We did bring that issue specifically to the HSRB last year to get them to weigh in on this -- I'm sorry, SAP. Too many panels and advisories. So, we brought it to the SAP and asked them if they thought those would be appropriate representative test species for a general tick claim to be protective generally of ticks for people. They concurred on that.

JERRY: Could you characterize did AMCA weigh in on it, American Mosquito Control Association? I was wondering if you characterize were they in support or not

in support?

MS. McLAIN: I didn't realize this would be a memory test. I do remember definitely them being vocal on this issue. I feel like they were in strong support of the concept and offered up a variety of cautionary notes to guide us and to provide us with input and feedback as we moved forward on this, which we have considered a lot of feedback as we move forward, especially from this PPDC.

I believe that it was voiced through this advisory panel through past years, and we've taken all of the advice seriously as we've been trying to weigh how to move this forward. So, that's the best I can do.

MS. MONELL: Liz.

LIZ: Regarding the repellency, I can imagine that once you get HSRB involved, that there's probably the studies that would be involved are going to probably be kind of expensive. Has there been a cost benefit to the efficacy that you're going to be requesting or will it go to OMB and they'll make that decision?

MS. McLAIN: No, this is a voluntary program. It also helps to support the registration of the product.

So, there's no requirement to put the graphic on your product. If folks want to go through the studies -- a lot of data that we already have in house can be used to support the graphics, maybe not all of it.

So, part of the product's information that will support use of the graphic is probably already in house. So, some companies may be looking at one test in order to complete their set of data that they may need. Some would be looking at a complete series of tests, depending on how old their product was and what kind of data they have to back it up.

So, really, this is partially a voluntary program, and it's partially trying to encourage folks to bring them up to where we in modern times would like them to be in terms of providing efficacy data to the agency.

UNIDENTIFIED MALE: So, I'm from SC Johnson. We make repellants under the off brand, so we've done a few of these tests ourselves in the past. If the agency is open to the idea of clustering or bridging, we'd be happy to talk to you about that, either from an ERC or from a tox standpoint.

MS. McLAIN: Absolutely. I encourage you to

contact Kelly Sherman (phonetic), and she will work with us to engage you in this.

MS. HOUSENGER: Okay, the final topic is discussion topics for the next PPDC. But before we do that, the last time we met with the PPDC, we had a webinar. I wanted to get people's general sense. I know it's always better to be with each other, but did that work and should we consider it in the future? I see a head nodding no. Was that the general sense? It seemed good for us, as they're expensive.

UNIDENTIFIED FEMALE: Very expensive. I have to say that the travel alone is about $30,000.

MR. HOUSENGER: Cheryl.

CHERYL: It was very hard for me to participate when people could come to me in my office, even though I was in the webinar. I really wasn't all there. I kept getting pulled away.

MR. HOUSENGER: You should lock your door.

CHERYL: I probably should. I should just have been at home. But there's something about face to face and there's something about multi-tasking. As great as webinars are, they're not as effective as the face to

face. We all know that.

MR. HOUSENGER: Mark.

MARK: Thank you. First of all, I miss that when you send the Leer jet for me, I always appreciate that. I had a hard time with it. I mean, it was adequate, so it was a reasonable form of communication. I think it was certainly not as good as face to face for a lot of reasons, the communication just in general and of course I think people can see from some of the presentations yesterday and today the advantage of face to face presentations and being able to develop Power Points that way. So, I think that's a much better way to communicate.

Because of the communication that's always part of the networking of stakeholders, I would say it's inadequate for that. This is much more adequate.

VALENTIN: This is Valentin. If I may comment whenever you think I should go.

MR. HOUSENGER: Go ahead. You can go now.

VALENTIN: First of all, really, I want to apologize for not being able to participate in person. I believe I'm the only one. But the last webinar we had, I

think it was really hard to be able to focus on the conversation because we'd have a lot of interruptions. We would hear background songs, music. We would hear people having conversations with their colleagues over the phone. It was really hard to hear. But I think that being in person is always a plus. It's always nice to see the faces of people that are talking and just kind of building relationships with other individuals. I think it's great.

MR. HOUSENGER: We have two more.

MR. GREGG: Richard Gregg here. I also was not able to participate actually at the last minute. I definitely prefer, if possible, the face to face. I did participate on the first webinar, and I agree with the comments that have already been said about that.

MR. HOUSENGER: So, we have two more comments. If they're not positive, then I'm not sure we -- anybody like the webinar? No, all right.

Let's talk about discussion comments for the next PPDC. Margie, do you have any dates? Is there we talk about dates?

MS. MONELL: No.

MR. HOUSENGER: We don't talk about dates here. No, I didn't say that. Topics? No topics. Of course, Ray. Go ahead.

RAY: I'd like to suggest three topics for consideration at the next PPDC meeting. Worker protection standards should be an obvious one, drinking water and spray drift issues.

MS. MONELL: While I have that thought, the worker protection standard, I just want to remind everyone the closing date for public comment is August 18th.

MR. HOUSENGER: Mark.

MARK: As one might anticipate, I want to have a discussion on school integrated pest management programs, the status from the new Center of Expertise particular to the national change agent core development and the pilot, also workgroup action on incorporating sustainability factors into school integrated pest management, and action on enhancing cooperator and regional activities with regard to cooperative agreements.

MR. HOUSENGER: Dave.

DAVE: A couple things. One is, and I believe I've requested this before, but it's an ongoing issue with us that there doesn't seem like there's a consistent evaluation of pathways to get into urban waterways, which is the primary thing that brings me here. A discussion of what OPP can do to make sure that each branch and each division that's tasked, whether it's in registration or registration review, that they consistently consider how these things get into either waste water or storm water pathways, because it's too all over the board and it's impossible, really, to keep track of that. I'd like to have some discussion of really the problems that exist and then what EPA can do about it.

The other thing, I'd like there to be an exploration of sort of building on what Matt Keiffer said yesterday about the asymmetry and the approach of the tox 21 effort, in that there's a lot of -- I think it's good that there's a lot of effort in sort of looking forward technology of being able to evaluate and predict the risk. But there's inadequate effort looking at how can those tools be used to develop the clinical tools, to develop epidemiological tools, and to develop

environmental surveillance tools. It's very much underutilizing that capability.

I realize that you can't do everything, but I would like to have some sort of a discussion that could possibly lead to that committee looking at what's the direction with that and what is the need for significant resources being applied to those problems, because you can't just rely on the looking forward, the predictive tools, without having that back stop. That's a significant policy issue. I think that's actually what we're really here about, is advising on policy. I'm sure there's other people that have different opinions about that, but I'm thinking that would be a worthy subject to explore.

MR. HOUSENGER: Cynthia.

CYNTHIA: Thank you. I would like to suggest that we have a session at the next meeting on incident reporting and FIFRA 682. This relates to OPP's efforts on information technology, on endangered species, on the MOU with the Fish and Wildlife Service implementing the Migratory Bird Treaty Act, on 21st century computational technology. Incident reporting is an important back

stop.

Some things we could discuss would include the thresholds for wildlife reporting, disaggregating the data, for example, for bee specific incidents, biomarkers, and what kinds of incidents we can actually get data for, what do we have the biomarkers for, what tests need to be developed.

And we can hear about your efforts to merge incident data reporting with other federal agencies, with states, with other countries, so that registration reviews can be informed by the best possible science and by on the ground experience.

MR. HOUSENGER: Cheryl.

CHERYL: So, I would like to have more emphasis on the drinking water aspects. I see we had an information piece in here, which is great. But there continues to be -- sorry, he said we could go on our soap boxes if we came back off -- but there continues to be a disconnect between the advanced, data driver, tiered based system that exists for food dietary and what's done with water. A lot of risk cups are full of just modeled theoretical water.

There's been some efforts to try to collect more monitoring data. There's been efforts to look at statistical analysis of monitoring versus the models. There's a proposal for biosector. So, I'd like to have an update on that. I think it's really important to have a more cohesive dietary risk assessment for both food and water.

MR. HOUSENGER: Matt.

MATT: I want to add to Cynthia's list of issues that need to be addressed when we're talking about incident reporting and 682. That is, I think in the wake of HIPAA, we have a problem that we didn't foresee. Those issues may have a substantial impact on the efficacy of 682 and our expectations from it.

What I mean by that is, HIPAA, and I'm sure you've all heard of it, it's the Healthcare Information Portability Act -- I think that's the actual name -- and it prevents physicians from sharing information that identifies patients with anyone that is not part of the patient's care. There's substantial fines and penalties associated with doing that. I think that strikes fear into the hearts of a lot of physicians when it comes to

reporting anything to anyone other than people that they're required to report to.

682 is not a mandatory surveillance system that physicians report to. Therefore, in the absence of a mandatory requirement, they're not released from their HIPAA burden. So, I think this is really going to have an impact that we need to discuss, because the system of 682 isn't keeping up with the new healthcare regulations. We need to discuss the implications.

MR. HOUSENGER: Doug.

DOUG: I think you laid the groundwork well for ESA and I'd like to continue to update on that, plus maybe even considering a working group on that.

MR. HOUSENGER: Okay, Virginia.

VIRGINIA: I'd also like to echo Cynthia's suggestion about incident reporting and add also efforts by the agency to collect more information about human and worker health and exposures.

MR. HOUSENGER: Mark.

MARK: I think it would be beneficial to get an update on the situation with invasive species, vis a vis, pesticide tools available, looking at strategies,

tactics, and tools where there aren't pesticides to use, particularly in two of our most recent introductions.

MR. HOUSENGER: Anyone on the phone?

VALENTIN: Yes, this is Valentin. Very quickly. I think it would be kind of nice to get an update with regards to spray drift when it comes to farmworkers and children, since there has been several drifts happening in the State of Washington. There was one that happened last year here in Oregon. I think it would be kind of nice to get an update on the work that EPA is doing regarding drift.

MR. GREGG: This is Richard Gregg again. I'm for the drinking water and the spray drift.

UNIDENTIFIED MALE: This is not really a topic; it's really more the conduct of the meeting. I thought that this meeting -- and realize that it's always a balancing act, but I think that this meeting, several of the topics were overly loaded with presentation and not enough opportunity for discussion.

MR. HOUSENGER: Okay.

UNIDENTIFIED FEMALE: This is quick on that note. Could I ask you all to give us some kind of

glossary to the alphabet soup? It would be so nice to know what the acronyms stand for before they're repeated over and over. It would be really great.

MR. HOUSENGER: That we can do. All right, well, thank you very much to everyone who traveled from afar and even near and for making my first PPDC so enjoyable. I was dreading it. But, hopefully, we'll schedule another one sometime, and we'll get that out to you.

Margie, is there anything as DFO that you need to say to wrap it up? Oh, we still have public comments. That's what you were going to say.

Julie Spagnoli.

MS. SPAGNOLI: This will be very quick. This goes back to endangered species. We heard reference that they are looking at nonagricultural uses. We also just want to make sure that there's consideration for, as we're doing the habitat evaluations and refinements, that there's a consideration that within even an urban area, that you do have distinctions in habitat or habitat potentials within an urban area. You have parks. You have non-developed areas within an urban area that may or

may not affect the usage in, let's say, a residential area.

So, if a perimeter treatment is being made around a home, even though it may be within, let's say, a half a mile of a park, whether it's going to have any impact on that park. I know this is the whole issue with getting to these refinements, but within urban areas, I think we have to look at that additional refinement that an urban area can have habitats and have areas that are not habitats. So, just taking that into consideration as we move forward on the endangered species assessments. Thank you.

MR. HOUSENGER: Marcia Duke, NMPA.

MS. DUKE: Hi, Marcia Duke from NMPA. Just a quick comment on the comparative safety claims. I think the agency has done a tremendous job of moving very deliberately before they ever allow a comparative safety claim on a label.

We had a recent experience in our industry. There's two parts to the bio-based claim. There's going through and being essentially carbon dated and allowing the claim of bio base, whether that gets to a pesticide

or not. It's just a level of carbon in the product.

The other part of the bio-based program is putting preferential myths in contracts, US government contracts, for those products. We're sort of concerned from a public health perspective, because, one, there's not very many products on those bio-based lists, and there was a product that was on the bio-based list that was a 25B that recently the FTC took significant action against so much so that it shot the company down.

So, we're just concerned because those products are to be given preferential treatment in any US government contract. So, we don't have products on the list for lots of species. And for the species that do have a product, a lot of them there's no efficacy for. And for those that there might be, then that's all there is.

So, we're concerned there's a public health pasture out there that might not be able to be treated from a US government perspective.

MR. HOUSENGER: All right, I think that wraps it up. Thank you from the federal corner here for attending, too. They're out partners in a lot of this

and, I think, shed a lot of light on a lot of complex issues for everybody.

So, thank you. Safe travels home. Good weekend. Bye.

(Whereupon, the meeting was concluded.)

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